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 June 30, 2019

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading symbol(s):**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value	GERN	The Nasdaq Stock Market LLC

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 July 26, 2019:**
Common Stock, $0.001 par value	188,423,106 shares

GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2019

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	JUNE 30, 2019 (UNAUDITED)	DECEMBER 31, 2018 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,710	$ 10,575
Restricted cash	270	269
Marketable securities	134,778	152,714
Interest and other receivables	838	1,168
Prepaid and other current assets	1,166	1,332
Total current assets	154,762	166,058
Noncurrent marketable securities	9,497	18,582
Property and equipment, net	100	59
Operating lease, right-of-use asset	402	—
Other assets	1,464	585
	$ 166,225	$ 185,284
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,210	$ 982
Accrued compensation and benefits	2,756	2,642
Amount due to Janssen Biotech, Inc.	1,576	2,610
Operating lease liability	402	—
Accrued liabilities	3,237	1,317
Total current liabilities	9,181	7,551
Commitments and contingencies		
Stockholders' equity:		
Common stock	187	186
Additional paid-in capital	1,192,338	1,189,194
Accumulated deficit	(1,035,762)	(1,011,464)
Accumulated other comprehensive gain (loss)	281	(183)
Total stockholders' equity	157,044	177,733
	$ 166,225	$ 185,284

See accompanying notes.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2019	2018	2019	2018
Revenues:				
License fees and royalties	$ 101	$ 208	$ 158	$ 526
Operating expenses:				
Research and development	10,134	3,204	16,040	5,644
General and administrative	5,191	4,246	10,643	9,561
Total operating expenses	15,325	7,450	26,683	15,205
Loss from operations	(15,224)	(7,242)	(26,525)	(14,679)
Interest and other income	1,113	717	2,275	1,111
Change in fair value of equity investment	(98)	(350)	—	(475)
Other expense	(30)	(59)	(48)	(77)
Net loss	$ (14,239)	$ (6,934)	$ (24,298)	$ (14,120)
Basic and diluted net loss per share	$ (0.08)	$ (0.04)	$ (0.13)	$ (0.08)
Shares used in computing basic and diluted net loss per share	186,556,082	174,475,244	186,475,055	167,538,530

See accompanying notes.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2019	2018	2019	2018
Net loss	$ (14,239)	$ (6,934)	$ (24,298)	$ (14,120)
Net unrealized gain on marketable securities	182	254	464	130
Comprehensive loss	$ (14,057)	$ (6,680)	$ (23,834)	$ (13,990)

See accompanying notes.

GERON CORPORATION
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT SHARE DATA)
(UNAUDITED)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Gain (Loss)	Equity
Balance at December 31, 2018	186,392,682	$ 186	$ 1,189,194	$ (1,011,464)	$ (183)	$ 177,733
Net loss	—	—	—	(10,059)	—	(10,059)
Other comprehensive income	—	—	—	—	282	282
Stock-based compensation related to issuance of common stock and options in exchange for services	13,365	—	22	—	—	22
Stock-based compensation for equity-based awards to employees and directors	—	—	1,426	—	—	1,426
401(k) contribution	—	—	9	—	—	9
Balance at March 31, 2019	186,406,047	186	1,190,651	(1,021,523)	99	169,413
Net loss	—	—	—	(14,239)	—	(14,239)
Other comprehensive income	—	—	—	—	182	182
Issuance of common stock in connection with at market offering, net of issuance costs of $73	108,386	—	101	—	—	101
Stock-based compensation related to issuance of common stock and options in exchange for services	5,097	—	11	—	—	11
Stock-based compensation for equity-based awards to employees and directors	—	—	1,434	—	—	1,434
Issuance of common stock under equity plans	118,871	1	141	—	—	142
Balance at June 30, 2019	186,638,401	$ 187	$ 1,192,338	$ (1,035,762)	$ 281	$ 157,044

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Gain (Loss)	Equity
Balance at December 31, 2017	159,877,239	$ 160	$ 1,089,684	$ (985,840)	$ (207)	$ 103,797
Cumulative effect of accounting principle change	—	—	—	1,393	—	1,393
Net loss	—	—	—	(7,186)	—	(7,186)
Other comprehensive loss	—	—	—	—	(124)	(124)
Issuance of common stock in connection with at market offering, net of issuance costs of $48	776,788	1	1,552	—	—	1,553
Stock-based compensation related to issuance of common stock and options in exchange for services	8,308	—	71	—	—	71
Stock-based compensation for equity-based awards to employees and directors	—	—	1,614	—	—	1,614
401(k) contribution	—	—	10	—	—	10
Balance at March 31, 2018	160,662,335	161	1,092,931	(991,633)	(331)	101,128
Net loss	—	—	—	(6,934)	—	(6,934)
Other comprehensive income	—	—	—	—	254	254
Issuance of common stock in connection with at market offering, net of issuance costs of $2,096	21,865,344	22	82,284	—	—	82,306
Stock-based compensation related to issuance of common stock and options in exchange for services	10,295	—	49	—	—	49
Issuance of common stock under equity plans	9,097	—	14	—	—	14
Stock-based compensation for equity-based awards to employees and directors	—	—	1,545	—	—	1,545
Balance at June 30, 2018	182,547,071	$ 183	$ 1,176,823	$ (998,567)	$ (77)	$ 178,362

See accompanying notes.

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

	SIX MONTHS ENDED JUNE 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (24,298)	$ (14,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	26	31
Accretion and amortization on investments, net	(958)	(111)
Change in fair value of equity investment, including foreign currency translation	3	513
Stock-based compensation for services by non-employees	33	120
Stock-based compensation for employees and directors	2,860	3,159
Amortization related to 401(k) contributions	9	10
Operating lease expense	334	—
Changes in assets and liabilities:		
Current and noncurrent assets	(386)	146
Current liabilities	894	(1,611)
Net cash used in operating activities	(21,483)	(11,863)
Cash flows from investing activities:		
Purchases of property and equipment	(67)	—
Purchases of marketable securities	(66,408)	(107,067)
Proceeds from maturities of marketable securities	94,851	37,850
Net cash provided by (used in) investing activities	28,376	(69,217)
Cash flows from financing activities:		
Proceeds from issuances of common stock, net of issuance costs	243	83,873
Net cash provided by financing activities	243	83,873
Net increase in cash, cash equivalents and restricted cash	7,136	2,793
Cash, cash equivalents and restricted cash at the beginning of the period	10,844	16,603
Cash, cash equivalents and restricted cash at the end of the period	$ 17,980	$ 19,396

See accompanying notes.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The terms "Geron", the "Company", "we" and "us" as used in this report refer to Geron Corporation. The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 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, 2018, included in the Company's Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2018 has been derived from audited financial statements at that date.

Net Loss Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the periods presented, without consideration for 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 a warrant to purchase our common stock. Diluted net loss per share excludes potential dilutive securities 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 six months ended June 30, 2019 and 2018, the diluted net loss per share calculation excludes potential dilutive securities of 35,795,314 and 26,306,263, respectively, related to outstanding stock options and warrant 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. Our marketable debt securities include commercial paper and corporate notes.

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 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 six months ended June 30, 2019 and 2018. 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 date. 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.

Leases

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating leases are included in operating lease, right-of-use assets and lease liabilities in our condensed balance sheets. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of remaining lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, to calculate the net present value of lease payments, we apply our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment as of the lease commencement date. We may adjust the right-of-use assets for certain adjustments, such as initial direct costs paid or incentives received. In addition, we include any options to extend or terminate the lease in the expected lease term when it is reasonably certain that we will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term.

For lease agreements entered into after January 1, 2019 that include lease and non-lease components, such components are generally accounted for separately. We have also elected not to recognize on our condensed balance sheets leases with terms of one year or less. See "New Accounting Pronouncements – Recently Adopted" in this Note 1 on Summary of Significant Accounting Policies for additional information on the adoption of the new accounting standard for leases.

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.

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 consideration, 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 date, 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. For example, 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. At each reporting date, 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 during the reporting period 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 collaboration 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 collaboration agreements. 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 collaborative partners and research-related overhead. Research and development costs are expensed as incurred, including costs incurred under our collaboration and/or license agreements.

In May 2019, we assumed the imetelstat investigational new drug, or IND, sponsorship from Janssen Biotech, Inc., or Janssen, upon which we became sponsors of the ongoing clinical trials of imetelstat in the United States: Phase 2 trial in relapsed/refractory myelofibrosis, referred to as IMbark and a Phase 2/3 trial in lower risk myelodysplastic syndromes, referred to as IMerge. In the second quarter of 2019, we assumed sponsorship in certain countries outside of the United States. We expect to obtain country-specific health authority and ethics committee approvals for change of sponsorship to us in remaining countries outside of the United States on a country-by-country basis during the third quarter of 2019. Until full sponsorship responsibilities for imetelstat transfer from Janssen to us, Janssen will continue supporting ongoing clinical trials of imetelstat during the transition of the program to us. For the clinical development activities performed by Janssen in the past and during the transition period under the collaboration and license agreement, or Collaboration Agreement, which was terminated effective September 28, 2018, 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. We conduct a similar process for clinical development activities being performed by us. However, additional information may become available to us which would allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

Depreciation and Amortization

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

Stock-Based Compensation

We recognize stock-based compensation expense based on grant-date fair values of service-based instruments on a straight-line basis over the requisite service period, which is generally the vesting period. For performance-based stock options with vesting based on the achievement of certain strategic milestones, stock-based compensation expense is recognized over the period from the date the performance condition is determined to be probable of occurring through the date the applicable condition is expected to be met and is reduced for estimated forfeitures, as applicable. If the performance condition is not considered probable of being achieved, no stock-based compensation expense is recognized until such time as the performance condition is considered probable of being met, if at all. If that assessment of probability of the performance condition changes, the impact of the change in estimate would be recognized in the period of the change. 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 six months ended June 30, 2019 and 2018 which was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2019	2018	2019	2018
Research and development	$ 413	$ 266	$ 653	$ 421
General and administrative	1,021	1,279	2,207	2,738
Stock-based compensation expense included in operating expenses	$ 1,434	$ 1,545	$ 2,860	$ 3,159

As stock-based compensation expense recognized in our condensed statements of operations for the three and six months ended June 30, 2019 and 2018 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. We have not recognized any stock-based compensation expense for performance-based stock options in our condensed statements of operations for the three and six months ended June 30, 2019 and 2018, as achievement of the specified strategic milestones was not considered probable at that time.

Stock Options

We grant service-based and performance-based options under our equity plans to employees, non-employee directors and consultants. The service-based vesting period for employee options is generally four years from the date of the option grant. Performance-based options vest upon the achievement of specified strategic milestones. The fair value of service-based and performance-based options granted during the six months ended June 30, 2019 and 2018 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2019	2018
Dividend yield	0%	0%
Expected volatility range	0.802 to 0.980	0.821 to 0.832
Risk-free interest rate range	1.79% to 2.56%	2.55% to 2.94%
Expected term range	5.25 yrs to 6.44 yrs	5.25 yrs

Employee Stock Purchase Plan

The fair value of employees' purchase rights during the six months ended June 30, 2019 and 2018 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2019	2018
Dividend yield	0%	0%
Expected volatility range	1.333 to 1.653	0.437 to 0.475
Risk-free interest rate range	2.56% to 2.63%	1.53% to 1.76%
Expected term range	6 mos to 12 mos	6 mos to 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 our common stock do not correspond to option terms and the trading volume of options is limited. The risk-free interest rate range is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term in effect on the date of grant for an award. The expected term of options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Non-Employee Stock-Based Awards

With the adoption of ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, beginning January 1, 2019, we measure share-based payments to non-employees based on the grant-date fair value of the equity awards to be issued. 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. See "New Accounting Pronouncements – Recently Adopted" in this Note 1 for additional information on the adoption of ASU 2018-07.

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 February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 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, measured at the present value of the lease payments. Recognition, measurement and presentation of

expenses will depend on classification as a finance or operating lease. In July 2018, the FASB issued ASU 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 adopted Topic 842 on January 1, 2019 using the modified retrospective approach as allowed under ASU 2018-11, and we elected to utilize the available practical expedients. Financial results for the reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Accounting Standards Codification Topic 840, *Leases*, or Topic 840.

In connection with the adoption of Topic 842 as of January 1, 2019, we recorded an operating lease, right-of-use asset and a corresponding operating lease liability of approximately $736,000 for the net present value of remaining lease payments of our current operating lease for our office space in Menlo Park. The adoption of Topic 842 did not have a material impact on our condensed statements of operations. See Note 4 on Operating Leases for further discussion of our operating lease obligations.

As of January 1, 2019, we also adopted ASU 2018-07 which simplifies 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. Since all of our share-based awards to nonemployees were fully vested before the adoption of ASU 2018-07, no cumulative-effect adjustment was recognized to the opening balance of retained earnings on January 1, 2019. The adoption of ASU 2018-07 did not have a material impact on our 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 is the inclusion of the annual disclosure requirement of changes in stockholders' equity in Rule 3-04 of Regulation S-X to interim periods. With the adoption of this new rule on January 1, 2019, condensed statements of stockholders' equity for the current and year-to-date reporting periods and the corresponding prior periods are presented.

New Accounting Pronouncements – Issued But Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. Subsequent to issuing ASU 2016-13, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses*, or ASU 2018-19, for the purpose of clarifying certain aspects of ASU 2016-13. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief*, or ASU 2019-05, to provides entities with more flexibility in applying the fair value option on adoption of the credit impairment standard. ASU 2018-19 and ASU 2019-05 have the same effective date and transition requirements as ASU 2016-13. ASU 2016-13 will be effective for fiscal years beginning after December 15, 2019, using a modified retrospective approach. Early adoption is permitted. We plan to adopt ASU 2016-13 and related updates as of January 1, 2020. We do not expect the adoption of this standard to 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,* or ASU 2018-13, 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. We plan to adopt ASU 2018-13 as of January 1, 2020. 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 financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, or ASU 2018-18. The amended guidance precludes presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The new guidance is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early

adoption is permitted. We plan to adopt ASU 2018-18 as of January 1, 2020. We do not expect the adoption of ASU 2018-18 to have a material impact on our financial statements given the termination of the Collaboration Agreement in September 2018.

2. FAIR VALUE MEASUREMENTS

Cash Equivalents and Marketable Securities

Cash equivalents, restricted cash and marketable securities by security type at June 30, 2019 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	$ 15,457	$ —	$ —	$ 15,457
Restricted cash:				
Certificate of deposit	$ 270	$ —	$ —	$ 270
Marketable securities:				
Commercial paper (due in less than one year)	$ 42,000	$ 83	$ (1)	$ 42,082
Corporate notes (due in less than one year)	92,546	155	(5)	92,696
Corporate notes (due in one to two years)	9,448	50	(1)	9,497
	$ 143,994	$ 288	$ (7)	$ 144,275

Cash equivalents, restricted cash and marketable securities by security type at December 31, 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	$ 7,003	$ —	$ —	$ 7,003
Restricted cash:				
Certificate of deposit	$ 269	$ —	$ —	$ 269
Marketable securities:				
Commercial paper (due in less than one year)	$ 57,594	$ 22	$ (29)	$ 57,587
Corporate notes (due in less than one year)	95,238	7	(118)	95,127
Corporate notes (due in one to two years)	18,647	—	(65)	18,582
	$ 171,479	$ 29	$ (212)	$ 171,296

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 June 30, 2019 and December 31, 2018 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 June 30, 2019:						
Commercial paper (due in less than one year)	$ 5,492	$ (1)	$ —	$ —	$ 5,492	$ (1)
Corporate notes (due in less than one year)	11,318	(4)	4,400	(1)	15,718	(5)
Corporate notes (due in one to two years)	1,053	(1)	—	—	1,053	(1)
	$ 17,863	$ (6)	$ 4,400	$ (1)	$ 22,263	$ (7)
As of December 31, 2018:						
Commercial paper (due in less than one year)	$ 22,628	$ (29)	$ —	$ —	$ 22,628	$ (29)
Corporate notes (due in less than one year)	66,557	(82)	14,221	(36)	80,778	(118)
Corporate notes (due in one to two years)	18,582	(65)	—	—	18,582	(65)
	$ 107,767	$ (176)	$ 14,221	$ (36)	$ 121,988	$ (212)

The gross unrealized losses related to commercial paper and corporate notes as of June 30, 2019 and December 31, 2018 were due to changes in interest rates and not credit risk. We determined that the gross unrealized losses on our marketable securities as of June 30, 2019 and December 31, 2018 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. Commercial paper, corporate notes and equity investments are categorized as Level 2 within the fair value hierarchy as their fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows.

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of June 30, 2019 and December 31, 2018 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 June 30, 2019:				
Money market funds(1)	$ 15,457	$ —	$ —	$ 15,457
Commercial paper(2)	—	42,082	—	42,082
Corporate notes(2)(3)	—	102,193	—	102,193
Equity investment(4)	—	582	—	582
Total	$ 15,457	$ 144,857	$ —	$ 160,314
As of December 31, 2018:				
Money market funds(1)	$ 7,003	$ —	$ —	$ 7,003
Commercial paper(2)	—	57,587	—	57,587
Corporate notes(2)(3)	—	113,709	—	113,709
Equity investment(4)	—	585	—	585
Total	$ 7,003	$ 171,881	$ —	$ 178,884

(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 further discussion below of this equity investment.

Equity Investment

In December 2007, we received 13,842,625 ordinary shares in Sienna Cancer Diagnostics Limited, or Sienna, in connection with a license we granted to Sienna for our human telomerase reverse transcriptase, or hTERT, technology for use in human diagnostics. Upon receipt, the shares were recorded at a zero cost basis under the cost method of accounting. With the adoption of ASU 2016-01 on January 1, 2018, our equity investment in Sienna must be reported at fair value at each reporting date and any resulting change in fair value is recognized in our condensed statements of operations. As of June 30, 2019, the fair value of our shares in Sienna was $582,000. For the three months ended June 30, 2019 and 2018, we recognized a decrease in fair value of equity investment of $98,000 and $350,000, respectively, related to observable price changes. There was no change in the fair value of equity investment for the six months ended June 30, 2019, compared to a decrease in fair value of $475,000 for the comparable period in 2018, related to observable price changes. For the three and six months ended June 30, 2019, we also recognized a loss of $8,000 and $3,000, respectively, compared to a loss of $38,000 for each of the comparable periods in 2018, related to foreign currency translation, which are included in other expense in our condensed statements of operations.

3. FORMER 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. Under the Collaboration Agreement, Janssen initiated two clinical trials of imetelstat: a Phase 2 trial in relapsed/refractory myelofibrosis, referred to as IMbark, and a Phase 2/3 trial in lower risk myelodysplastic syndromes, referred to as IMerge. Under the terms of the Collaboration Agreement, prior to the termination, development costs for IMbark and IMerge were shared between us and Janssen on a 50/50 basis, including costs related to patents licensed to Janssen.

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. Under the termination provisions of the Collaboration Agreement, Janssen is required to provide certain operational support for the imetelstat program during transition of the program to us. As of May 14, 2019, we assumed the imetelstat investigational new drug, or IND, sponsorship from Janssen. In the second quarter of 2019, we assumed sponsorship in certain countries outside of the United States. We expect to obtain country-specific health authority and ethics committee approvals for change of sponsorship to us in the remaining countries outside of the United States on a country-by-country basis during the third quarter of 2019. The transition process is expected to be completed by the end of the third quarter of 2019, including transfer of the remaining non-clinical, manufacturing, and ex-U.S. clinical operational responsibilities from Janssen. Each company is responsible for its own costs incurred related to transition activities unless otherwise specified in the Collaboration Agreement. On June 14, 2019, we entered into a Clinical Supply Agreement, or Supply Agreement, with Janssen to purchase certain inventories of drug product, drug substance and raw materials for imetelstat manufacturing. Under the Supply Agreement, we will pay Janssen approximately $7,500,000 for drug product upon shipment of the product to our specified drug distribution centers, which is expected to occur in the third quarter of 2019. We have also agreed to pay up to approximately $6,700,000 for drug substance and raw materials upon testing and confirmation such materials meet certain specifications and expect such testing to occur in the third and fourth quarters of 2019. We are not obligated to purchase materials that do not pass testing and conform to our specifications.

Until the sponsorship responsibilities for imetelstat fully transfer from Janssen to us, Janssen will continue supporting ongoing clinical trials of imetelstat. Since September 28, 2018, our responsibility for imetelstat development costs incurred by Janssen, including continuing support of ongoing clinical trials of imetelstat, increased from 50% to 100%. As of June 30, 2019, the amount due to Janssen of $1,576,000 on our condensed balance sheet primarily represents the amount owed to Janssen for operational support of the imetelstat program for the three months ended June 30, 2019.

4. OPERATING LEASES

As described in Note 1 on Summary of Significant Accounting Policies – New Accounting Pronouncements Recently Adopted, we adopted Topic 842 as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with historical accounting under Topic 840.

Menlo Park Office Space Lease

We have an operating lease for our office space at 149 Commonwealth Drive, Menlo Park, California, that commenced in February 2018 and expires in January 2020. We have an option to extend the lease for one additional period of two years, which we did not include in determining the right-of-use asset or lease liability as we did not consider it reasonably certain that we would exercise such option. Since the operating lease is a net lease, as the non-lease components (i.e., common area maintenance) are paid separately from rent based on actual costs incurred, such non-lease components were not included in the right-of-use asset and liability and are reflected as an expense in the period incurred.

The components of lease costs included in operating expenses in our condensed statements of operations were as follows:

(In thousands)	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease costs	$ 175	$ 348
Variable lease costs (1)	6	8
Total lease costs	$ 181	$ 356

(1) Variable lease costs represent non-lease components, such as common area maintenance charges.

The operating lease liability on the condensed balance sheet reflects the present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, we applied our incremental borrowing rate based on the information available as of the January 1, 2019 adoption date. As of June 30, 2019, future minimum payments under the operating lease were as follows (in thousands):

2019	$	350
2020		58
Total lease payments		408
Less: imputed interest		(6)
Total	$	402

As of June 30, 2019, the weighted average remaining lease term is 7 months and the weighted average discount rate used to determine the operating lease liability was 5%.

New Jersey Office Space Lease

In April 2019, we entered into an operating lease agreement for office space located at 3 Sylvan Way, Parsippany, New Jersey. The initial term of the lease is 11 years with an option to extend for an additional five years and a one-time option to terminate the lease without cause as of the 103rd month anniversary of the commencement date of the lease. We have not yet occupied the space as it is being renovated for our use. The lease term commences upon the earlier of the date of completion of the construction work or the date upon which we occupy and use the space for its intended purpose. Since we do not yet have control of the space, as defined by Topic 842, during the construction period and do not expect to gain control of the space until on or near the construction completion date, we will not record a right-of-use asset and corresponding lease liability until we occupy the space, which we expect to occur by the end of the third quarter of 2019. Upon the commencement of the lease, the aggregate minimum future lease payments for the initial lease term is approximately $3,700,000, net of a seven-month rent abatement period. Under the lease, we are also obligated to pay certain variable expenses separately from the base rent, including electricity and common area maintenance. Such costs will be expensed in the period they are incurred.

We have performed an evaluation of our other contracts with vendors in accordance with Topic 842 and have determined that, except for the operating leases described above and a nominal financing lease for office equipment, none of our contracts contain a lease.

5. STOCKHOLDERS' EQUITY

Authorized Common Stock

On June 6, 2019, we filed a Certificate of Amendment to our Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of our common stock from 300,000,000 shares to 450,000,000 shares. The foregoing amendment was approved by our stockholders at our 2019 annual meeting of stockholders held on June 6, 2019.

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. During the six months ended June 30, 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 other 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. For the three and six months ended June 30, 2019, we sold an aggregate of 108,386 shares of our common stock pursuant to the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately $101,000, after deducting sales commissions and other offering expenses payable by us. For the three and six months ended June 30, 2018, we sold an aggregate of 9,447,026 shares of our common stock pursuant to the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately $36,208,000, after deducting sales commission and other 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.

6. SUBSEQUENT EVENT

In July 2019, we sold an aggregate of 1,784,705 shares of our common stock pursuant to the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately $2,471,000, after deducting sales commissions and other offering expenses payable by us. For further discussion of the 2018 Sales Agreement, see Note 5 on Stockholders' Equity.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "expects," "plans," "intends," "will," "should," "projects," "believes," "predicts," "anticipates," "estimates," "potential" or "continue," or the negative thereof or other comparable terminology. These statements are within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements appear throughout the Form 10-Q and are statements regarding our intent, belief, or current expectations, primarily with respect to our business and related industry developments. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-Q. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A, entitled "Risk Factors," and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part I, Item 2 of this Form 10-Q.

OVERVIEW

The following discussion should be read in conjunction with the unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Form 10-Q and with the sections entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission, or SEC, on March 7, 2019.

Business Overview

We are a late-stage clinical biopharmaceutical company that is focused on the development and potential commercialization of innovative therapeutics for hematologic myeloid malignancies. We have global rights to imetelstat, a first-in-class telomerase inhibitor, which was discovered and developed at Geron. We believe clinical data from two Phase 2 clinical trials of imetelstat (IMerge, for patients with lower risk myelodysplastic syndromes, or MDS, and IMbark, for patients with relapsed/refractory myelofibrosis, or MF, as discussed in detail below) initiated by Janssen Biotech, Inc., or Janssen, support further development of imetelstat in hematologic myeloid malignancies. In May 2019, we assumed the imetelstat investigational new drug, or IND, sponsorship from Janssen upon which we became sponsors of the ongoing IMerge and IMbark clinical trials of imetelstat in the United States.

Based on the data from the Phase 2 portion of IMerge, we plan to open patient screening and enrollment in a Phase 3 clinical trial (Part 2 of IMerge) in August 2019. We plan to conduct an End of Phase 2 meeting with the United States Food and Drug Administration, or the FDA, by the end of the first quarter of 2020 to discuss the IMbark Phase 2 data and regulatory strategies for potential approval of imetelstat in relapsed/refractory MF, and will subsequently provide a decision regarding late-stage development of imetelstat in relapsed/refractory MF, if any.

IMerge (Phase 2/3 Clinical Trial) in Lower Risk Myelodysplastic Syndromes (MDS)

Trial Design

IMerge is a two-part Phase 2/3 clinical trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk, also referred to as lower risk MDS who are relapsed after or refractory to prior treatment with erythropoiesis stimulating agents, or ESAs. Part 1 of IMerge was designed as a Phase 2, open-label, single-arm trial to assess the efficacy and safety of a 7.5 mg/kg dose of imetelstat administered as an intravenous infusion every four weeks in approximately 30 patients. The first patient was dosed in January 2016. To be eligible for the Phase 2 portion of IMerge, patients were required to be transfusion dependent, defined as requiring at least four units of packed red blood cells, or RBCs, over an eight week period during the 16 weeks prior to entry into the trial.

The primary efficacy endpoint of IMerge is the rate of RBC transfusion independence, or RBC-TI, lasting at least eight weeks, defined as the proportion of patients without RBC transfusion during any consecutive eight weeks since entry into the trial, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the rate of hematologic improvement-erythroid, or HI-E, defined as the proportion of patients with a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with

the prior RBC transfusion burden. Other secondary efficacy endpoints include the time to and duration of RBC-TI; the proportion of patients achieving Complete Response, or CR, or Partial Response, or PR, according to the 2006 International Working Group, or IWG, criteria for MDS; the amount and relative change in RBC transfusions; the proportion of patients requiring the use of myeloid growth factors and the dose; assessments of the change in the patients' quality of life using several validated instruments; as well as an assessment of overall survival and time to progression to acute myeloid leukemia, or AML.

Thirty-two patients were initially enrolled in the Phase 2 portion of IMerge, of which a cohort of 13 patients had not received prior treatment with either an hypomethylating agent, or HMA, or lenalidomide and did not have a deletion 5q chromosomal abnormality, also known as non-del(5q). Preliminary data from the Phase 2 portion 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 versus the overall trial population (8-week RBC-TI rate: 54% vs. 34%). The safety profile in the Phase 2 portion of IMerge 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.

To increase the clinical experience and confirm the benefit-risk profile of imetelstat from the 13-patient initial cohort, Janssen expanded new patient enrollment in the Phase 2 portion of IMerge and enrolled 25 additional patients in an expansion cohort. In November 2017, the first patient was dosed in the expansion cohort and enrollment was completed in February 2018.

The combined initial cohort of 13 patients and the expansion cohort of 25 patients (n=38) represent a target patient population of transfusion dependent, non-del(5q) lower risk MDS patients who were relapsed or refractory to ESAs and naïve to HMA and lenalidomide treatment. These patients depend on serial RBC transfusions to manage anemia and fatigue. Moreover, dependency on RBC transfusions is associated with iron overload leading to secondary organ complications which results in poor survival. Therefore, the ultimate goal for most clinical trials in lower risk MDS is to enable patients to become transfusion independent for as long as possible. Preliminary data from the combined initial and expansion cohorts (n=38) were reported at the 60th American Society of Hematology, or ASH, Annual Meeting in December 2018.

Recently Reported Clinical Data from the Phase 2 Portion of IMerge

In June 2019, an oral presentation was made at the EHA Annual Congress meeting reporting updated efficacy and safety data for an aggregate of 38 patients from the combined initial and expansion cohorts of the Phase 2 portion of IMerge. In the EHA presentation, data were reported using a clinical cut-off date of April 30, 2019. The 8-week RBC-TI rate for the combined cohorts was 42% (16/38) and 29% (11/38) of patients achieved a durable response with 24-week RBC-TI. The median duration of RBC-TI was 85.9 weeks (range: 8.0-140.9). The median follow-up was 15.7 months and the median treatment duration was 8.5 months (range: 0.02-37.5). The median number of treatment cycles was 9.0 (range: 1-39) and the median dose intensity was 95.2% of the dose of 7.5 mg/kg every four weeks. The baseline characteristics of the 38 patients highlight the high transfusion burden of these patients, with a median baseline transfusion burden of 8 units per 8 weeks, and with the majority of the patients having received more than 4 units per 8 weeks prior to study entry.

Patient Baseline Characteristics	**n=38**
Median age (range), years	71.5 (46-83)
Male, n (%)	25 (66%)
Eastern Cooperative Oncology Group (ECOG) Performance Standard 0-1, n (%)	34 (89%)
International Prognostic Scoring System risk, n (%) Low Intermediate-1	 24 (63%) 14 (37%)
Baseline median RBC transfusion burden (range), units/8 weeks Patients with >4 units/8 weeks at baseline, n (%)	8 (4-14) 35 (92%)
World Health Organization 2001 category, n (%) Refractory Anemia with Ringed Sideroblasts (RARS) or Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts (RCMD-RS) All others	 27 (71%) 11 (29%)
Prior ESA use, n (%)	34 (89%)
Serum erythropoietin (sEPO) > 500 mU/mL, n (%)	12[a] (32%)

[a] Of the 37 patients with sEPO levels reported.

Key efficacy data reported in the June 2019 EHA presentation are summarized in the table below:

Key Efficacy Outcomes	**n=38**
Rate of 8-week RBC-TI, n (%)	16 (42%)
Rate of 24-week RBC-TI, n (%)	11 (29%)
Median time to onset of RBC-TI (range), weeks	8.3 (0.1-40.7)
Median duration[a] of RBC-TI (range), weeks	85.9 (8.0-140.9)
Hematologic improvement-erythroid, or HI-E, n (%) ≥1.5 g/dL increase in hemoglobin lasting ≥ 8 weeks Transfusion reduction by ≥ 4 units/8 weeks	26 (68%) 12 (32%) 26 (68%)
Mean relative reduction of RBC transfusion burden from baseline, %	-68%

[a] Kaplan Meier method

As summarized in the table below, the safety profile was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. Reversible and manageable Grade 3/4 neutropenias and cytopenias were reported in 61% and 55% of the patients, respectively, and they were without significant clinical consequences. Furthermore, 91% of the observed Grade 3/4 neutropenias and 92% of the observed Grade 3/4 thrombocytopenias were reversible within four weeks. Most frequent non-hematologic toxicities are listed in the table below. Grade 3 liver function test, or LFT, elevations reported in the trial were reversible.

Treatment Emergent Adverse Events (TEAE)	**All Grades n=38 (n, %)**	**Grade 3/4 n=38 (n, %)**
Hematologic Adverse Events		
Thrombocytopenia	25 (66%)	23 (61%)
Neutropenia	22 (58%)	21 (55%)
Anemia	10 (26%)	8 (21%)
Non-Hematologic Adverse Events		
Back Pain[a]	7 (18%)	0
Alanine Aminotransferase increased	7 (18%)	2 (5%)
Aspartate Aminotransferase increased	6 (16%)	3 (8%)
Bronchitis	6 (16%)	3 (8%)
Other Adverse Events[b]	6 (16%)	0
Headache	6 (16%)	1 (3%)

[a] In 3/7 (43%) patients back pain was an adverse event associated with infusion-related reaction.

[b] nasopharyngitis, diarrhea, constipation, edema peripheral and asthenia.

Planned Phase 3 Clinical Development for Imetelstat

Based on the results of the Phase 2 portion of IMerge, we intend to continue the development of imetelstat in lower risk MDS. In doing so, we will be leveraging the prior experience of several members of our newly recruited clinical/regulatory development team with imetelstat gained during the Phase 2 portion of the trial, as well as their broader experience developing other oncology products. In August 2019, we plan to open patient screening and enrollment in the Phase 3 portion of IMerge. The planned Phase 3 portion of IMerge is designed as a double-blind, randomized, placebo-controlled trial of approximately 170 patients to evaluate imetelstat in non-del(5q) lower risk MDS patients who are transfusion dependent, are relapsed after or refractory to prior treatment with an ESA, and have not received treatment with either an HMA or lenalidomide. This is the same patient population as the target patient population in the Phase 2 portion of IMerge. Moreover, the dose of imetelstat, as well as the primary and secondary endpoints, will be the same as those used in the Phase 2 portion of IMerge. In addition, many of the clinical trial sites that participated in the Phase 2 portion of IMerge will be participating in the Phase 3 portion of IMerge.

IMbark (Phase 2 Clinical Trial) in Relapsed/Refractory Myelofibrosis (MF)

Trial Design

IMbark was designed as a Phase 2 clinical trial to evaluate two doses of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in approximately 200 patients with Intermediate-2 or High-risk MF who have relapsed after or are refractory to prior treatment with a janus kinase, or JAK, inhibitor, or relapsed/refractory MF. In December 2018, at the ASH Annual Meeting, with a clinical cut-off date of October 22, 2018 and a median follow-up of 27.4 months (range: 0.2-33.0), we reported a median overall survival, or OS, for the 9.4 mg/kg dosing arm of 29.9 months. In May 2019 with a clinical cut-off date of April 30, 2019, we reported a median OS in the 9.4 mg/kg dosing arm of 28.1 months. Our data compare favorably to the median overall survival of 14 to 16 months reported in medical literature for patients previously treated with JAK inhibitors.

Recently Reported Comparative Analyses of IMbark Data and Real-World Data

Statistical analyses comparing IMbark clinical trial data to closely matched real-world data, or RWD, were recently presented in a poster presentation at the EHA Annual Congress meeting in June 2019. The goal of the analyses was to further assess the potential OS benefit of imetelstat in relapsed/refractory MF patients treated with 9.4 mg/kg in IMbark compared to a closely matched patient population from RWD who were treated with best available therapy, or BAT.

The RWD were collected at the Moffitt Cancer Center from patients who had discontinued treatment from a JAK inhibitor and were subsequently treated with BAT. To mimic the effect of randomization and improve comparability, a propensity score analysis approach was taken to match individual patients within each of the datasets to balance the populations with respect to baseline characteristics and prognostic factors that may impact OS. Guidelines for inclusion and exclusion criteria as defined in the IMbark clinical protocol and the following baseline patient characteristics were used for matching purposes:

- Age
- Platelet count
- Time from diagnosis to JAK inhibitor discontinuation
- JAK inhibitor duration
- Spleen size
- Janus Kinase-2 mutation
- Sex
- Dynamic International Prognostic Scoring System score
- ECOG performance status
- MF type
- Transfusion status

Of the 59 patients treated with imetelstat 9.4 mg/kg in IMbark, two could not be matched with RWD and were excluded from the analyses. Similarly, of the 96 patients treated with BAT from RWD, 58 patients did not meet the matching criteria. Therefore, the populations used for the analyses consisted of 57 patients from IMbark and 38 patients from RWD. Using the data from these matched populations prior to statistical adjustments, the calculated median OS was 33.8 months for the imetelstat-treated patients and 12.0 months for the patients from RWD treated with BAT, resulting in a hazard ratio of 0.35 and a p-value of 0.0003, as shown in the table below.

A propensity score analysis approach was used for each of the datasets and two statistical adjustment methods were applied to calculate median OS for each of the datasets (ATO and sIPTW, as indicated in the table below). Based on either of the statistical adjustment methods used, median OS of 30.7 months was reported for the imetelstat-treated patients. This was more than double the median OS of 12.0 months for patients from RWD treated with BAT. The hazard ratios for all three statistical methods were similar (0.33-0.35). Based on hazard ratios, there was a 65% to 67% lower risk of death for patients treated with imetelstat, compared to closely matched patients from RWD treated with BAT in relapsed/refractory MF.

	Unadjusted Statistical Method		Statistical Adjustment Methods			
			Average Treatment Effect for Overlap Population (ATO)		Stabilized Inverse Probability Treatment Weighting (sIPTW)	
Main Analysis	**Imetelstat (IMbark)**	**RWD BAT (Moffitt)**	**Imetelstat (IMbark)**	**RWD BAT (Moffitt)**	**Imetelstat (IMbark)**	**RWD BAT (Moffitt)**
Median overall survival	33.77 months	12.04 months	30.69 months	12.04 months	30.69 months	12.04 months
Hazard ratio	0.35		0.35		0.33	
P-value	0.0003		0.0019		0.0003	

Two sensitivity analyses were conducted on the datasets to assess the potential impact on OS as a result of early deaths post-JAK inhibitor discontinuation observed in RWD and the use of hematopoietic stem cell transplantation as a subsequent therapy. The results of the sensitivity analyses were consistent with results from the main analysis.

While we believe these analyses suggest favorable OS for imetelstat-treated relapsed/refractory MF patients compared to BAT in closely matched patients from RWD, comparative analyses between RWD and our clinical trial data have several limitations. For instance, the analyses create a balance between treatment groups with respect to commonly available covariates, but do not take into account the unmeasured and unknown covariates that may affect the outcomes of the analyses. Potential biases are introduced by factors which include, for example, the selection of the patients included in the analyses, misclassification in the matching process, the small sample size, and estimates that may not represent the outcomes for the true treated patient population. For these and other reasons, such comparative analyses should be considered carefully and with caution, and should not be relied upon as demonstrative or otherwise predictive or indicative of any future clinical trial results of imetelstat in relapsed/refractory MF.

Potential Late-Stage Development in Relapsed/Refractory MF

We have recently refined our strategies for potentially pursuing regulatory approval of imetelstat in relapsed/refractory MF. As a result, we plan to perform analyses necessary to support these strategies for future potential discussions with regulatory authorities. We believe the results of these analyses may enhance the potential for reaching agreement with the FDA on a timely and cost-effective regulatory strategy for imetelstat in relapsed/refractory MF. We plan to conduct an End of Phase 2 meeting with the FDA by the end of the first quarter of 2020. Subsequent to the End of Phase 2 meeting, we expect to provide a decision regarding late-stage development of imetelstat in relapsed/refractory MF, if any. This decision will be influenced by, among other things, our assessment of what would be required to achieve clinical and regulatory success in relapsed/refractory MF, including the cost and duration of any potential clinical trials required for regulatory approvals in the United States and European Union.

Status of Former 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. 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 termination provisions of the Collaboration Agreement, Janssen is required to provide certain operational support for the imetelstat program through September 2019 during transition of the program to us. Each company is responsible for its own costs incurred related to transition activities unless otherwise specified in the Collaboration Agreement. As of May 14, 2019, we assumed the imetelstat U.S. IND sponsorship from Janssen, upon which we became sponsors of the ongoing IMerge and IMbark clinical trials of imetelstat in the United States, and we assumed sponsorship in certain countries outside of the United States in the second quarter of 2019. We expect to obtain country-specific health authority and ethics committee approvals for change of sponsorship to us in

remaining countries outside of the United States on a country-by-country basis during the third quarter of 2019. We expect the program transition to be completed by the end of September 2019, including the transfer of the remaining non-clinical, manufacturing and ex-U.S. clinical and regulatory responsibilities from Janssen. In June 2019, we entered into a Clinical Supply Agreement, or Supply Agreement, with Janssen to purchase certain inventories of drug product, drug substance and raw materials for imetelstat manufacturing. Under the Supply Agreement, we will pay Janssen approximately $7.5 million for drug product upon shipment of the product to our specified drug distribution centers, which is expected to occur in the third quarter of 2019. We have also agreed to pay up to approximately $6.7 million for drug substance and raw materials, upon testing, which we expect to occur in the third and fourth quarters of 2019, and confirmation that such materials meet certain specifications. We are not obligated to purchase materials that do not pass testing and conform to our specifications.

Until the sponsorship responsibilities for imetelstat in countries outside of the United States fully transfer from Janssen to us, Janssen will continue supporting IMbark and the Phase 2 portion of IMerge. Patients currently enrolled in IMbark and the Phase 2 portion of IMerge continue to receive treatment and follow-up under the respective trial protocols. After September 28, 2018, the effective termination date of the Collaboration Agreement, our responsibility for imetelstat development costs, including ongoing support of IMbark and the Phase 2 portion of IMerge, and costs for the prosecution of patents that were licensed to Janssen under the Collaboration Agreement increased from 50% to 100%.

For a further discussion of the former Collaboration Agreement with Janssen, see Note 3 on Former 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.

Financial Overview

We had approximately $162.3 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities as of June 30, 2019. We will require substantial additional capital in order to further advance the imetelstat program, including conducting the research and development and clinical and regulatory activities necessary to bring imetelstat to market, such as completing the planned Phase 3 portion of IMerge and potential clinical trials in other indications, and establishing sales and marketing capabilities to commercialize imetelstat in the United States on our own, if regulatory approval is granted. If approved for marketing by regulatory authorities, we plan to seek potential commercialization partners for territories outside of the United States. 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, and have not reported any profit since. 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 June 30, 2019, we had an accumulated deficit of approximately $1.0 billion. Since our inception, we have primarily financed our operations through the sale of equity securities, interest income on our marketable securities and payments we received under our collaborative and licensing arrangements.

Substantially all of our revenues to date have been payments under collaboration 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. In any event, imetelstat 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, general and administrative expenses, and losses to substantially increase in future periods as we undertake sole financial 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 six months ended June 30, 2019, as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, other than the adoption of the new accounting pronouncement on January 1, 2019 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 Pronouncement – Recently Adopted

Leases

We adopted Topic 842 on January 1, 2019 using the modified retrospective approach as allowed under ASU 2018-11, and we elected to utilize the available practical expedients. Financial results for the reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 840.

In connection with the adoption of Topic 842 as of January 1, 2019, we recorded an operating lease, right-of-use asset and a corresponding operating lease liability for the net present value of remaining lease payments of our current operating lease for our office space in Menlo Park. To calculate the net present value of lease payments, we apply our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment as of the lease commencement date. We may adjust the right-of-use asset for certain adjustments, such as initial direct costs paid or incentives received. In addition, we include any options to extend or terminate the lease in the expected lease term when it is reasonably certain that we will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term. The adoption of Topic 842 did not have a material impact on our condensed statements of operations. See Note 4 on Operating Leases in Notes to Condensed Financial Statements of this Form 10-Q for further discussion of our operating lease obligation.

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 undertake sole financial responsibility for the development of imetelstat 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.

We recognized license fee revenues of $18,000 in each of the periods for the three and six months ended June 30, 2019, compared to $92,000 and $340,000 for the same periods in 2018 related to our various agreements. The decrease in license fee revenues for the three and six months ended June 30, 2019 compared to the same periods in 2018 reflects a reduction in the number of active license agreements in 2019 for research licenses related to our human telomerase reverse transcriptase, or hTERT, technology

as a result of patent expirations on the underlying technology. We recognized royalty revenues of $83,000 and $140,000 for the three and six months ended June 30, 2019, respectively, compared to $116,000 and $186,000 for the same periods in 2018. The decrease in royalty revenues for the three and six months ended June 30, 2019 compared to the same periods in 2018 reflects expiration of licenses which eliminated the obligation to pay royalties on product sales.

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 2019 than in previous years, and to be eliminated by the end of 2019, due to upcoming patent expirations on such technology.

Research and Development Expenses

During the three and six months ended June 30, 2019 and 2018, 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 six months ended June 30, 2019, direct external expenses included costs for our contract research organization, or CRO, consultants and other clinical-related vendors and 100% of clinical development costs incurred by Janssen for operational support of the imetelstat program during the transition period. For the three and six months ended June 30, 2018, direct external expenses primarily consisted of our 50% 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 $10.1 million and $16.0 million for the three and six months ended June 30, 2019, respectively, compared to $3.2 million and $5.6 million for the same periods in 2018. The increase in research and development expenses for the three and six months ended June 30, 2019 compared to the same periods in 2018 primarily reflects higher direct external costs for clinical development activities. Such costs included: a) fees to our CRO, consultants and other clinical-related vendors for imetelstat program transition; b) start-up expenses for the planned Phase 3 portion of IMerge; and c) 100% reimbursement to Janssen for operational support of the imetelstat program. In addition, increased personnel-related expenses for additional development headcount have been incurred in 2019 compared to 2018.

Research and development expenses for the three and six months ended June 30, 2019 and 2018 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2019	2018	2019	2018
	(Unaudited)			
Direct external expenses	$ 6,827	$ 2,444	$ 10,918	$ 4,331
Personnel-related expenses	2,617	623	4,139	1,037
All other expenses	690	137	983	276
Total research and development expenses	$ 10,134	$ 3,204	$ 16,040	$ 5,644

Since cost sharing between Janssen and us for imetelstat clinical development ceased on September 28, 2018, the effective date of termination of the Collaboration Agreement, we expect research and development expenses to increase in future periods as we undertake sole financial responsibility for the imetelstat development program, including all ongoing or potential future clinical trials, engage third parties and other service providers to conduct clinical trials of imetelstat, and hire additional senior personnel to oversee the program. Under the terms of the Collaboration Agreement, Janssen is required to provide operational support for the imetelstat program, including continuing to support ongoing imetelstat clinical trials, during transition of the program to us. We reimburse Janssen for 100% of the costs for such operational support. However, costs associated with transition activities, such as transfer of the sponsorship of ongoing imetelstat clinical trials, moving databases and related systems and transmitting regulatory files, are being incurred by each company, unless otherwise specified in the Collaboration Agreement. We expect the program transition to be completed by the end of September 2019.

At this time, we cannot provide reliable estimates of how much time or investment will be necessary to advance imetelstat toward commercialization. For a more complete discussion of the risks and uncertainties associated with the development of imetelstat, see the sub-sections entitled “Risks Related to the Development of Imetelstat” and “Risks Related to Regulatory Approval and Commercialization of Imetelstat” in Part II, Item 1A entitled “Risk Factors” and elsewhere in this Form 10-Q.

General and Administrative Expenses

General and administrative expenses were $5.2 million and $10.6 million for the three and six months ended June 30, 2019, respectively, compared to $4.2 million and $9.6 million for the same periods in 2018. The increase in general and administrative expenses for the three and six months ended June 30, 2019 compared to the same periods in 2018 primarily reflects higher corporate and patent legal costs and additional personnel to support operational activities. We expect general and administrative expenses to 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 continue to hire additional personnel to support our operations.

Interest and Other Income

Interest and other income was $1.1 million and $2.3 million for the three and six months ended June 30, 2019, respectively, compared to $717,000 and $1.1 million for the same periods in 2018. The increase in interest and other income for the three and six months ended June 30, 2019 compared to the same period in 2018 primarily reflects higher yields on our marketable securities portfolio and the increase in the size of our marketable securities portfolio 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, in the first half of 2018. 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, we remeasure the fair value of our equity investment in Sienna Cancer Diagnostics Limited, or 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 June 30, 2019 and 2018, the decrease in the fair value of our equity investment in Sienna resulting from observable price changes in Sienna's stock was $98,000 and $350,000, respectively. There was no change in the fair value of equity investment for the six months ended June 30, 2019, compared to a decrease of $475,000 for the same period in 2018. 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 $30,000 and $48,000 for the three and six months ended June 30, 2019, respectively, compared to $59,000 and $77,000 for the same periods in 2018. 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 six months ended June 30, 2019 included a loss of $8,000 and $3,000, respectively, related to foreign currency translation for our equity investment in Sienna, compared to a loss of $38,000 for each of the comparable 2018 periods. 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 June 30, 2019, we had cash, restricted cash, cash equivalents, and current and noncurrent marketable securities of $162.3 million, compared to $182.1 million at December 31, 2018. The net decrease in cash, restricted cash, cash equivalents, and current and noncurrent marketable securities during the six months ended June 30, 2019 was the result of 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 we undertake sole financial responsibility for the development of the imetelstat program.

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 other 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 other 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 other offering expenses payable by us. From May 2019 through July 2019, we sold an aggregate of 1,893,091 shares of our common stock under the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately $2.6 million after deducting sales commissions and other offering expenses payable by us. As of July 31, 2019, approximately $57.8 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 further advance the imetelstat program, including conducting the research and development and clinical and regulatory activities necessary to bring imetelstat to market, such as completion of the planned Phase 3 portion of IMerge and potential clinical trials in other indications, and to establish sales and marketing capabilities to commercialize imetelstat in the United States on our own, if regulatory approval is granted. 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 potential 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 current and future clinical trials, including the planned Phase 3 portion of IMerge, 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, such as the End of Phase 2 meeting with FDA planned to be conducted by the end of the first quarter of 2020, and 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 pursue the development, manufacturing and commercialization of imetelstat;
- our ability to establish, enforce and maintain collaborative or other strategic arrangements for research, development, clinical testing and manufacturing of imetelstat and potential future commercialization and marketing;
- 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 successfully recruit and retain additional key personnel to support the development and potential future 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;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation; and
- the costs of maintaining and operating facilities in California and New Jersey, including higher expenses for travel, telecommunications and administrative oversight.

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 potential commercial activities for imetelstat. In order to further advance the imetelstat program, including completion of the planned Phase 3 portion of IMerge and potential clinical trials in other indications, we will need 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, 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 will need additional funds to meet operational needs and capital requirements to advance the imetelstat program in clinical development and potential commercialization, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which could adversely affect our business and we might cease operations.

Cash Flows from Operating Activities. Net cash used in operations for the six months ended June 30, 2019 and 2018 was $21.5 million and $11.9 million, respectively. The increase in net cash used in operations for the six months ended June 30, 2019 compared to the same period in 2018 primarily reflects higher payments for research and development expenses in connection with the transition of the imetelstat program from Janssen to us, start-up activities for the Phase 3 portion of IMerge and increases in development headcount.

Cash Flows from Investing Activities. Net cash provided by investing activities for the six months ended June 30, 2019 was $28.4 million. Net cash used in investing activities for the six months ended June 30, 2018 was $69.2 million. The increase in net cash provided by investing activities in 2019 compared to 2018 primarily reflects a higher rate of maturities than purchases of marketable securities in 2019.

Cash Flows from Financing Activities. Net cash provided by financing activities for the six months ended June 30, 2019 and 2018 was $243,000 and $83.9 million, respectively. In the second quarter of 2019, we sold an aggregate of 108,386 shares of our common stock for net cash proceeds of approximately $101,000, after deducting sales commissions and other offering expenses payable by us, under the 2018 Sales Agreement with B. Riley FBR. In the first six months of 2018, we sold 22,642,132 shares of our common stock for net cash proceeds of approximately $83.9 million, after deducting sales commissions and other offering expenses payable by us, under the 2015 Sales Agreement with MLV and the 2018 Sales Agreement with B. Riley FBR. See Note 5 on

Stockholders' Equity in Notes to Condensed Financial Statements of this Form 10-Q for additional information about the 2015 Sales Agreement with MLV and the 2018 Sales Agreement with B. Riley FBR.

Contractual Obligations

Our future minimum contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC.

In June 2019, we entered into a Clinical Supply Agreement, or Supply Agreement, with Janssen to purchase certain inventories of drug product, drug substance and raw materials for imetelstat manufacturing. Under the Supply Agreement, we will pay Janssen approximately $7.5 million for drug product upon shipment of the product to our specified drug distribution centers, which is expected to occur in the third quarter of 2019. We have also agreed to pay up to approximately $6.7 million for drug substance and raw materials upon testing and confirmation such materials meet certain specifications and expect such testing to occur in the third and fourth quarters of 2019. We are not obligated to purchase materials that do not pass testing and conform to our specifications.

In April 2019, we entered into an operating lease agreement for office space located at 3 Sylvan Way, Parsippany, New Jersey. The initial term of the lease is 11 years with an option to extend for an additional five years and a one-time option to terminate the lease without cause as of the 103rd month anniversary of the commencement date of the lease. We have not yet occupied the space as it is being renovated for our use. The lease term commences upon the earlier of the date of completion of the construction work or the date upon which we occupy and use the space for its intended purpose, which we expect to occur by the end of the third quarter of 2019. Upon the commencement of the lease, the aggregate minimum future lease payments for the initial lease term is approximately $3.7 million, net of a seven-month rent abatement period. Under the lease, we are also obligated to pay certain variable expenses separately from the base rent, including electricity and common area maintenance.

Other than as described above, during the six months ended June 30, 2019, there have been no other material changes from the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2019, 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, 2018.

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 Annual Report on Form 10-K for the year ended December 31, 2018, or the Form 10-K. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock. We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described under Part I, Item 1A, "Risk Factors" included in the Form 10-K.

RISKS RELATED TO 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 to develop imetelstat or 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 potential commercial launch is subject to significant risks and uncertainties, including, among other things, our ability to:

- open patient screening and enrollment in the planned Phase 3 portion of IMerge for imetelstat in patients with lower risk MDS in August 2019, or at all;
- proceed with further clinical development, or identify a feasible registration pathway, if any, for imetelstat in patients with Intermediate-2 or High risk MF who have relapsed after or are refractory to prior treatment with a JAK inhibitor, or relapsed/refractory MF;
- successfully perform the analyses necessary to support our recently refined strategies for potential regulatory approval in relapsed/refractory MF, and satisfactorily provide to the FDA the data or analyses they require in order to conduct an End of Phase 2 meeting by the end of the first quarter of 2020;
- obtain sufficient feedback from the End of Phase 2 meeting with the FDA by the end of the first quarter of 2020 to enable us to make a timely decision regarding late-stage development of imetelstat in relapsed/refractory MF, if any;
- cause the IND for imetelstat to be maintained without such IND being placed on full or partial clinical hold by the United States Food and Drug Administration, or FDA;
- generate additional safety and efficacy data from current clinical trials of imetelstat, including the Phase 2 portion of IMerge and IMbark, and potential future clinical trials of imetelstat, including the planned Phase 3 portion of IMerge, 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 commence, enroll and complete, potential future clinical trials of imetelstat in hematologic myeloid malignancies, including the planned Phase 3 portion of IMerge;

- collaborate successfully with clinical trial sites, academic institutions, clinical research organizations, or CROs, contractors, 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 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 scope and type of clinical development and other data will be required before the FDA and other regulatory authorities might grant us marketing approval, if any, and
  - what the length of time and cost for us will be to complete any such requirements;
- enter into and maintain arrangements with third parties to provide services needed to further research and develop imetelstat, including maintaining the agreement with our CRO, or to manufacture imetelstat, in each case at commercially reasonable costs;
- enter into and maintain 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, including obtaining funding necessary to conduct our operations, to advance imetelstat to and through potential future clinical trials, including the planned Phase 3 portion of IMerge, regulatory approval and potential commercial launch; and
- recruit and retain personnel to support the development of imetelstat, including completion of the planned Phase 3 portion of IMerge and potential clinical development of imetelstat in other indications.

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 the planned Phase 3 portion of IMerge, and completion of the extension phase of IMbark and the Phase 2 portion of IMerge, could be interrupted, further delayed or abandoned for a variety of reasons.*

Currently, there are two ongoing clinical trials of imetelstat, the extension phase of IMbark and the Phase 2 portion of IMerge. Completion of these clinical trials, and the commencement of any potential future clinical trials of imetelstat, including the planned Phase 3 portion 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 current clinical trials, including the Phase 2 portion of IMerge and the extension phase of IMbark, and any potential future clinical trials, including the planned Phase 3 portion of IMerge, 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 anticipated commencement of screening and enrollment of the planned Phase 3 portion of IMerge to be delayed beyond August 2019 or prevent us from commencing, conducting or completing the planned Phase 3 portion 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 the Phase 2 portion of IMerge, including assessing the durability of RBC-TI responses; and (iii) designing, commencing, enrolling, conducting and completing the planned Phase 3 portion of IMerge, and promptly or adequately reporting data from such trials;
- determining a feasible registration path, if any, for imetelstat in relapsed/refractory MF, after performing analyses necessary to support recently refined strategies for potential regulatory approval and conducting an End of Phase 2 meeting with the FDA by the end of the first quarter of 2020;
- 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 the Phase 2 portion of IMerge, and safety or futility findings by the data review committees of potential future clinical trials of imetelstat, such as the planned Phase 3 portion 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 on commercially reasonable terms 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 and supply 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 our CRO, laboratory service providers and clinical trial sites, on all aspects of clinical development;
- obtaining timely review and clearances by regulatory authorities outside of the United States for the transfer of sponsorship to Geron, or protocol amendments which may be sought for the planned Phase 3 portion 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 expected commencement of screening and enrollment of the planned Phase 3 portion of IMerge to be delayed beyond August 2019 or prevent us from commencing, conducting or completing the planned Phase 3 portion of IMerge; and
- obtaining institutional review boards or ethics committee approvals for the transfer of sponsorship to Geron, or other clinical trial protocols or protocol amendments, including any future refinements to the trial design we may seek for the planned Phase 3 portion of IMerge, which could, for example, cause the expected commencement of screening and enrollment of the planned Phase 3 portion of IMerge to be delayed beyond August 2019 or prevent us from commencing, conducting or completing the planned Phase 3 portion of IMerge.

Failures or delays with respect to any of these events could adversely affect our ability to commence, conduct and complete potential future clinical trials of imetelstat, including the planned Phase 3 portion of IMerge, which could increase development costs, or interrupt, further delay or halt our development or potential 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 could 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, including the planned Phase 3 portion of IMerge. For example, adverse events and dose-limiting toxicities observed in previous clinical trials of imetelstat include:

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

Such adverse events and other safety issues, including deaths, were also observed in IMbark and the Phase 2 portion of IMerge. If patients in any potential future clinical trials of imetelstat, including the planned Phase 3 portion 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 Phase 2 portion 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 Phase 2 portion 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, 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 potential 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 or statistical analyses from clinical trials should be considered carefully and with caution since final data may be materially different from preliminary data or statistical analyses, 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 of imetelstat conducted at Mayo Clinic, or 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 the 9.4 mg/kg dosing arm 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. Likewise, although the statistical analyses comparing IMbark data to closely matched real-world data, or RWD, recently reported at the EHA Annual Congress meeting in June 2019, suggest favorable overall survival for imetelstat-treated relapsed/refractory MF patients compared to best available therapy using closely matched patients' RWD, such comparative analyses between RWD and our clinical trial data have several limitations. For instance, the analyses create a balance between treatment groups with respect to commonly available covariates, but do not take into account the unmeasured and unknown covariates that may affect the outcomes of the analyses. Potential biases are introduced by factors which include, for example, the selection of the patients included in the analyses, misclassification in the matching process, the small sample size, and estimates that may not represent the outcomes for the true treated patient population. For these and other reasons, such comparative analyses should be considered carefully and with caution, and should not be relied upon as demonstrative or otherwise predictive or indicative of any future clinical trial results of imetelstat in relapsed/refractory MF.

Similarly, in the Phase 2 portion of IMerge, the initial data review for the expansion cohort that was conducted by Janssen in the second quarter of 2018, which Janssen called a "data snapshot," 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 since the median follow-up time of the expansion cohort at the time of the data snapshot was less than half the length of time the 13-patient initial cohort had been followed when their data were first reported, or the higher overall baseline transfusion burden of the expansion cohort. Although the latest reported 8-week RBC-TI rate in June 2019 is higher since the "data snapshot", we cannot assure you that the 8-week RBC-TI rate reported for the combined cohorts in the Phase 2 portion of IMerge will improve further with longer follow-up, or at all, or that the 8-week RBC-TI rate of patients to be enrolled in the planned Phase 3 portion of IMerge, if any, will be comparable to what has been reported in the 13-patient initial cohort, the 25-patient expansion cohort, or the combined cohorts. In this regard, because patients remaining in the treatment phase in the Phase 2 portion of IMerge continue to receive imetelstat, data continue to be generated from the trial and will continue to evolve until all patients have ceased treatment. More mature data that may be reported from the Phase 2 portion of IMerge in the future may materially differ from data previously reported. Thus, the reported data should be considered carefully and with caution.

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 treatment phase continue to receive imetelstat in the Phase 2 portion of IMerge, 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 of the planned Phase 3 portion of IMerge, or could cause us to abandon further development of imetelstat entirely. Data from the planned Phase 3 portion of IMerge could materially differ from the overall conclusions reported for the Phase 2 portion 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 the Phase 2 portion of IMerge was reported at the ASH Annual Meetings in December 2017 and December 2018, and at the EHA Annual Congress meetings in June 2018 and June 2019. 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 the Phase 2 portion 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, commence and conduct future clinical trials of imetelstat, including the planned Phase 3 portion 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 the planned Phase 3 portion 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 follow-up in the extension phase of IMbark, our ability to continue to assess overall survival, or OS, would be adversely affected. If we experience difficulties in retaining patients in the treatment or follow-up phase of the Phase 2 portion of IMerge, our ability to continue to assess the durability of RBC-TI responses would be adversely affected. In addition, we may encounter challenges in enrolling and retaining patients in potential future clinical trials of imetelstat, including the planned Phase 3 portion 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, during and after the transition of the imetelstat program from Janssen to us;
- 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, and their willingness to participate in clinical trials of imetelstat during and after the transition of the imetelstat program from Janssen to us;
- 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, perceptions based on the transition of the imetelstat program from Janssen to us, or personal issues.

In addition, potential future clinical trials of imetelstat, including the planned Phase 3 portion of IMerge, will compete, with other clinical trials for product candidates that are in the same therapeutic areas with imetelstat and such trials may also be conducted at the same clinical sites, and this competition will reduce the number and type of patients available to enroll or remain in the imetelstat clinical trials. 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, including the planned Phase 3 portion of IMerge, 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 the planned Phase 3 portion 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.

Although we recently have hired individuals who have experience conducting Phase 3 clinical trials, as a company we have no experience in conducting large-scale, late-stage clinical trials, such as the planned Phase 3 portion 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 commence, enroll, conduct or complete the planned Phase 3 portion 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 are seeking to develop, 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 commence, enroll, conduct and complete large-scale, late-stage clinical trials, such as the planned Phase 3 portion 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 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 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 current and potential future clinical trials of imetelstat 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, we have retained a CRO to support our imetelstat clinical development activities, including the planned Phase 3 portion of IMerge, and any failure by our CRO to perform its contractual obligations, or disputes with our CRO about the quality of its performance or other matters, could cause the expected commencement of screening and enrollment of the planned Phase 3 portion of IMerge to be delayed beyond August 2019 or prevent us from commencing, conducting or completing the planned Phase 3 portion of IMerge, or could otherwise further delay or halt our imetelstat clinical 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 any imetelstat clinical trials, including the planned Phase 3 portion of IMerge, 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 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.*

Although in May 2019, Janssen transferred the imetelstat investigational new drug, or IND, sponsorship to us, and we assumed sponsorship in certain countries outside of the United States in the second quarter of 2019, there are many remaining responsibilities that must also be transitioned to us under the terms of the Collaboration Agreement. Although we expect that the transition will proceed until the end of September 2019, and will include the transfer of all ongoing clinical, regulatory, medical affairs and non-clinical activities to us, these responsibilities may not be transitioned to us on a timely basis, or at all. For example, we expect to obtain country-specific health authority and ethics committee approvals for a change of sponsorship to us in remaining countries outside of the United States on a country-by-country basis during the third quarter of 2019; however, these approvals may not occur on a timely basis, or at all. Moreover, although we have entered into a supply agreement, or Supply Agreement, with Janssen to purchase certain inventories of drug product, drug substance and raw materials for imetelstat manufacturing, the material may not meet our specifications, or Janssen may fail to ship the material to us on a timely basis, or at all.

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, failure to obtain the necessary regulatory approvals for the transition in all jurisdictions, failure by us or our contractors to successfully assume all clinical trial responsibilities, and/or unwillingness and/or inability by Janssen to fully perform all of the transition activities and its obligations to us under the Supply Agreement 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 remainder of the transition period, we will 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 remainder of 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;
- Janssen may not adequately support the timely and orderly transition of clinical trial sites to us;
- failure by Janssen to comply with applicable regulatory guidelines could result in our inability to assume regulatory responsibility in all countries outside of the United States, and to plan for and commence future clinical trials of imetelstat, including the planned Phase 3 portion 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 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 of 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 potentially 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 the planned Phase 3 portion of IMerge, 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 the planned Phase 3 portion of IMerge, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit a New Drug Application, or 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, we are planning to conduct an End of Phase 2 meeting with the FDA by the end of the first quarter of 2020 to discuss regulatory strategies for potential approval of imetelstat in relapsed/refractory MF. In preparation for that meeting, we plan to perform analyses to support our proposed strategies. The FDA may require more or different data or analyses than what has been generated or that we plan to generate in the future, which would further delay our decision regarding, or may preclude altogether, any late-stage development of imetelstat in relapsed/refractory MF. 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, including potentially by us in the future, 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. Such regulatory changes in the United Kingdom or elsewhere could adversely affect and/or delay our ability to obtain approval of, and market and sell, imetelstat in the United States or other countries. 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 for MDS, does not guarantee approval and may not lead to a faster development, regulatory review or approval process.

In October 2017, the FDA granted 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. 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 an NDA 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 potential 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 ship materials as agreed under the Supply Agreement, or our failure 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.*

Although we have agreed under the Supply Agreement to purchase existing inventories of drug product from Janssen and plan to purchase inventories of drug substance and raw materials from Janssen that meet our specifications in order to supply the Phase 2 portion of IMerge and potential future clinical trials of imetelstat, including the planned Phase 3 portion of IMerge, we may not receive these inventories on a timely basis, or at all, the materials may not meet the necessary quality standards, or the quantity of materials that meets our quality standards is insufficient to supply potential future clinical trials of imetelstat, including the planned Phase 3 portion of IMerge. Accordingly, we continue to work to re-establish our own manufacturing supply chain in order to be able to manufacture and supply imetelstat for future clinical and commercial uses meeting applicable regulatory standards. 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, we may be unable to establish a manufacturing supply chain capable of providing imetelstat for clinical trials and potential future commercial uses. In addition, Janssen may not perform as agreed or may default in its obligations to ship drug product, drug substance and raw materials for imetelstat manufacturing. Any of these occurrences 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 the planned Phase 3 portion of IMerge, or to commercialize imetelstat in the future.*

Our planned imetelstat manufacturing supply chain is expected 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. While we are currently in the process of establishing arrangements with third parties for the manufacture of imetelstat, our failure to establish such arrangements in a timely manner, or at all, 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 may not 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 manufacturing activities 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. For example, manufacturing delays could adversely impact the commencement or completion of potential future clinical trials or potential future commercial sales, 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 willing or 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.

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 continue to hire experienced personnel in clinical science, biostatistics, clinical operations, pharmacovigilance, quality, 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 regions 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 continue to expand, we expect that we will need to manage new and additional relationships with various service providers, vendors, suppliers and other third parties, as well as additional office locations, for example, our recently leased office in northern New Jersey. Such continued 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 the planned Phase 3 portion 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. In addition, the outcome of our future efforts to seek to acquire and/or in-license other oncology products, product candidates, programs or companies in order to diversify our product candidate portfolio are highly uncertain and may be unsuccessful. As a result, 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 potential 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, which will require substantial additional capital than our current resources.

In order to advance the imetelstat program, including completing the planned Phase 3 portion of IMerge and potential clinical trials in other indications, as well as potential commercialization activities in the United States, we will need to raise substantial additional capital. In addition, 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 further 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 advance the imetelstat program, including completing the planned Phase 3 portion of IMerge or clinical trials in other indications, or 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 or commercialization 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.

We have never 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 approvals, 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 or claims related to clinical trial conduct.

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 or claims related to clinical trial conduct if the use of imetelstat is alleged to have injured patients, including any injuries alleged to arise from any hepatotoxicity or hemorrhagic event associated with the use of imetelstat. We currently have limited clinical trial liability insurance, and we may not be able to maintain this type of insurance for any clinical trials, including the planned Phase 3 portion of IMerge, 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, including biotechnology and biopharmaceutical companies, that experience volatility in the market price of their securities. This risk is especially relevant for us because we often experience significant stock price volatility in connection with our product development activities. In fact, we and certain of our officers have previously been named as defendants in purported class action securities lawsuits and/or derivative lawsuit.

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 significant 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, future clinical trials of imetelstat, if any, including the planned Phase 3 portion of IMerge, or other business activities. 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 potential future 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. We may experience employment-related disputes as we seek to expand our personnel resources. 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 or use 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 and commercialization 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. Under the Hatch-Waxman Act, a patent may be eligible for future patent term restoration of up to five years under certain circumstances. Depending upon the timing, duration and specifics of any potential marketing approval of imetelstat, one or more of our owned or licensed U.S. patents may be eligible for patent term extension under the Hatch-Waxman Act. Similar extensions are also available in certain foreign countries and territories, such as in Japan and in Europe. However, should we seek such a patent term extension, we may not be granted any such patent term extension and/or the applicable time period of patent protection afforded could be less than five years.

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, enforcing and extending 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 loss of intellectual property rights could impair our ability to exclude others from commercializing products similar or identical to 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 future 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, 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 imetelstat 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 or 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 in patent applications that are subject to the law before the implementation of the AIA, 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 seek to enable potential global commercialization of imetelstat, 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 and hematologic malignancies, 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:

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

We may be subject to infringement claims that are costly to defend, and such claims may limit our ability to use disputed technologies and prevent us from pursuing research, development, manufacturing or commercialization of imetelstat.

The commercial success of imetelstat will depend upon our ability to research, develop, manufacture, market and sell imetelstat without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and many pharmaceutical companies, including potential competitors, have substantial patent portfolios. In the event our technologies infringe the rights of others or require the use of discoveries and technologies controlled by third parties, we may be prevented from pursuing research, development, manufacturing or commercialization of imetelstat, or may be required to obtain licenses to those patents or other proprietary rights or develop or obtain alternative technologies. For example, we are aware that certain third parties have or may be prosecuting patents and patent estates that may relate to imetelstat, and while we believe these patents will expire before imetelstat is able to be commercialized and/or that these patents are invalid and/or would not be infringed by the manufacture, use or sale of imetelstat, it is possible that the owner(s) of these patents will assert claims against us in the future. If that were to occur, we would need to obtain unblocking licenses from such third parties, develop alternative non-infringing technologies, which we may not be able to do at an acceptable cost or on acceptable terms, or at all, or cease the development of imetelstat. In addition, while Janssen has terminated the Collaboration Agreement, we are

still subject to indemnification obligations to Janssen under the Collaboration Agreement, including with respect to claims of third party patent infringement.

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

We may become aware of discoveries and technologies controlled by third parties that are advantageous or necessary to further develop or manufacture imetelstat. For example, as we transition the imetelstat program from Janssen to us, we may learn of changes to the imetelstat manufacturing process made by Janssen which would require us to obtain licenses to third party intellectual property rights. Under such circumstances, we may initiate negotiations for licenses to other technologies as the need or opportunity arises. We may not be able to obtain a license to a technology required to pursue the research, development, manufacture or commercialization of imetelstat on commercially favorable terms, or at all, or such licenses may be terminated on certain grounds, including as a result of our failure to comply with the obligations under such licenses. If we do not obtain a necessary license or if such a license is terminated, we may need to redesign such technologies or obtain rights to alternative technologies, which may not be possible, and even if possible, could cause further delays in the development efforts for imetelstat and could increase the development and/or production costs of imetelstat. In cases where we are unable to license necessary technologies, we could be subject to litigation and prevented from pursuing research, development, manufacturing or commercialization of imetelstat, which would materially and adversely impact our business. Failure by us to obtain rights to alternative technologies or a license to any technology that may be required to pursue research, development, manufacturing or commercialization of imetelstat would further delay potential future clinical trials of imetelstat and any applications for regulatory approval, impair our ability to sell imetelstat, if approved, and therefore result in decreased sales of imetelstat for us. Occurrence of any of these events would materially and adversely affect our business, and might cause us to cease operations.

We may become involved in disputes with past or future collaborator(s), including Janssen, over intellectual property inventorship, ownership or use, and publications by us, or by investigators, scientific consultants, research collaborators or others. Such disputes could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant impact on our business.

Inventions discovered under research, material transfer or other collaboration agreements, including our Collaboration Agreement with Janssen which was terminated effective September 28, 2018, may become jointly owned by us and the other party to such agreements in some cases, and may be the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who invents and owns a particular invention, or whether it is jointly owned, and disputes can arise regarding inventorship, ownership and use of those inventions. These disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect our license rights to these inventions. In addition, clinical trial investigators, scientific consultants and research collaborators generally have contractual rights to publish data and other proprietary information, subject to review by the trial sponsor. Publications by us, or by investigators, scientific consultants, previous employees, research collaborators or others, either with permission or in contravention of the terms of their agreements with us or with Janssen or otherwise, may impair our ability to obtain patent protection or protect proprietary information which would have a material adverse effect on our business, and might cause us to cease operations.

Much of the information and know-how that is critical to our business is not patentable, and we may not be able to prevent others from obtaining this information and establishing competitive enterprises.

We sometimes rely on trade secrets to protect our proprietary technology, especially in circumstances in which we believe patent protection is not appropriate or available. We attempt to protect our proprietary technology in part by confidentiality agreements with our employees, consultants, collaborators and contractors. We cannot provide assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors, any of which would harm our business significantly.

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

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

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including cloud-based systems, to support business processes as well as internal and external communications. Our computer and information technology systems, and those of our collaborators, service providers and contractors, are potentially vulnerable to breakdown, malicious intrusion, malware, computer viruses, natural disasters, terrorism, war, and telecommunication and electrical failures that may result in damage to or the impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. In addition, we rely on our collaborators, service providers, including our CRO, and contractors to establish and maintain appropriate information technology systems and data security protections. However, except for contractual duties and obligations, we have limited ability to control their actions related to such matters. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our imetelstat development program. For example, the loss of clinical study data from completed, ongoing or planned clinical trials could result in delays in potential regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

In addition, our computer and information technology systems, as well as those of our collaborators, service providers and contractors, are potentially vulnerable to data security breaches, whether by employees, contractors, consultants, malware, phishing attacks, or other cyber-attacks, that may expose confidential information, intellectual property, proprietary business information or personal information to unauthorized persons. If a data security breach affects our systems or those of third parties upon which we rely, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information by our collaborators, service providers, contractors or us, our reputation could be materially damaged, and we could be subject to significant fines, increased costs or loss of revenue. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. These may include state breach notification laws, and the EU General Data Protection Regulation (EU) 2016/679, or GDPR. Accordingly, a data security breach or privacy violation that leads to unauthorized access to, disclosure or modification of personal information (including protected health information), that prevents access to personal information or materially compromises the privacy, security, or confidentiality of the personal information, could result in fines, increased costs or loss of revenue as a result of:

- harm to our reputation;
- fines or penalties imposed on us by regulatory authorities;
- additional compliance obligations or enforcement measures under federal, state or foreign laws;
- remediation and corrective action we undertake as required by law or as otherwise necessary;
- litigation and potential civil or criminal liability; and
- requirements to verify the accuracy of affected data.

If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our computer and information technology systems, because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems, change frequently, become more sophisticated, and often are not recognized until launched against a target, we or our collaborators, service providers or contractors may be unable to anticipate these techniques or to implement adequate preventative

measures. In addition, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny.

Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.*

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. Although we became Privacy Shield certified by the U.S. Department of Commerce's International Trade Administration in April 2019, there is a risk that our Privacy Shield certification could be revoked or held by a court of competent jurisdiction to be an invalid basis for the transfer of personal data outside of the European Economic Area. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, California enacted the California Consumer Privacy Act (CCPA) on June 28, 2018, which takes effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CRO, and contractors must comply. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

Our failure to obtain additional capital when needed could force us to further delay, reduce or eliminate development of imetelstat, including the planned Phase 3 portion of IMerge, or our potential future imetelstat commercialization efforts, which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.*

Successful drug development and commercialization requires significant amounts of capital. We will require substantial additional capital in order to further advance the imetelstat program, including conducting the research and development and clinical and regulatory activities necessary to bring imetelstat to market, such as completion of the planned Phase 3 portion of IMerge and potential clinical trials in other indications, and to establish sales and marketing capabilities to commercialize imetelstat in the United States on our own, if regulatory approval is granted. 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 potential 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 current and future clinical trials, including the planned Phase 3 portion of IMerge, 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, such as the End of Phase 2 meeting with the FDA planned to be conducted by the end of the first quarter of 2020, and 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 pursue the development, manufacturing and commercialization of imetelstat;
- our ability to establish, enforce and maintain collaborative or other strategic arrangements for research, development, clinical testing and manufacturing of imetelstat and potential future commercialization and marketing;
- 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 successfully recruit and retain additional key personnel to support the development and potential future 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;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation; and
- the costs of maintaining and operating facilities in California and New Jersey, including higher expenses for travel, telecommunications and administrative oversight.

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 potential commercial activities for imetelstat. In order to further advance the imetelstat program, including completion of the planned Phase 3 portion of IMerge and potential clinical trials in other indications, we will need 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, 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 will need additional funds to meet operational needs and capital requirements to advance the imetelstat program in clinical development and potential commercialization, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which could adversely affect our business and we might cease operations.

We currently have no source of product revenue and may never become consistently profitable.*

Although we were profitable in 2015 due to the recognition of revenue in connection with the upfront payment from Janssen under the Collaboration Agreement, we have otherwise never been profitable and have incurred operating losses every year since our operations began in 1990. We will not receive any future milestone-based or royalty payments from Janssen relating to imetelstat, nor will Janssen share the cost of ongoing or future clinical trials of imetelstat or the costs for patents that were licensed to them under the terminated Collaboration Agreement, after September 28, 2018. We expect to continue to incur significant additional operating losses and our operating losses are likely to substantially increase given our sole financial responsibility for imetelstat clinical development activities. As of June 30, 2019, our accumulated deficit was approximately $1.0 billion. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations.

Substantially all of our revenues to date have been payments under collaboration agreements and milestones, royalties and other revenues from our licensing arrangements. With the termination of the Collaboration Agreement effective September 28, 2018, we have no ongoing collaboration agreements related to imetelstat. Any revenues generated from our remaining licensing agreements related to our human telomerase reverse transcriptase, or hTERT, technology are expected to be minimal, and will be insufficient to sustain our operations. The patents underlying our license agreements related to our hTERT technology are expiring, and accordingly we expect revenues under such license agreements to be eliminated by the end of 2019. We have no current plans to enter into any new corporate collaboration, partnership or license agreements that result in revenues.

We also expect to experience increased negative cash flow for the foreseeable future as we fund our operations and imetelstat clinical development activities advance. This will result in decreases in our working capital, total assets and stockholders' equity. Further, we may be unable to replenish our working capital by future financings. We will need to generate significant revenues to achieve consistent future profitability. We may never achieve consistent future profitability. Even if we do become profitable in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve consistent future profitability could negatively impact the market price of our common stock and our ability to sustain operations.

The comprehensive U.S. tax reform bill passed in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law legislation, known as the Tax Cuts and Jobs Act of 2017, that significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The legislation, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; reduction in the percentage of allowable expenses eligible for orphan drug credit purposes; limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks; immediate deductions for certain new investments instead of deductions for depreciation expense over time; and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall long-term impact of the federal tax law changes are uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the federal tax law changes. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

Our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the 2017 federal income tax law changes, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the federal tax law changes. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. If a limitation were to

apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods. In addition, a portion of the carryforwards may expire before being available to reduce future income tax liabilities which could adversely impact our financial position.

RISKS RELATED TO OUR COMMON STOCK AND FINANCIAL REPORTING

Historically, our stock price has been extremely volatile.*

Historically, our stock price has been extremely volatile. Between July 1, 2009 and June 30, 2019, our stock has traded as high as $9.24 per share and as low as $0.91 per share. Between July 1, 2016 and June 30, 2019, the price has ranged between a high of $6.99 per share and a low of $0.95 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- termination of the Collaboration Agreement by Janssen in September 2018;
- announcements regarding the research and development of imetelstat, or results of, further delays in, discontinuation of, or further modifications or refinements to any clinical trials of imetelstat for any reason, including as a result of the failure to successfully transition the imetelstat program to us by Janssen, or our inability, for any reason, to successfully continue the development of imetelstat;
- preliminary, interim or final clinical trial data reported with respect to current or potential future clinical trials of imetelstat, and investor perceptions thereof;
- not receiving timely regulatory clearances or approvals in any jurisdiction, whether within or outside of the United States, including, if we do not obtain regulatory clearance to commence, conduct or continue clinical trials of imetelstat in MF, MDS or any additional hematologic myeloid malignancies in a timely manner or at all, or to amend any clinical trial protocol with respect to the anticipated conduct of the planned Phase 3 portion of IMerge or any potential future clinical trials of imetelstat;
- announcements regarding the safety of imetelstat and partial or full clinical holds placed on the imetelstat IND by the FDA or other regulatory authorities, or other regulatory developments related to imetelstat;
- the experimental nature of imetelstat;
- the terms and timing of any future collaboration agreements for the development and potential commercialization of imetelstat in countries outside of the United States that we may establish;
- the demand in the market for our common stock;
- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, potential future collaborative partners or our competitors;
- fluctuations in our operating results;
- increased or continuing operating losses as a result of our sole financial responsibility for the development and potential future commercialization of imetelstat or otherwise;
- general domestic and international market conditions or market conditions relating to the biopharmaceutical and pharmaceutical industries;
- announcements concerning imetelstat proprietary rights;
- comments by securities analysts or other third parties, including blogs, articles and other media;
- large stockholders exiting their position in our common stock or an increase in the short interest in our common stock;
- announcements of or developments concerning potential future litigation, including any securities class action litigation initiated as a result of the termination of the Collaboration Agreement;
- the issuance of common stock to partners, vendors or investors to raise additional capital; and
- the occurrence of any other risks and uncertainties discussed under the heading “Risk Factors.”

Stock prices and trading volumes for many biopharmaceutical companies fluctuate widely for a number of reasons, including factors which may be unrelated to their businesses or results of operations, such as media coverage, statements made on message boards and social media forums, legislative and regulatory measures and the activities of various interest groups or organizations. In

addition to the risk factors described in this section, overall market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock and the return on your investment.

In addition, as further discussed in the Risk Factor above titled *"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",* class action litigation has often been instituted against companies, including us, whose securities have experienced periods of volatility in market price. Any such litigation brought against us in the future could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in further delays of potential future clinical trials or commercialization efforts.

We may fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

Our common stock is currently traded on the Nasdaq Global Select Market. The Nasdaq Stock Market LLC has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum closing bid price of $1.00 per share of our common stock. On December 21, 2018, the closing price of our common stock was $0.98 per share, and while the closing price of our common stock rose to $1.02 per share on December 26, 2018, and has subsequently remained at or above the minimum closing bid price of $1.00 per share from December 26, 2018 through the date of filing of this Quarterly Report on Form 10-Q, it may in the future fall below the closing minimum bid price of $1.00 per share. If the closing bid price of our common stock were to fall below $1.00 per share for 30 consecutive trading days, or we do not meet other listing requirements, we would fail to be in compliance with Nasdaq's listing standards. There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, The Nasdaq Stock Market LLC may initiate the delisting process with a notification letter. If we were to receive such a notification, we would be afforded a grace period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock would need to maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

The sale of a substantial number of shares may adversely affect the market price of our common stock.

As of June 30, 2019, we had 450,000,000 shares of common stock authorized for issuance and 186,638,401 shares of common stock outstanding. In addition, we had reserved 45,465,319 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrant as of June 30, 2019. In addition, under the universal shelf registration statement filed by us in May 2018 and declared effective by the SEC in July 2018, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of $250 million.

Future sales of our common stock or the perception that such sales could occur, or the issuance of common stock to fund our operations and imetelstat development, including pursuant to our 2018 Sales Agreement with B. Riley FBR, could cause immediate dilution and adversely affect the market price of our common stock. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding warrant, also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities, which could negatively affect the market price of our common stock and the return on your investment.

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

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

In addition, if in the future, we issue preferred stock that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting

power of our common stock, the rights of holders of our common stock or the market price of our common stock could be adversely affected.

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

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

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

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.*

Our amended and restated bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf,
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders;
- any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws, or
- any action asserting a claim governed by the internal affairs doctrine.

The exclusive forum provisions in our bylaws may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our current or former directors, officers, or other employees, which may discourage such lawsuits against us and our current or former directors, officers, and other employees. Alternatively, if a court were to find the exclusive forum provisions contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material and adverse impact on our business and our financial condition.

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an annual assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. In addition, our independent registered public accounting firm must provide an opinion annually on the effectiveness of our internal control over financial reporting.

The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that material weaknesses or significant deficiencies will not exist or otherwise be discovered in the future. If material weaknesses or other significant deficiencies occur, such weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

RISKS RELATED TO COMPETITIVE FACTORS

Competitors may develop products, product candidates or technologies that are superior to or more cost-effective than ours, which may significantly impact the development and commercial viability of imetelstat, 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.

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

If approved for commercial sale for the treatment of lower risk MDS, imetelstat would compete against a number of treatment options, including erythropoiesis stimulating agents and other hematopoietic growth factors; immunomodulators, such as lenalidomide by Celgene Corporation, or Celgene; hypomethylating agents, such as azacitidine by Celgene and decitabine by Janssen; in addition to investigational treatments that may be further along in development than imetelstat, such as oral versions of azacitidine; histone deacetylase inhibitors; TGF-beta superfamily inhibitors, such as luspatercept by Acceleron Pharma, Inc., or Acceleron, in collaboration with Celgene; PI3 Kinase inhibitors; proteasome inhibitors; aminopeptidase inhibitors, such as tosedostat by CTI Biopharma Corporation, or CTI Biopharma; TLR2-specific antibodies; TPO agonists, such as romiplostim by Amgen Inc.; anti-CD33 antibodies; anti-CD38 antibodies, such as daratumumab by Genmab A/S in collaboration with Janssen; anti-CD123 antibodies, such as talacotuzumab by Janssen; antagonists of Toll-like receptor signaling; retinoic acid receptor alpha agonists, such as SY-1425 by Syros Pharmaceuticals; hypoxia-inducible factor prolyl hydroxylase inhibitors, such as roxadustat by FibroGen, Inc.; Fas ligand inhibitors; immune checkpoint regulators; and JAK-STAT pathway inhibitors.

If approved for commercial sale for the treatment of MF, imetelstat would compete against Incyte Corporation's ruxolitinib, or Jakafi®, which is orally administered. In clinical trials, Jakafi® reduced spleen size, abdominal discomfort, early satiety, bone pain, night sweats and itching in MF patients. Recently, there have also been reports of overall survival benefit as well as improvement in bone marrow fibrosis from Jakafi® treatment. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cell counts; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include erythropoiesis stimulating agents, androgens, danazol, corticosteroids, thalidomide and lenalidomide. There are other investigational treatments for MF further along in development than imetelstat, such as pacritinib by CTI Biopharma, momelotinib by Sierra Oncology, and fedratinib by Celgene, which have reported results from Phase 3 clinical trials. Other investigational treatments for MF include inhibitors of the JAK-STAT pathway, such as NS-018 by NS Pharma, Inc.; histone deacetylase inhibitors; interleukin-3 receptor targeted agents; inhibitors of heat shock protein 90; hypomethylating agents; PI3 Kinase and mTOR inhibitors; anti-fibrosis antibodies, such as PRM-151 from Promedior, Inc.; hedgehog and SMO inhibitors; PIM kinase inhibitors; IAP inhibitors; anti-LOX2 inhibitors; recombinant pentraxin 2 protein; KIP-1 activators; TGF-beta superfamily inhibitors, such as sotatercept and luspatercept by Acceleron, in collaboration with Celgene; FLT inhibitors; BET inhibitors, such as CPI-0610 by Constellation Pharmaceuticals, Inc.; SMAC mimetics, such as LCL161 by Novartis Pharmaceuticals Corporation and other tyrosine kinase inhibitors.

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

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

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

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

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

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

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

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

The established use of conventional products competitive with imetelstat may limit or preclude the potential for imetelstat to receive market acceptance upon any commercialization. We may be unable to demonstrate any pharmacoeconomic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for hematologic myeloid malignancies.

Third-party payors may decide that any potential improvement that imetelstat may provide to clinical outcomes in hematologic myeloid malignancies is not adequate to justify the costs of treatment with imetelstat. If the health care community does not accept imetelstat for any of the foregoing reasons, or for any other reason, our ability to further develop or potentially commercialize imetelstat may be negatively impacted or precluded altogether, which would seriously and adversely affect our business and business prospects, and might cause us to cease operations.

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

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

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

We cannot be sure that coverage and reimbursement will be available for imetelstat, if approved for commercial sale, and, if reimbursement is available, what the level of reimbursement will be. There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which marketing approval is obtained. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize imetelstat, even if marketing approval is obtained, which would negatively impact our business and business prospects.

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

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

While the Supreme Court upheld the constitutionality of most elements of the ACA in June 2012 and upheld the ACA against challenges to nationwide tax subsidies in July 2015, other judicial and Congressional challenges against the ACA have been brought, and are likely to be brought in the future. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress

as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was enacted, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012, signed into law in January 2013, among other things, also reduced Medicare payments to certain providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In the future, we anticipate additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices, or the amounts of reimbursement available for imetelstat. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in light of the rising cost of prescription drugs and biologics. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, and reform government program reimbursement methodologies for drugs, some of which are included in the Trump administration's budget proposal for fiscal year 2019. Additionally, the Trump administration released a "Blueprint" that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While a number of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on future worldwide sales of imetelstat, if approved.

Cost control initiatives also could decrease the price that we may receive for imetelstat in the future. If imetelstat is not considered cost-effective or adequate third-party reimbursement for the users of imetelstat cannot be obtained, then we may be unable to maintain price levels sufficient to realize an appropriate return on our investment in imetelstat. Any of these events would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities, including prescription drug manufacturers (or a party acting on its behalf), from knowingly and willfully, directly or indirectly, soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, lease or recommendation of, any good, facility, item or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. The ACA, among other things, amended the intent

requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation;

- the federal civil and criminal false claims and civil monetary penalties laws, including the federal civil False Claims Act and its qui tam or whistleblower provisions which permit a private individual to bring an action on behalf of the government to enforce the civil False Claims Act, prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, transmission and breach reporting of individually identifiable health information, upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers, and healthcare entities, or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, including the GDPR, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements will comply with applicable healthcare, privacy and data security laws and regulations will involve substantial costs. For example, the GDPR, which became effective on May 25, 2018, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR has increased our responsibility and potential liability in relation to personal data that we process or control compared to prior EU law, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions in the GDPR, that will go into effect

beginning January 1, 2020, and we cannot determine the impact such laws, regulations and standards will have on our business. In any event, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare or privacy laws, including the GDPR, in light of the lack of applicable precedent and regulations.

Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. If our operations are found to be in violation of any of these or any other healthcare and privacy-related regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
3.1	Restated Certificate of Incorporation	3.3	8-K	May 18, 2012	000-20859
3.2	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	June 7, 2019	000-20859
10.1#	Change Order No. 1 under Work Order No. 1 under Master Services Agreement by and between the Registrant and Parexel International (IRL) Limited, dated June 19, 2019				
10.2	Office Lease Agreement by and between Registrant and 3 Sylvan Realty LLC, effective as April 30, 2019	10.18	10-Q	May 2, 2019	000-20859
31.1	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated August 1, 2019				
31.2	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated August 1, 2019				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 1, 2019 **				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 1, 2019 **				
101	The following materials from the Registrant's June 30, 2019 Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Balance Sheets as of June 30, 2019 and December 31, 2018, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2019 and 2018, (iii) Condensed Statements of Stockholders' Equity for the three and six months ended June 30, 2019 and 2018, (iv) Condensed Statements of Cash Flows for the six months ended June 30, 2019 and 2018 and (v) Notes to Condensed Financial Statements				

Portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the registrant if publicly disclosed.

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

SIGNATURE

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

GERON CORPORATION

Date: August 1, 2019

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

CHANGE ORDER #1

Client Name:	GERON Corporation
Drug Name or Number:	Imetelstat
Protocol Number:	63935937MDS3001
Parexel Project Number:	**[***]**
Change Order Number:	1
Change Order Date:	June 19, 2019
Parexel Project Manager:	**[***]**

Parexel and Client signed a Work Order dated January 30, 2019. The parties wish to amend said Work Order as applicable and hereby agree as follows:

1. The items listed on Change in Scope Log #1, attached as Attachment 1 to this Change Order, dated June 19, 2019 shall be incorporated in said Work Order.

2. The total contract value changes as follows:

	[***]	**[***]**	**[***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

3. Section 7 of the Work Order shall be replaced in its entirety with the following:

Parexel Key Personnel. The following Parexel Key Personnel, as defined in Section 2.5 of the Agreement, are assigned to the Project covered by this Work Order:

Title	Name	Telephone Number	Email
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE GERON CORPORATION HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO GERON CORPORATION IF PUBLICLY DISCLOSED.

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

4. Section 8 of the Work Order shall be replaced in its entirety with the following:

Parexel Sub-Processors. The following Parexel Sub-Processors, as defined in **Attachment E** of the Agreement, are assigned to the Project:

- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
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- [***]
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- [***]

Any changes to Sub-Processors shall be made pursuant to Sections 7.4 and 7.5 of **Attachment E**.

5. The Specifications and Assumptions Exhibit A in the Work Order shall be replaced in its entirety by Attachment 2 in this Change Order #1.

6. The Task and Responsibility Exhibit B in the Work Order shall be replaced in its entirety by Attachment 3 in this Change Order #1.

7. The Budget Grid Summary in Exhibit F in the Work Order shall be replaced in its entirety by Attachment 4 in this Change Order #1.

8. The [***] Payment Schedule in Exhibit G in the Work Order shall be replaced in its entirety by Attachment 5 in this Change Order #1.

No term or condition other than the above shall be amended by this Change Order.

[Signatures on following page]

GERON Corporation	**Parexel International (IRL) Limited**
By: /s/ Andrew J. Grethlein	By: /s/ Mark Fives
Name: Andrew J. Grethlein, Ph.D.	Name: Mark Fives
Title: Executive Vice President and Chief Business Officer	Title: Senior Manager
Date: 19-Jun-2019	Date: 20-Jun-2019

ATTACHMENT 1
CHANGE IN SCOPE LOG 1

CHANGE IN SCOPE LOG

Change In Scope Log

	Protocol No.	63935937MDS3001
	Client Name	GERON Corporation
	Parexel Project No.	**[***]**
	Project Manager	**[***]**
	CIS No.	1
	Date	19-June-2019

Item#	Date Requested and Requestor	CIS Task description	Service Fee (Contract Currency)	Investigator Fees	Pass Through Costs
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

ATTACHMENT 2
SPECIFICATIONS AND ASSUMPTIONS

{7 pages omitted}

[***]

ATTACHMENT 3
TASKS & RESPONSIBILITIES

{21 pages omitted}

[***]

ATTACHMENT 4
BUDGET GRID SUMMARY

Table 1 – Budget Grid Summary

[***]

ATTACHMENT 5
[***] PAYMENT SCHEDULE

{2 pages omitted}

[***]

EXHIBIT 31.1

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

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

1. I have reviewed this quarterly report on Form 10-Q of Geron Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 1, 2019

/s/ JOHN A. SCARLETT

JOHN A. SCARLETT, M.D.
President and Chief Executive Officer

EXHIBIT 31.2

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

I, Olivia K. Bloom, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Geron Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 1, 2019

/s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

Executive Vice President, Finance, Chief Financial Officer and Treasurer

EXHIBIT 32.1

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

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

(i) the accompanying quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 1, 2019

/s/ JOHN A. SCARLETT

JOHN A. SCARLETT, M.D.

President and Chief Executive Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

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

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

(i) the accompanying quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 1, 2019

/s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

Executive Vice President, Finance, Chief Financial Officer and Treasurer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.