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, 2023

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: 000-20859

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.)**
919 EAST HILLSDALE BOULEVARD, SUITE 250, FOSTER CITY, CA	**94404**
(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 27, 2023:**
Common Stock, $0.001 par value	523,370,675 shares

GERON CORPORATION
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2023

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	JUNE 30, 2023 (UNAUDITED)	DECEMBER 31, 2022 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,903	$ 56,845
Restricted cash	535	364
Marketable securities	314,475	115,901
Interest and other receivables	1,187	3,144
Prepaid and other current assets	4,179	3,992
Total current assets	377,279	180,246
Noncurrent marketable securities	28,281	—
Property and equipment, net	1,147	793
Operating leases, right-of-use assets	3,841	4,147
Deposits and other assets	4,748	5,389
	$ 415,296	$ 190,575
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,673	$ 10,190
Accrued compensation and benefits	8,232	11,534
Operating lease liabilities	786	925
Debt	10,842	20,945
Accrued liabilities	45,036	33,100
Total current liabilities	72,569	76,694
Noncurrent operating lease liabilities	3,498	3,671
Noncurrent debt	40,802	30,212
Commitments and contingencies		
Stockholders' equity:		
Common stock	522	390
Additional paid-in capital	1,799,841	1,493,469
Accumulated deficit	(1,500,991)	(1,413,642)
Accumulated other comprehensive loss	(945)	(219)
Total stockholders' equity	298,427	79,998
	$ 415,296	$ 190,575

See accompanying notes.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022	2023	2022
Revenues:				
Royalties	$ 29	$ 73	$ 50	$ 196
Operating expenses:				
Research and development	35,490	20,606	62,709	42,705
General and administrative	16,490	7,443	29,384	14,142
Total operating expenses	51,980	28,049	92,093	56,847
Loss from operations	(51,951)	(27,976)	(92,043)	(56,651)
Interest income	4,738	330	8,591	442
Interest expense	(2,003)	(1,581)	(3,925)	(3,060)
Other income and (expense), net	(11)	1,110	28	1,054
Net loss	$ (49,227)	$ (28,117)	$ (87,349)	$ (58,215)
Basic and diluted net loss per share	$ (0.09)	$ (0.07)	$ (0.16)	$ (0.16)
Shares used in computing basic and diluted net loss per share	547,280,946	403,868,713	553,772,809	368,166,148

See accompanying notes.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022	2023	2022
Net loss	$ (49,227)	$ (28,117)	$ (87,349)	$ (58,215)
Net unrealized loss on marketable securities	(786)	(82)	(711)	(621)
Foreign currency translation adjustments	1	11	(15)	12
Comprehensive loss	$ (50,012)	$ (28,188)	$ (88,075)	$ (58,824)

See accompanying notes.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	390,262,524	$ 390	$ 1,493,469	$ (1,413,642)	$ (219)	$ 79,998
Net loss	—	—	—	(38,122)	—	(38,122)
Other comprehensive income	—	—	—	—	75	75
Foreign currency translation adjustment	—	—	—	—	(16)	(16)
Issuance of common stock and pre-funded warrant to purchase common stock in public offering, net of issuance costs of $14,507	68,007,741	68	213,269	—	—	213,337
Issuance of common stock in connection with exercise of warrants	44,983,193	45	59,790	—	—	59,835
Stock-based compensation related to issuance of common stock and options in exchange for services	9,360	1	111	—	—	112
Issuance of common stock under equity plans	5,469,028	5	7,870	—	—	7,875
Stock-based compensation for equity-based awards to employees and directors	—	—	2,961	—	—	2,961
Balance at March 31, 2023	508,731,846	509	1,777,470	(1,451,764)	(160)	326,055
Net loss	—	—	—	(49,227)	—	(49,227)
Other comprehensive loss	—	—	—	—	(786)	(786)
Foreign currency translation adjustment	—	—	—	—	1	1
Issuance of common stock in connection with exercise of warrants	12,842,857	13	17,754	—	—	17,767
Stock-based compensation related to issuance of common stock and options in exchange for services	6,327	—	99	—	—	99
Issuance of common stock under equity plans	361,074	—	573	—	—	573
Stock-based compensation for equity-based awards to employees and directors	—	—	3,945	—	—	3,945
Balance at June 30, 2023	521,942,104	$ 522	$ 1,799,841	$ (1,500,991)	$ (945)	$ 298,427

GERON CORPORATION
CONDENSED CONSOLIDATED 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, 2021	323,731,591	$ 324	$ 1,398,006	$ (1,271,741)	$ (173)	$ 126,416
Net loss	—	—	—	(30,098)	—	(30,098)
Other comprehensive loss	—	—	—	—	(539)	(539)
Foreign currency translation adjustment	—	—	—	—	1	1
Stock-based compensation related to issuance of common stock and options in exchange for services	5,284	—	15	—	—	15
Stock-based compensation for equity-based awards to employees and directors	—	—	1,692	—	—	1,692
Balance at March 31, 2022	323,736,875	324	1,399,713	(1,301,839)	(711)	97,487
Net loss	—	—	—	(28,117)	—	(28,117)
Other comprehensive loss	—	—	—	—	(82)	(82)
Foreign currency translation adjustment	—	—	—	—	11	11
Issuance of common stock, pre-funded warrant and warrants to purchase common stock in public offering, net of issuance costs of $5,066	53,333,334	53	69,863	—	—	69,916
Stock-based compensation related to issuance of common stock and options in exchange for services	4,637	—	13	—	—	13
Issuance of common stock under equity plans	589,913	1	760	—	—	761
Stock-based compensation for equity-based awards to employees and directors	—	—	2,058	—	—	2,058
Balance at June 30, 2022	377,664,759	$ 378	$ 1,472,407	$ (1,329,956)	$ (782)	$ 142,047

See accompanying notes.

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

	SIX MONTHS ENDED JUNE 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (87,349)	$ (58,215)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	220	129
Accretion and amortization on investments, net	(4,963)	304
Amortization of debt issuance costs/debt discounts	487	704
Stock-based compensation for services by non-employees	211	28
Stock-based compensation for employees and directors	6,906	3,750
Amortization of right-of-use assets	306	285
Changes in assets and liabilities:		
Current and noncurrent assets	2,411	(5,507)
Current and noncurrent liabilities	5,805	(4,094)
Net cash used in operating activities	(75,966)	(62,616)
Cash flows from investing activities:		
Purchases of property and equipment	(574)	(120)
Purchases of marketable securities	(355,718)	(57,049)
Proceeds from maturities of marketable securities	133,115	90,406
Net cash (used in) provided by investing activities	(223,177)	33,237
Cash flows from financing activities:		
Proceeds from issuances of common stock from equity plans	8,448	761
Proceeds from issuance of common stock from public offering and pre-funded warrant, net of paid issuance costs	213,337	69,916
Proceeds from exercise of warrants	77,602	—
Debt discount and issuance costs for debt financing	—	(114)
Net cash provided by financing activities	299,387	70,563
Effect of exchange rates on cash, cash equivalents and restricted cash	(15)	2
Net increase in cash, cash equivalents and restricted cash	229	41,186
Cash, cash equivalents and restricted cash at the beginning of the period	57,209	35,235
Cash, cash equivalents and restricted cash at the end of the period	$ 57,438	$ 76,421

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 and its wholly-owned subsidiaries, Geron UK Limited, or Geron UK, a United Kingdom company, and Geron Netherlands B.V., or Geron Netherlands, a Netherlands company. Geron UK was incorporated in September 2021, and its operations commenced in January 2022. Geron Netherlands was incorporated in February 2023, and its operations commenced in June 2023.

The accompanying unaudited condensed consolidated 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 United States, or U.S., generally accepted accounting principles, or GAAP, 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, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 or any other period. These unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited financial statements for each of the three years ended December 31, 2022, included in our Annual Report on Form 10-K for the year ended December 31, 2022, or the Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2022 has been derived from audited financial statements at that date.

Prior Period Reclassification

The prior period presentations of other comprehensive loss in the condensed consolidated statements of stockholders' equity and accrued liabilities have been updated to conform to current period presentation. See Note 3 on Accrued Liabilities.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Geron Corporation and its wholly-owned subsidiaries, Geron UK and Geron Netherlands. For Geron UK and Geron Netherlands, we have eliminated intercompany accounts and transactions. We prepare the financial statements of Geron UK and Geron Netherlands using the local currency as the functional currency. We translate the assets and liabilities of Geron UK and Geron Netherlands at rates of exchange at the balance sheet date and translate income and expense items at average monthly rates of exchange. The resultant translation adjustments are included in accumulated other comprehensive income (loss), a separate component of stockholders’ equity, on our condensed consolidated balance sheets.

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 for the periods presented without consideration of potential common shares. In connection with previous public offerings, we issued pre-funded warrants to purchase shares of our common stock. These pre-funded warrants are exercisable immediately at an exercise price of $0.001 per share each, and as of June 30, 2023, none of these pre-funded warrants have been exercised. These pre-funded warrants, which represent an aggregate of 51,430,477 shares of common stock, have been included in the computation of basic net loss per share, since their exercise price is negligible and they may be exercised at any time.

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 additional shares of common stock that would have been outstanding if potentially dilutive securities had been issued, as determined using the treasury-stock method. Potential dilutive securities consist of outstanding stock options and warrants to purchase our common stock. Diluted net loss per share excludes potential dilutive securities 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 consolidated statements of operations. Since we incurred a net loss for the three and six months ended June 30, 2023 and 2022, the diluted net loss per share calculation excludes potential dilutive securities of 97,584,078 and 153,703,476, respectively, related to outstanding stock options and warrants as their effect would have been anti-dilutive.

Use of Estimates

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. 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, operating leases, right-of-use

assets, lease liabilities, 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 U.S. Treasury securities, government-sponsored enterprise securities, commercial paper and corporate notes.

We classify our marketable debt securities as available for sale. We record available-for-sale debt 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 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 income on our condensed consolidated statements of operations. See Note 2 on Fair Value Measurements.

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 leases, right-of-use assets and lease liabilities on our condensed consolidated 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 present value of remaining lease payments within the 12 months following the balance sheet date are classified as current lease liabilities. The present value of lease payments not within the 12 months following the balance sheet date are classified as noncurrent lease liabilities. 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 estimated rate 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 consolidated balance sheets leases with terms of one year or less.

Debt Issuance Costs and Debt Discounts

Debt issuance costs include legal fees, accounting fees, and other direct costs incurred in connection with the execution of our debt financing. Debt discounts represent costs paid to the lenders. Debt issuance costs and debt discounts are deducted from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt using the effective interest method.

Revenue Recognition

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 Agreements

In connection with the divestiture of Geron's human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc. which acquired Asterias Biotherapeutics, Inc.) in 2013, we are entitled to receive royalties on sales of certain research or commercial products utilizing Geron's divested intellectual property.

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 date, we estimate the sales incurred by each licensee during the reporting period based on historical experience and accrue the associated royalty amount.

Restricted Cash

Restricted cash consists of funds maintained in separate money market or certificate of deposit accounts for credit card purchases.

Research and Development Expenses

Research and development expenses currently consist of expenses incurred in developing and testing imetelstat and research related to potential next generation telomerase inhibitors. These expenses include, but are not limited to, payroll and personnel expense, lab supplies, non-clinical studies, clinical trials, including support for investigator-led 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 and research-related overhead.

Our current imetelstat clinical trials are being supported by contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In that 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 maintain various stock incentive plans under which stock options and restricted stock awards can be granted to employees, non-employee directors and consultants. We also have an employee stock purchase plan for all eligible employees. We recognize stock-based compensation expense based on grant-date fair values of service-based stock options 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 the 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 determination of grant-date fair values for our service-based and performance-based stock options and employee stock purchases using the Black Scholes option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. The grant-date fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant. We evaluate whether an adjustment to the assumptions of fair value of our common stock and historical volatility are required if observed prices of our common stock materially differ from historical information.

The following table summarizes the stock-based compensation expense included in operating expenses on our condensed consolidated statements of operations related to stock options and employee stock purchases for the three and six months ended June 30, 2023 and 2022, which was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2023	2022	2023	2022
Research and development	$ 1,590	$ 1,012	$ 2,896	$ 1,867
General and administrative	$ 2,355	1,046	$ 4,010	1,883
Stock-based compensation expense included in operating expenses	$ 3,945	$ 2,058	$ 6,906	$ 3,750

As stock-based compensation expense recognized in our condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022 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 on our condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022, as achievement of the specified strategic milestones was not considered probable at that time.

Stock Options

We grant service-based and performance-based stock options under our equity plans to employees, non-employee directors and consultants. The service-based vesting period for employee stock options is generally four years from the date of the stock option grant. Performance-based stock options vest upon the achievement of specified strategic milestones. The fair value of service-based stock options granted during the six months ended June 30, 2023 and 2022 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2023	2022
Dividend yield	0%	0%
Expected volatility range	81.5% to 81.9%	77.7% to 79.9%
Risk-free interest rate range	3.4% to 4.1%	1.7% to 3.4%
Expected term	6 years	5.5 years

Employee Stock Purchase Plan

The fair value of employees' stock purchase rights during the six months ended June 30, 2023 and 2022 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2023	2022
Dividend yield	0%	0%
Expected volatility range	61.0% to 81.1%	50.9% to 61.4%
Risk-free interest rate range	0.1% to 4.8%	0.1% to 0.4%
Expected term range	6 months to 12 months	6 months to 12 months

Dividend yield is based on historical cash dividend payments and Geron has paid no cash dividends to date. The expected volatility range is based on historical volatilities of our stock, since traded options on Geron 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 stock options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that stock options granted are expected to be outstanding. The expected term of employees' stock purchase rights is equal to the purchase period.

Non-Employee Stock-Based Awards

We measure share-based payments to non-employees based on the grant-date fair value of the equity awards. We recognize stock-based compensation expense for the fair value of the vested portion of non-employee stock-based awards on our condensed consolidated statements of operations.

Segment Information

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

Recent Accounting Pronouncements

New Accounting Pronouncements – Recently Adopted

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-13, *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. 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 provide entities with more flexibility in applying the fair value option on adoption of the credit impairment standard. In November 2019, the FASB issued ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses*, or ASU 2019-11, which expands the scope of the practical expedient that allows entities to exclude the accrued interest component of amortized cost from various disclosure. We adopted ASU 2016-13 and related updates as of January 1, 2023. Adoption of this new guidance did not have a material impact on our condensed consolidated financial statements.

New Accounting Pronouncements – Issued But Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, or ASU 2020-06. The key elements of ASU 2020-06 aim to reduce unnecessary complexity in GAAP for certain financial instruments with characteristics of liabilities and equity. In addressing the complexity, the FASB focused on amending the guidance on convertible instruments and the guidance on the derivatives scope exception for contracts in an entity's own equity. For convertible instruments, the FASB decided to reduce the number of accounting models for convertible debt instruments and convertible preferred stock. For contracts in an entity's own equity, the FASB observed that the application of the derivatives scope exception guidance results in accounting for some contracts as derivatives while accounting for economically similar contracts as equity. The FASB also decided to improve and amend the related earnings per share guidance. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years for public business entities that are not smaller reporting companies. For all other entities, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. We plan to adopt ASU 2020-06 as of January 1, 2024. We do not expect the adoption of this standard to have a material impact on our condensed consolidated financial statements.

Other recent accounting pronouncements issued by the FASB did not or are not believed by management to have a material impact on our condensed consolidated financial statements.

2. FAIR VALUE MEASUREMENTS

Cash Equivalents and Marketable Securities

Cash equivalents, restricted cash and marketable securities by security type at June 30, 2023 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	$ 34,417	$ —	$ —	$ 34,417
	$ 34,417	$ —	$ —	$ 34,417
Restricted cash:				
Money market fund	$ 263	$ —	$ —	$ 263
Certificate of deposit	272	—	—	272
	$ 535	$ —	$ —	$ 535
Marketable securities:				
Government-sponsored enterprise securities (due in less than one year)	$ 78,280	$ 20	$ (224)	$ 78,076
Government-sponsored enterprise securities (due in one to two years)	18,680	—	(141)	18,539
Commercial paper (due in less than one year)	202,540	7	(365)	202,182
Corporate notes (due in less than one year)	34,354	1	(138)	34,217
Corporate notes (due in one to two years)	9,854	—	(112)	9,742
	$ 343,708	$ 28	$ (980)	$ 342,756

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2022 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	$ 39,771	$ —	$ —	$ 39,771
	$ 39,771	$ —	$ —	$ 39,771
Restricted cash:				
Money market fund	$ 93	$ —	$ —	$ 93
Certificate of deposit	271	—	—	271
	$ 364	$ —	$ —	$ 364
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 12,983	$ —	$ (62)	$ 12,921
Municipal securities (due in less than one year)	3,000	—	(24)	2,976
Government-sponsored enterprise securities (due in less than one year)	9,860	—	(14)	9,846
Commercial paper (due in less than one year)	64,285	6	(92)	64,199
Corporate notes (due in less than one year)	26,014	—	(55)	25,959
	$ 116,142	$ 6	$ (247)	$ 115,901

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, 2023 and December 31, 2022 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, 2023:						
Government-sponsored enterprise securities (due in less than one year)	$ 58,651	$ (224)	$ —	$ —	$ 58,651	$ (224)
Government-sponsored enterprise securities (due in one to two years)	18,538	(141)	—	—	18,538	(141)
Commercial paper (due in less than one year)	169,851	(365)	—	—	169,851	(365)
Corporate notes (due in less than one year)	29,211	(138)	—	—	29,211	(138)
Corporate notes (due in one to two years)	8,746	(112)	—	—	8,746	(112)
	$ 284,997	$ (980)	$ —	$ —	$ 284,997	$ (980)
As of December 31, 2022:						
U.S. Treasury securities (due in less than one year)	$ 11,424	$ (57)	$ 1,497	$ (5)	$ 12,921	$ (62)
Municipal securities (due in less than a year)	—	—	2,976	(24)	2,976	(24)
Government-sponsored enterprise securities (due in less than one year)	9,845	(14)	—	—	9,845	(14)
Commercial paper (due in less than one year)	52,454	(92)	—	—	52,454	(92)
Corporate notes (due in less than one year)	1,998	(2)	23,962	(53)	25,960	(55)
	$ 75,721	$ (165)	$ 28,435	$ (82)	$ 104,156	$ (247)

The gross unrealized losses related to U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper and corporate notes as of June 30, 2023 and December 31, 2022 were due to changes in interest rates and not credit risk. If an available-for-sale security's fair value is less than its amortized cost basis, we evaluate whether the decline is the result of a credit loss, in which case an impairment is recorded through an allowance for credit losses. We have not recorded any allowances for credit losses on our available-for-sale securities for the three and six months ended June 30, 2023 and 2022 as we have not identified any unrealized losses for these securities attributable to credit factors. Our exposure to unrealized losses may increase in the future due to the economic pressures or uncertainties associated with macroeconomic or other global economic conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises.

Fair Value on a Recurring Basis

We categorize financial instruments recorded at fair value on our condensed consolidated 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. Money market funds are categorized as Level 1 within the fair value hierarchy as their fair values are based on quoted prices available in active markets. U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper, and corporate notes are categorized as Level 2 within the fair value hierarchy as their fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows.

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of June 30, 2023 and December 31, 2022 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, 2023:				
Money market funds[1][2]	$ 34,680	$ —	$ —	$ 34,680
Certificate of deposit[2]	272	—	—	272
Government-sponsored enterprise securities[3][4]	—	96,615	—	96,615
Commercial paper[3]	—	202,182	—	202,182
Corporate notes[3][4]	—	43,959	—	43,959
Total	$ 34,952	$ 342,756	$ —	$ 377,708
As of December 31, 2022:				
Money market funds[1][2]	$ 39,864	$ —	$ —	$ 39,864
Certificate of deposit[2]	271	—	—	271
U.S. Treasury securities[3]	—	12,921	—	12,921
Municipal securities[3]	—	2,976	—	2,976
Government-sponsored enterprise securities[2]	—	9,846	—	9,846
Commercial paper[3]	—	64,199	—	64,199
Corporate notes[3]	—	25,959	—	25,959
Total	$ 40,135	$ 115,901	$ —	$ 156,036

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

(2) Included in restricted cash on our condensed consolidated balance sheets.

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

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

3. ACCRUED LIABILITIES

Accrued liabilities consisted of the following as of June 30, 2023 and December 31, 2022:

(In thousands)	JUNE 30, 2023	DECEMBER 31, 2022
CRO and clinical trial costs	$ 22,776	$ 17,040
Manufacturing activities	11,798	5,321
Legal settlements	7,000	8,350
Professional legal and accounting fees	857	1,318
Interest payable	584	561
Other	2,021	510
	$ 45,036	$ 33,100

4. DEBT

On September 30, 2020, we, Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)), or SVB, entered into a term loan facility, or the Original Loan Agreement, consisting of up to $75,000,000 aggregate principal amount available to us, as amended in August 2021. On June 30, 2022, or the Effective Date, we entered into a second amendment to the Original Loan Agreement, or as amended, the Loan Agreement. Under the second amendment, the aggregate principal amount available to us increased from $75,000,000 to $125,000,000, with such principal being available in a series of tranches, subject to certain terms and conditions.

As of June 30, 2023, a total of $50,000,000 has been drawn under the Loan Agreement. As of June 30, 2023, $55,000,000 remains as committed principal that can be drawn as follows: (a) one tranche of $10,000,000 is available from January 1, 2023 until December 15, 2023, subject to the achievement of certain clinical and regulatory milestones, and satisfaction of certain other requirements; (b) a second tranche of $20,000,000 is available from September 15, 2023 until September 15, 2024, subject to the achievement of certain clinical and regulatory milestones, and satisfaction of certain capitalization requirements; and (c) a final tranche of $25,000,000 is available through December 31, 2024, subject to approval by an investment committee comprised of Hercules and SVB. With the exception of the final tranche, and subject to achievement of the applicable milestones and other requirements with respect to each tranche, draw downs are at our election.

Under the Loan Agreement, if we choose to prepay the principal with respect to any future draw down after the Effective Date, any such prepayment within the first 36 months after the Effective Date will be subject to a prepayment charge equal to 1.5% of the principal amount prepaid. No prepayment charge will be assessed for any prepayment occurring more than 36 months after the Effective Date.

Under the Loan Agreement, the maturity date, interest only payment dates, end of term charges, collateral, events of default, representations, warranties and covenants remain consistent with the terms of the Original Loan Agreement, except as follows:

- Beginning June 1, 2022 and prior to the regulatory approval for imetelstat, or the potential Regulatory Approval, if any, we are required to maintain a minimum cash balance in an amount equal to the greater of: 50% of the outstanding principal amount under the Loan Agreement or $30,000,000.
- After the potential Regulatory Approval, if any, the minimum cash requirement may be satisfied through one of the following three options, as elected by us: (a) maintaining a cash balance in an amount not less than 40% of the outstanding principal amount under the Loan Agreement; (b) maintaining a cash balance in an amount not less than 25% of the outstanding principal amount under the Loan Agreement, if our market cap is or exceeds $750,000,000; or (c) maintaining six month net product revenues of at least 70% of net product revenues forecasted by us, should any potential Regulatory Approval for imetelstat be obtained.

We are in compliance with the covenants under the Loan Agreement as of June 30, 2023. The interest-only payment period was extended from April 2023 to April 2024 upon the achievement of positive top-line results from the IMerge Phase 3 clinical trial in January 2023.

As of June 30, 2023, the net carrying value of the debt under the Loan Agreement was $51,644,000, which includes the principal amount of $50,000,000 less net unamortized debt discounts and issuance costs of $483,000 plus accrued end of term charge of $2,127,800. The carrying value of the debt approximates the fair value as of June 30, 2023. The debt discounts and debt issuance costs are being amortized to interest expense over the life of the outstanding loan amounts using the effective interest rate method.

The following table presents future minimum payments, including interest and the end of term charge, under the Loan Agreement as of June 30, 2023 (in thousands):

Remainder of 2023	$ 3,558
2024	39,277
2025	20,031
Total	62,866
Less: amount representing interest	(9,592)
Less: unamortized debt discount and issuance costs	(483)
Less: unaccrued end of term charge	(1,147)
Less: current portion of debt	(10,842)
Noncurrent portion of debt	$ 40,802

5. CONTINGENCIES AND UNCERTAINTIES

Purported Securities Lawsuits

Between January 23, 2020 and March 5, 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed on March 19, 2020. The other two lawsuits, filed in the U.S. District Court, or the Court, for the Northern District of California, or the Northern District, were consolidated by the Court on May 14, 2020, and on August 20, 2020, the lead plaintiffs filed a consolidated class action complaint. The consolidated class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to IMbark during the period from March 19, 2018, to September 26, 2018. The consolidated class action complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose facts related to the alleged failure of IMbark to meet the two primary endpoints of the trial, spleen response rate and Total Symptom Score, and that our stock price dropped when such information was disclosed. The plaintiffs in the consolidated class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On October 22, 2020, lead plaintiffs filed an amended consolidated class action complaint. We filed a motion to dismiss the amended consolidated class action complaint on November 23, 2020. On April 12, 2021, the Court granted in part and denied in part our motion to dismiss. Our answer to the amended consolidated class action complaint was filed on May 13, 2021. On September 30, 2021, lead plaintiffs filed their motion for class certification, and on April 2, 2022, the Court granted the lead plaintiffs' motion for class certification. On September 2, 2022, the parties agreed to a settlement and entered into a Stipulation and Agreement of Settlement, or the Stipulation, which is subject to Court approval. On October 13, 2022, the Court preliminarily approved the parties' settlement, and permitted notice to be distributed to the class members. On March 30, 2023, the Court held a hearing on the motion for final approval of settlement and plan of allocation and ordered supplemental notice be sent to all of the class members. A second final approval hearing is scheduled for August 24, 2023. Final approval of the settlement by the Court is subject to a number of conditions and contingencies out of our control. There can be no guarantee that all of these conditions and contingencies will occur. Should a material condition or contingency to the settlement fail to occur, one or both of the parties to the settlement may exercise their right to terminate the settlement agreement.

Under the terms of the Stipulation, in exchange for the release and dismissal with prejudice of all claims against the defendants in the consolidated class action complaint, we agreed to pay and/or to cause our insurance carriers to pay a total of $24,000,000, comprised of $17,000,000 in cash, which was paid into an escrow account under our available insurance coverage and, at our election, $7,000,000 in either shares of our common stock and/or cash which is payable after final approval of the settlement by the Court. The proposed settlement does not constitute an admission of fault or wrongdoing by Geron or our Chief Executive Officer. The proposed settlement remains subject to final approval by the Court and certain other conditions. As of June 30, 2023 and December 31, 2022, our portion of the settlement amount of $7,000,000 has been included in accrued liabilities on our condensed consolidated balance sheets.

Between April 23, 2020 and June 8, 2021, seven shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former members of our board. Of these actions, or the Derivative Lawsuits, two were filed in the Northern District, two were filed in the Court of Chancery of the State of Delaware, or the Chancery Court, two were filed in the U.S. District Court for the District of Delaware, or the District of Delaware, and one was filed in the Superior Court of California for the County of San Mateo, or the San Mateo Superior Court, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and/or violations of Section 14 of the Exchange Act, based on the same underlying facts as the consolidated class action lawsuit described above. The plaintiffs seek damages, corporate governance reforms, equitable relief, restitution, and an award of reasonable costs, including attorneys' fees. The status of the seven Derivative Lawsuits is currently as follows:

- On July 2, 2021, we filed a motion to dismiss the consolidated shareholder derivative actions filed in the Chancery Court, or the Chancery Court Derivative Lawsuits. On September 1, 2021, the plaintiffs filed a consolidated amended complaint in the Chancery Court Derivative Lawsuits. On October 12, 2021, we filed our motion to dismiss the consolidated amended complaint. The Chancery Court heard oral argument on the motion on February 15, 2022, and, on June 22, 2022, issued an order staying its decision on our motion to dismiss until after final resolution of the consolidated class action lawsuit described above. On December 21, 2022, the parties in the Chancery Court Derivative Lawsuits entered into a Stipulation of Settlement, or the Derivative Stipulation, that, subject to final approval by the Chancery Court, will resolve the Chancery Court Derivative Lawsuits. On May 17, 2023, following a hearing, the Chancery Court entered an order approving the Derivative Stipulation and dismissing the Chancery Court Derivative Lawsuits with prejudice;

- The consolidated shareholder derivative actions filed in the District of Delaware have been stayed pending the ruling on our motion to dismiss the Chancery Court Derivative Lawsuits. On December 21, 2022, the parties in the consolidated District of Delaware derivative actions entered into the Derivative Stipulation, that, subject to final approval by the Chancery Court, will resolve the consolidated District of Delaware derivative actions. On May 30, 2023, the parties in the consolidated District of Delaware derivative actions, pursuant to the Derivative Stipulation, sought dismissal of the consolidated District of Delaware derivative actions with prejudice, which the Court granted on May 31, 2023;
- The consolidated shareholder derivative actions filed in the Northern District were initially stayed through the ruling on our motion to dismiss in the consolidated securities class action lawsuit described above and then subsequently were stayed through the ruling on the lead plaintiffs' motion for class certification in the consolidated securities class action lawsuit. Subsequent to the grant of class certification in the consolidated securities class action lawsuit, on May 3, 2022, the Northern District entered an order providing plaintiffs until June 7, 2022, to file an amended complaint. On June 7, 2022, plaintiffs filed an amended shareholder derivative complaint. On July 6, 2022, the Northern District entered an order staying the consolidated shareholder derivative actions filed in the Northern District until the earlier of either a public announcement of a settlement in the consolidated securities class action lawsuit or a final, non-appealable judgment in the consolidated securities class action lawsuit. On December 21, 2022, the parties in the consolidated derivative actions in the Northern District entered into the Derivative Stipulation, that, subject to final approval by the Chancery Court will resolve the consolidated derivative actions in the Northern District. On May 30, 2023, the parties in the consolidated derivative actions in the Northern District, pursuant to the Derivative Stipulation, sought dismissal of the consolidated derivative actions in the Northern District with prejudice, which the Court granted the same day; and
- Our motion to dismiss the shareholder derivative action pursuant to the forum selection clause in our amended and restated bylaws was filed in the San Mateo Superior Court on August 5, 2021. At the hearing on the motion to dismiss on November 2, 2021, the court granted our motion to dismiss and stayed the case until April 19, 2022. At the case management conference on April 19, 2022, the court continued the stay until June 14, 2022. At the case management conference on June 14, 2022, the court continued the stay until December 13, 2022. On December 13, 2022, the court dismissed the action without prejudice.

Under the terms of the Derivative Stipulation, in exchange for the release and dismissal with prejudice of all claims against the defendants in the consolidated shareholder derivative actions filed in the Northern District, the District of Delaware, and the Chancery Court, the parties agreed to a cash settlement of $1,350,000 which was accrued on our consolidated balance sheet as of December 31, 2022. In the second quarter of 2023, our insurance carriers paid $525,000 in cash, and we paid $825,000 in cash, for an aggregate total payment of $1,350,000. The settlement does not constitute an admission of fault or wrongdoing by our current officers or current and former members of our board.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense against the pending lawsuits and any other related lawsuits, and we may not prevail. In addition, we have and may continue to incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible additional costs to us, if any, from these matters, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages or legal costs that we may be required to pay. Such amounts could be material to our condensed consolidated financial statements if we do not prevail in the defense against the pending lawsuits and any other related lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits, other than settlement amounts under the Stipulation. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

Indemnifications to Officers and Directors

Our corporate bylaws require that we indemnify our directors, as well as those who act as directors and officers of other entities at our request, against expenses, judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceedings arising out of their services to Geron. In addition, we have entered into separate indemnification agreements with each of our directors and officers which provide for indemnification of these directors and officers under similar circumstances and under additional circumstances. The indemnification obligations are more fully described in our bylaws and the indemnification agreements. We purchase standard insurance to cover claims or a portion of the claims made against our directors and officers. Since a maximum obligation is not explicitly stated in our bylaws or in our indemnification agreements and will depend on the facts and circumstances that arise out of any future claims, the overall maximum amount of the obligations cannot be reasonably estimated.

Severance Plan

We have an Amended and Restated Severance Plan, or Severance Plan, that applies to all employees that are (i) above the Vice President level, (ii) hired by the Company before January 1, 2022, or (iii) not subject to performance improvement plans, and provides

for, among other benefits: (x) a severance payment upon a Change of Control Triggering Event and Separation from Service and (y) a severance payment for each non-executive employee upon a Non-Change of Control Triggering Event and Separation from Service. As defined in the Severance Plan, a Change of Control Triggering Event and Separation from Service requires a "double trigger" where: (i) an employee is terminated by us without cause in connection with a change of control or within 12 months following a change of control provided, however, that if an employee is terminated by us in connection with a change of control but immediately accepts employment with our successor or acquirer, the employee will not be eligible for the benefits outlined in the Severance Plan, (ii) an employee resigns because in connection with a change of control, the offered terms of employment (new or continuing) by us or our successor or acquirer within 30 days after the change of control results in a material change in the terms of employment, or (iii) after accepting (or continuing) employment with us after a change of control, an employee resigns within 12 months following a change of control due to a material change in the terms of employment. Under the Severance Plan, a Non-Change of Control Triggering Event and Separation from Service is defined as an event where a non-executive employee is terminated by us without cause. Severance payments range from three to 18 months of base salary, depending on the employee's position with us, payable in a lump sum payment. The Severance Plan also provides that the provisions of employment agreements entered into between us and executive or non-executive employees supersede the provisions of the Severance Plan. As of June 30, 2023, all our executive officers have employment agreements with provisions that may provide greater severance benefits than those in the Severance Plan.

Risks Related to Global Economic, Political and Health Conditions

Our business is subject to various risks and uncertainties, including risks and uncertainties associated with macroeconomic or other global economic conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues. Occurrences of such events have caused and may cause in the future and unpredictable impacts on global societies, economies, financial markets and business practices. Specifically for our business, such risks and uncertainties have adversely affected and may continue to adversely affect our ability to:

- continue to develop imetelstat or advance imetelstat to subsequent clinical trials, including receiving regulatory approval for or to commercialize imetelstat, on a timely basis or at all;
- conduct and complete current imetelstat clinical trials on a timely basis or at all;
- establish sales, marketing and distribution capabilities, or obtain coverage and adequate third-party payor reimbursement, to successfully commercialize imetelstat, if regulatory approval is obtained;
- open clinical sites or recruit, enroll and retain patients in current or future clinical trials of imetelstat;
- manufacture and supply imetelstat in adequate quantities that meet specifications that may be approved or required by regulatory authorities and on timelines necessary for current and potential future clinical trials and potential commercial uses;
- execute on our business strategy and/or our operations by our employees without any restrictions; and
- obtain additional capital to continue the development of imetelstat in current and any potential future clinical trials of imetelstat, and establish potential future imetelstat commercialization efforts.

The extent to which macroeconomic or other global economic conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, ultimately impact our business, our regulatory and clinical development activities, clinical supply chain and other business operations, as well as the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our regulatory and clinical development activities, clinical supply chain and other business operations or the global economy as a whole. However, these effects could materially and adversely affect our business and business prospects, our financial condition and the future of imetelstat.

6. STOCKHOLDERS' EQUITY

Public Offering

On January 10, 2023 we completed the January 2023 offering consisting of 68,007,741 shares of our common stock and the 2023 pre-funded warrant. All of the securities were issued separately. The public offering price of the common stock was $2.45 per share. The public offering price of the 2023 pre-funded warrant was $2.449 per share. The 2023 pre-funded warrant has an exercise price of $0.001 per share and may be exercised at any time until the 2023 pre-funded warrant is exercised in full. As of June 30, 2023, none of the 2023 pre-funded warrant has been exercised. The net cash proceeds from this offering were $213,337,000, after deducting

the underwriting discount and other offering expenses paid by us, and exclude any future proceeds from the exercise of the 2023 pre-funded warrant.

Upon the issuance of the 2023 pre-funded warrant, we evaluated the terms of each warrant to determine the appropriate accounting and classification pursuant to FASB Accounting Standards Codification Topic 480, *Distinguishing Liabilities from Equity*, and FASB Accounting Standards Codification Topic 815, *Derivatives and Hedging*. Warrants are classified as liabilities when the warrant terms allow settlement of the warrant exercise in cash and classified as equity when the warrant terms only allow settlement in shares of common stock. The terms of the 2023 pre-funded warrant include certain provisions related to fundamental transactions and a cashless exercise provision in the event registered shares are not available, and do not include any mandatory redemption provisions. Based on our evaluation, we concluded the 2023 pre-funded warrant should be classified as equity with no subsequent remeasurement as long as such warrant continue to be classified as equity.

Warrant Exercises

In the first quarter of 2023, warrants to purchase 44,983,194 shares of Geron common stock were exercised for net cash proceeds of approximately $59,835,000. In the second quarter of 2023, warrants to purchase 12,842,857 shares of Geron common stock were exercised for net cash proceeds of approximately $17,767,000. The warrants were issued in connection with underwritten public offerings of common stock and pre-funded warrants, together with accompanying stock purchase warrants in May 2020 and April 2022. As of June 30, 2023, the following warrants remained outstanding:

- pre-funded warrants with an exercise price of $0.001 per share to purchase 51,430,477 shares of our common stock;
- stock purchase warrants with an exercise price of $1.30 per share to purchase 2,474,503 shares of our common stock related to the public offering of our common stock in May 2020; and
- stock purchase warrants with an exercise price of $1.45 per share to purchase 19,523,812 shares of our common stock related to the public offering of our common stock in April 2022.

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 consolidated financial statements and notes thereto included in Part I, Item 1 of this Form 10-Q; and the sections entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Form 10-K for the year ended December 31, 2022, as filed with the United States Securities and Exchange Commission, or SEC, on March 16, 2023, or 2022 Form 10-K.

Company Overview

Summary

We are a late-stage biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our investigational first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize winning science in a treatment that may alter the underlying course of these diseases.

Our lead indication for imetelstat is in Low or Intermediate-1 risk myelodysplastic syndromes, or lower risk MDS. In January 2023, we reported positive top-line results from our IMerge Phase 3 clinical trial. The trial met its primary endpoint of 8-week transfusion independence rate and a key secondary endpoint of 24-week transfusion independence rate, demonstrating highly statistically significant (i.e., $P<0.001$ for both) and clinically meaningful benefits in imetelstat versus placebo. Furthermore, statistically significant and clinically meaningful efficacy results were observed in the trial across key subtypes, including patients who were ringed sideroblast positive, or RS positive, and ringed sideroblast negative, or RS negative; patients with high and very high baseline transfusion burden; and patients classified as Low or Intermediate-1 risk according to the International Prognostic Scoring System, or IPSS.

Based on the positive top-line data from IMerge Phase 3 and the prior IMerge Phase 2, we submitted a New Drug Application, or NDA, to the FDA in the United States, or U.S., for the treatment of transfusion-dependent anemia in adult patients with low-to-intermediate-1 risk MDS who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents, or ESAs, in June 2023 and plan to submit a marketing authorization application, or MAA, in Europe in the fourth quarter of 2023. If the NDA is accepted for filing and imetelstat is approved for commercialization by the FDA in a timely manner, we anticipate commercial launch of imetelstat in lower risk MDS in the U.S. could occur in the first half of 2024. In Europe, we anticipate review of the planned MAA, if validated by the European Medicines Agency, or EMA, could take approximately 14 months and, if approved, we anticipate that the commercial launch of imetelstat in lower risk MDS in Europe could occur by the end of 2024.

We believe that the positive data from IMerge Phase 3 and IMerge Phase 2, as well as our prior Phase 2 clinical trial of imetelstat in patients with Intermediate-2 or High-Risk myelofibrosis who have relapsed after or are refractory to treatment with a janus associate kinase inhibitor, or JAK inhibitor, or relapsed/refractory MF, provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells enabling recovery of bone marrow and normal blood cell production, which suggest potential disease-modifying activity. We believe this potential for disease modification could differentiate imetelstat from currently approved treatments in myeloid hematologic malignancies. Accordingly, in addition to lower risk MDS, we are developing imetelstat for the treatment of several myeloid hematologic malignancies with the following ongoing clinical trials:

- IMpactMF, a Phase 3 clinical trial in relapsed/refractory MF with overall survival, or OS, as the primary endpoint, that currently is enrolling patients. Based on our current planning assumptions for enrollment and event (death) rates in the trial, we now expect the interim analysis for OS in IMpactMF may occur in the first half of 2025, and the final analysis may occur in the first half of 2026. Because these analyses are event-driven and it is uncertain whether actual rates for

enrollment and events will reflect current planning assumptions, the results may be available at different times than currently expected.

- IMproveMF, a Phase 1 combination clinical trial in first-line Intermediate-1, Intermediate-2 or High-Risk myelofibrosis, or frontline MF, that currently is enrolling patients and with respect to which we expect early data at the end of 2023; and
- IMpress, an investigator-led Phase 2 clinical trial in Intermediate-2 or High-Risk myelodysplastic syndromes, or higher risk MDS, and acute myeloid leukemia, or AML, in which the first patient was dosed in June 2023.

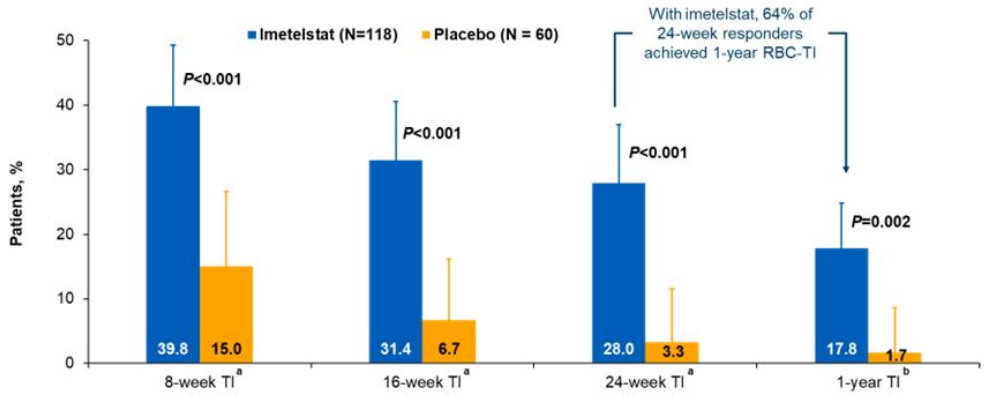
In June 2023, we opened an expanded access program, sometimes called compassionate use, whereby imetelstat could be used outside of a clinical trial for lower risk MDS patients with serious or life-threatening conditions who have exhausted their treatment options and are not eligible for, or able to participate in, a clinical trial. To be considered for expanded access, requests must be submitted to Geron by a qualified and licensed physician with expertise and facilities appropriate for the administration of imetelstat.

Recently Reported New Data from IMerge Phase 3

In June 2023, we reported new data and analyses from IMerge Phase 3 in at the European Hematology Association 2023 Hybrid Congress, or the EHA presentation. We believe these data expand on the potential differentiating qualities of imetelstat to address current unmet needs for lower risk MDS patients. Key highlights of each presentation are summarized as follows:

Presentation: *Continuous Transfusion Independence with Imetelstat in Heavily Transfused Non-Del(5q) Lower Risk Myelodysplastic Syndromes Relapsed/Refractory to Erythropoiesis Stimulating Agents in IMerge Phase 3*

This oral presentation reported top-line results from IMerge Phase 3 with a data cut-off of October 2022 for the primary analysis and a data cut-off of January 2023 for ≥1-yr transfusion independence, or TI. As reported in January 2023, imetelstat demonstrated statistically significant and clinically meaningful efficacy results in the trial, with robust 8-week TI, 24-week TI, and 1-year TI rates, as noted in the figure below.



[a]Data cutoff: October 13, 2022. [b]Data cutoff: January 13, 2023.
P-value determined by the Cochran-Mantel-Haenszel test, with stratification for prior RBC transfusion burden (≥4 to ≤6 vs >6 RBC units/8 weeks during a 16-week period prior to randomization) and baseline International Prognostic Scoring System risk category (low vs intermediate-1) applied to randomization.
RBC, red blood cell; TI, transfusion independence.

In the trial, 39.8% (47/118) of imetelstat-treated patients versus 15.0% (9/60) of placebo-treated patients achieved 8-week TI (P < 0.001). In addition, the rate of 8-week TI was also significantly higher for imetelstat-treated patients versus placebo-treated patients across MDS subgroups, including in RS negative and RS positive patients. Median TI duration using Kaplan Meier estimates (95% CI) was 51.6 (26.9–83.9) weeks for imetelstat-treated patients versus 13.3 (8.0–24.9) weeks for placebo-treated patients (P < 0.001). Key secondary endpoint of 24-week TI was achieved in 28.0% (33/118) of imetelstat-treated patients versus 3.3% (2/60) of placebo-treated patients receiving (P < 0.001). With 3 months additional follow-up, 17.8% (21/118) of imetelstat-treated patients versus 1.7% (1/60) of placebo-treated patients achieved 1-year TI (P = 0.002), representing 63.6% of 24-week TI imetelstat responders.

Two new analyses presented at EHA on TI responses by subgroups underscored the breadth of potential effect of imetelstat vs. placebo. The first analysis reported higher durability of TI for imetelstat-treated patients vs. placebo across MDS subgroups:

Durability of RBC-TI for 8-Week TI Responders Across Key LR MDS Subgroups

	Imetelstat median, weeks (95% CI)	Placebo median, weeks (95% CI)	Hazard ratio (95% CI)	P-value
Overall	51.6 (26.9–83.9)	13.3 (8.0–24.9)	0.23 (0.09–0.57)	**<0.001**
WHO category				
RS+	46.9 (25.9–83.9)	16.9 (8.0–24.9)	0.32 (0.11–0.95)	**0.035**
RS-	51.6 (11.9–NE)	11.2 (10.1–NE)	0.11 (0.01–1.43)	**0.062**
Prior RBC transfusion burden per IWG 2006				
4–6 units/8 weeks	51.9 (24.9–122.9)	16.9 (10.1–24.9)	0.35 (0.13–0.96)	**0.035**
6 units/8 weeks	39.9 (15.9–NE)	8.4 (8.0–NE)	0.04 (0.003–0.48)	**<0.001**
IPSS risk category				
Low	43.9 (25.0–NE)	15.1 (8.0–24.9)	0.26 (0.10–0.68)	**0.004**
Intermediate-1	51.6 (11.9–NE)	10.1 (NE–NE)	0.15 (0.01–2.47)	**0.128**
Baseline sEPO				
≤500 mU/mL	51.6 (26.9–83.9)	13.3 (8.0–24.9)	0.21 (0.075–0.61)	**0.002**
>500 mU/mL	122.9 (8.14–NE)	14.6 (12.3–NE)	0.34 (0.03–3.85)	**0.364**
Prior ESA use				
Yes	43.9 (26.9–80.0)	13.3 (8.0–24.9)	0.26 (0.10–0.72)	**0.006**
No	122.9 (8.14–NE)	14.6 (12.3–NE)	0.34 (0.03–3.85)	**0.364**

Data cutoff: October 13, 2022.

Hazard ratio (95% CI) from the Cox proportional hazard model, stratified by prior RBC transfusion burden (≥4 to ≤6 vs >6 RBC units/8 weeks during a 16-week period prior to randomization) and baseline IPSS risk category (low vs intermediate-1), with treatment as the only covariate. *P*-value (2-sided) for superiority of imetelstat vs placebo in hazard ratio based on stratified log-rank test.

ESA, erythropoiesis-stimulating agent; IPSS, International Prognostic Scoring System; IWG, International Working Group; LR-MDS, lower-risk myelodysplastic syndromes; NE, not estimable; RBC, red blood cell; RS, ring sideroblast; sEPO, serum erythropoietin; TI, transfusion independence.

The second analysis reported higher 24-week TI for imetelstat-treated patients vs. placebo across MDS subgroups:

Comparable 24-Week RBC-TI Rate Across Key LR MDS Subgroups

	Imetelstat n/N (%)	Placebo, n/N (%)	% Difference (95% CI)	P-value
Overall	33/118 (28.0)	2/60 (3.3)	24.6 (12.64–34.18)	**<0.001**
WHO category				
RS+	24/73 (32.9)	2/37 (5.4)	27.5 (10.00–40.37)	**0.003**
RS-	9/44 (20.5)	0/23 (0.0)	20.5 (-0.03–35.75)	**0.019**
Prior RBC transfusion burden per IWG 2006				
4–6 units/8 weeks	19/62 (30.6)	2/33 (6.1)	24.6 (5.68–38.66)	**0.006**
>6 units/8 weeks	14/56 (25.0)	0/27 (0.0)	25.0 (6.44–38.65)	**0.012**
IPSS risk category				
Low	23/80 (28.8)	2/39 (5.1)	23.6 (7.23–35.75)	**0.003**
Intermediate-1	10/38 (26.3)	0/21 (0)	26.3 (3.46–43.39)	**0.009**
Baseline sEPO				
≤500 mU/mL	29/87 (33.3)	2/36 (5.6)	27.8 (10.46–39.71)	**0.002**
>500 mU/mL	4/26 (15.4)	0/22 (0)	15.4 (-5.81–35.73)	**0.050**
Prior ESA use				
Yes	31/108 (28.7)	2/52 (3.8)	24.9 (11.61–35.00)	**<0.001**
No	2/10 (20)	0/8 (0.0)	20.0 (-23.47–55.78)	**0.225**

Data cutoff: October 13, 2022.

As previously reported in January 2023 with top-line results from the trial, the safety profile observed with imetelstat in IMerge Phase 3 was consistent with prior clinical experience with no new safety signals. The EHA presentation provided new data on the consequences of the grade 3-4 thrombocytopenia and neutropenia which were most often reported during treatment Cycles 1-3 and led to dose modifications. While approximately 50% of patients treated with imetelstat had dose reductions due to treatment emergent adverse events (TEAE), less than 15% of patients discontinued treatment due to TEAE. Discontinuation of imetelstat treatment in

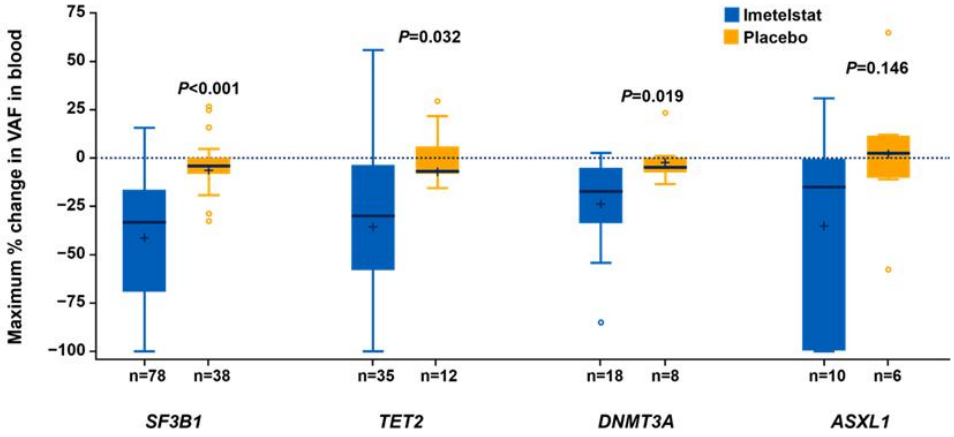
these patients due to a TEAE generally occurred late in treatment, with a median time to treatment discontinuation of 21.1 (range 2.3 to 44.0) weeks.

Presentation: *Disease Modifying Activity of Imetelstat in Patients with Heavily Transfused Non-Del(5q) Lower Risk Myelodysplastic Syndromes Relapsed/Refractory to Erythropoiesis Stimulating Agents in IMerge Phase 3*

This oral presentation reported new data on cytogenetic responses and reductions in bone marrow RS from IMerge Phase 3. In lower risk MDS, malignant clones carrying cytogenetic abnormalities, mutant alleles, or both arise from malignant stem and progenitor cells in the bone marrow. Specifically, SF3B1, involved in RNA splicing, and TET2, involved in DNA methylation, are recurrently mutated genes in lower risk MDS, which can be quantified by measuring change in variant allele frequency, or VAF, to denote disease burden.

Of the 178 patients enrolled in IMerge Phase 3, 22.0% of imetelstat-treated patients and 21.7% of placebo-treated patients had baseline cytogenetic abnormalities. Cytogenetic response was observed in 34.6% (9/26) of imetelstat treated patients (95% CI=17.2–55.7) versus 15.4% (2/13) of placebo-treated patients (95% CI=1.9–45.5). In addition, a higher percentage of patients treated with imetelstat (40.8%) vs. placebo (9.7%) had a ≥50% reduction in central bone marrow RS. TI responses were enriched in patients achieving a ≥50% reduction in central bone marrow RS.

Furthermore, the EHA presentation provided updated data on variant allele frequency (VAF) reductions and new analyses on the correlation of such reductions with clinical responses which provides further evidence of the potential disease-modifying activity of imetelstat. As shown below, reductions in VAF of genes frequently mutated in MDS were greater for imetelstat-treated patients than placebo: SF3B1 (P< 0.001), TET2 (P= 0.032), DNMT3A (P= 0.019) and ASXL1 (P=0.146). More patients treated with imetelstat vs. placebo had ≥50% VAF reduction in these mutations.

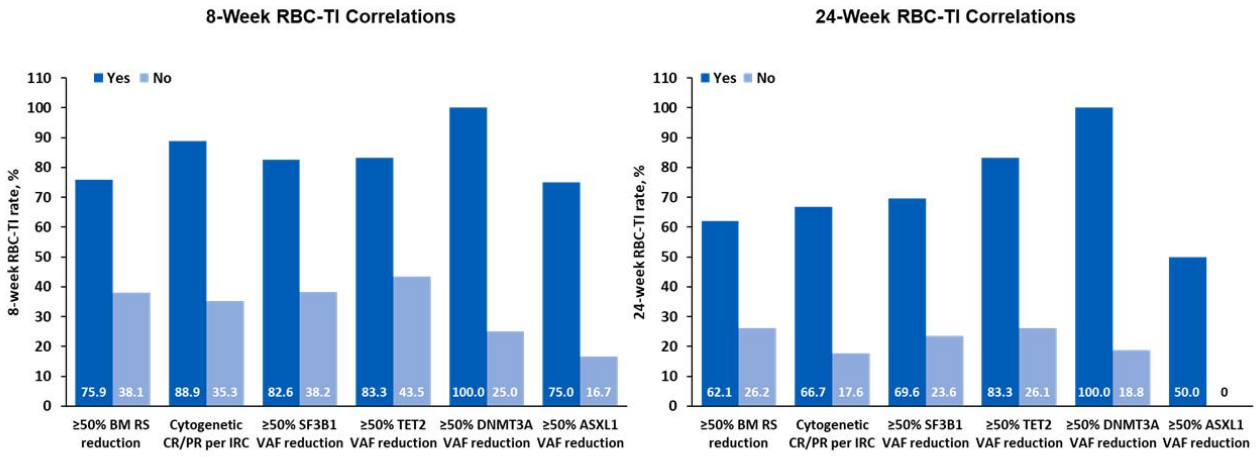


Data cutoff: October 13, 2022.
Note: Figure shows the comparison between each treatment group in the maximum percentage change from baseline in mutant VAF of the indicated gene. *P* value based on the two-sample *t*-test. Analyses included patients in the intent-to-treat population with a detectable mutant allele for the indicated gene (≥5%) prior to treatment and ≥1 postbaseline mutation assessment.
ASXL1, additional sex combs like-1; DNMT3A, DNA (cytosine-5)-methyltransferase 3A; MDS, myelodysplastic syndromes; NGS, next-generation sequencing; SF3B1, splicing factor 3b subunit 1; TET2, Tet methylcytosine dioxygenase 2; VAF, variant allele frequency.

For patients with the SF3B1 mutation, 29.5% (23/78) of those treated with imetelstat vs. 2.6% (1/38) on placebo (P= 0.001) had a ≥50% VAF reduction. Imetelstat treatment resulted in sustained reduction of SF3B1 VAF over time. In the imetelstat group, 82.6% (19/23) of patients had 8-week TI among patients who achieved ≥50% maximum reduction from baseline in SF3B1 VAF vs. 38.1% (21/55) of those who did not.

Similarly, a larger proportion of TI responders were imetelstat-treated patients achieving ≥50% reduction in TET2 VAF. In the imetelstat group, 83.3% (10/12) of patients had 8-week RBC-TI among patients who achieved ≥50% maximum reduction from baseline in TET2 VAF vs 43.5% (10/23) of those who did not.

As shown below, a larger proportion of 8-week and 24-week TI responders were imetelstat-treated patients achieving ≥50% reduction in SF3B1 and TET2 VAF. VAF reduction in SF3B1, TET2 and DNMT3A correlated with longer TI duration and increases in hemoglobin levels in imetelstat-treated patients. Further, 8-week and 24-week TI correlated with reduction in RS+ cells, cytogenetic responses and VAF reduction.



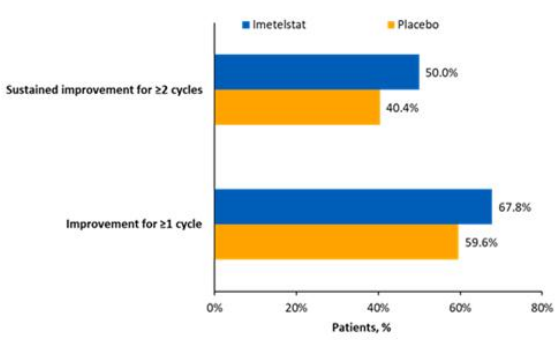
Data cutoff: October 13, 2022.
Note: *P* value calculated using Fisher exact test between yes vs no in each outcome.
ASXL1, additional sex combs like-1; BM, bone marrow; CR, complete response; DNMT3A, DNA (cytosine-5)-methyltransferase 3A; IRC, independent review committee; PR, partial response; RBC, red blood cell; RS, ring sideroblasts; TET2, Tet methylcytosine dioxygenase 2; SF3B1, splicing factor 3b subunit 1; TI, transfusion independence; VAF, variant allele frequency.

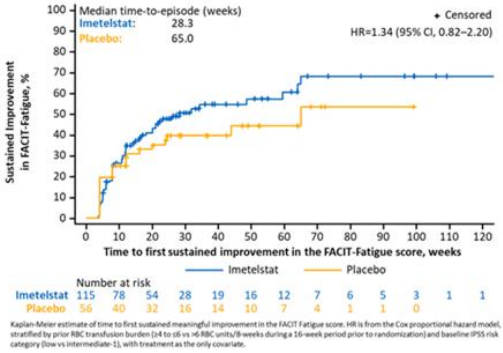
Presentation Title: *Analysis of Patient Reported Fatigue in IMerge Phase 3 Trial of Imetelstat vs. Placebo in Heavily Transfused Non-Del(5q) Lower Risk Myelodysplastic Syndromes Relapsed/Refractory to Erythropoiesis Stimulating Agents (ESA)*

This poster presentation described results from an exploratory analysis from IMerge Phase 3 of patient reported fatigue conducted using Functional Assessment of Chronic Illness Therapy, or FACIT, a validated 13-item patient questionnaire. Proportion of sustained meaningful deterioration/improvement was defined as percentage of patients with ≥3-point decrease/increase on the FACIT Fatigue Scale (0–52) for ≥2 consecutive nonmissed treatment cycles. Time-to-deterioration/improvement was estimated by Kaplan-Meier analysis.

In IMerge Phase 3, 118 patients on imetelstat and 57 patients on placebo were assessed for patient reported fatigues. Completion rates for the FACIT questionnaire were >85% at most visits throughout the study in both groups. The proportion of patients who experienced any episode of sustained, meaningful deterioration in fatigue during the trial was 43.2% for imetelstat-treated patients and 45.6% for placebo-treated patients with imetelstat-treated patients receiving fewer transfusion units over time. For patients treated with imetelstat, there was a numerically higher percentage of patients reporting any episode of sustained meaningful improvement in fatigue. Overall, 50.0% of imetelstat-treated patients reported sustained meaningful improvement in fatigue versus 40.4% of placebo-treated patients. In addition, imetelstat-treated patients reported a shorter median time to first sustained meaningful improvement in fatigue versus placebo-treated patients; 28.3 vs 65.0 weeks, respectively, hazard ratio=1.34 (95% CI, 0.82–2.20).

As shown in the figures below, after 12 weeks, more imetelstat-treated patients reported improvement in the FACIT Fatigue Scale than placebo-treated patients. In addition, in imetelstat-treated patients, a significantly higher proportion of TI responders had sustained meaningful improvement in fatigue scores versus non-responders. This was consistent across 8-week TI and 24-week TI and hematologic improvement-erythroid, or HI-E, response per 2006 International Working Group criteria, for imetelstat-treated patients, which was not an association observed in placebo-treated patients. Additional analysis showed that patients experiencing grade 3 or 4 neutropenia or thrombocytopenia had the same rates of sustained meaningful improvement in fatigue (52.5% and 53.4%, respectively) as the total imetelstat population (50%).





Financial Overview

Since our inception, we have primarily financed our operations through the sale of equity securities, interest income on our marketable securities and payments we received under our collaborative and licensing arrangements. As of June 30, 2023, we had approximately $400.2 million in cash, cash equivalents, restricted cash and marketable securities and a long-term principal debt balance of $50.0 million.

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. 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 under a former imetelstat collaboration agreement, until 2015 we had never been profitable, and we 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, 2023, we had an accumulated deficit of approximately $1.5 billion.

The significance of future losses, future revenues and any potential future profitability will depend primarily on the clinical and commercial success of imetelstat, our sole product candidate. In any event, imetelstat may require significant additional clinical testing prior to possible regulatory approval in the U.S. and other countries. We expect research and development expenses, general and administrative expenses, and losses to substantially increase in future periods as we continue to support the imetelstat development program, including the conduct and completion of IMpactMF, IMproveMF and IMpress, as well as the potential U.S. commercialization of imetelstat lower risk MDS.

Based on our current operating plan and our expectations regarding the timing of potential acceptance and approval of our NDA by the FDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with lower risk MDS, who have failed to respond to or have lost response to or are ineligible for ESAs, we believe that our existing cash, cash equivalents, restricted cash and current and noncurrent marketable securities will be sufficient to fund our projected operating requirements through the end of the third quarter of 2025, which includes estimated revenues from a potential U.S. commercial launch of imetelstat in lower risk MDS in the first half of 2024 and the revised timing expectations for interim and final analyses in IMpactMF. In the absence of potential additional proceeds from exercises of remaining outstanding warrants and potential drawdowns under the Loan Agreement, we will require substantial additional funding to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, as well as conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications, and our need for additional funds may arise sooner than planned. We cannot predict with any certainty whether and to what extent the remaining outstanding warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all.

If approved for marketing by regulatory authorities outside of the U.S., we may seek potential commercialization partners for such territories. Until the FDA or similar international regulatory authorities approve imetelstat for marketing in lower risk MDS, if at all, we cannot begin commercialization.

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, 2023, as compared to the critical accounting policies and estimates disclosed in our 2022 Form 10-K.

Our condensed consolidated 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 on Summary of

Significant Accounting Policies in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q describes the significant accounting policies used in the preparation of the condensed consolidated 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 consolidated 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 consolidated financial statements are fairly stated in accordance with accounting principles generally accepted in the United States, and present a meaningful presentation of our financial condition and results of operations.

RESULTS OF OPERATIONS

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future. 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.

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 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; the uncertain and unpredictable drug research and discovery process; overcoming disruptions and/or delays due to macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues; our need for substantial additional capital; enforcement of our patent and proprietary rights; reliance upon our CROs, contract manufacturing organizations, or CMOs, 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 several years, if at all.

Revenues

In connection with the divestiture of Geron's human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc., or Lineage, (formerly BioTime, Inc. which acquired Asterias Biotherapeutics, Inc.) in 2013, we are entitled to receive royalties on sales from certain research or commercial products utilizing Geron's divested intellectual property.

We recognized royalty revenues of $29,000 and $50,000 for the three and six months ended June 30, 2023, respectively, compared to $73,000 and $196,000 for the same periods in 2022. Royalty revenues in 2023 and 2022 primarily reflect estimated royalties from sales of cell-based research products from our divested stem cell assets.

Future license fee and royalty revenues are dependent on additional agreements being signed, if any, our current license agreement with Lineage being maintained and the underlying patent rights for the license remaining active. Historical revenues may not be predictive of future revenues. We expect royalty revenues in 2023 to be lower than in 2022 from sales of cell-based research products from our divested stem cell assets.

Research and Development Expenses

During the three and six months ended June 30, 2023 and 2022, our imetelstat program and our research discovery program related to potential next generation telomerase inhibitors were the only research and development programs we supported. For these research and development programs, we incur direct external, personnel-related and other research and development costs. For the three and six months ended June 30, 2023 and 2022, direct external expenses included costs for our CROs, consultants and other clinical-related vendors, as well as expenses for contract manufacturing and quality activities. Personnel-related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for our 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 for the three and six months ended June 30, 2023 and 2022 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2023	2022	2023	2022
	(Unaudited)			
Direct external expenses	$ 25,777	$ 13,819	$ 43,541	$ 28,926
Personnel-related expenses	7,757	5,401	15,456	11,222
All other expenses	1,956	1,386	3,712	2,557
Total research and development expenses	$ 35,490	$ 20,606	$ 62,709	$ 42,705

The increase in research and development expenses for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects the net result of higher manufacturing costs due to the timing of imetelstat manufacturing batches, increased personnel-related expenses for additional headcount, and higher clinical trial costs related to supporting IMerge Phase 3 and IMpactMF. We expect research and development expenses to increase in the future as we conduct and complete ongoing clinical trials of imetelstat. 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 Compliance Matters and Commercialization of Imetelstat” in Part II, Item 1A entitled “Risk Factors” and elsewhere in this quarterly report on Form 10-Q.

General and Administrative Expenses

General and administrative expenses were $16.5 million and $29.4 million for the three and six months ended June 30, 2023, respectively, compared to $7.4 million and $14.1 million for the same periods in 2022. The increase in general and administrative expenses for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects higher personnel-related expenses of approximately $4.8 million and $8.4 million, respectively, for additional headcount; as well as new costs for commercial preparatory activities of approximately $2.4 million and $4.1 million, respectively. We expect general and administrative expenses to increase in the future as the imetelstat program matures and potential stage-gated commercialization activities continue.

Interest Income

Interest income was $4.7 million and $8.6 million for the three and six months ended June 30, 2023, respectively, compared to $330,000 and $442,000 for the same periods in 2022. The increase in interest income for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects a larger marketable securities portfolio with the receipt of net cash proceeds from the underwritten public offering completed in January 2023 and cash proceeds from warrant exercises in the first half of 2023, as well as higher yields from recent marketable securities purchases. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Interest Expense

Interest expense was $2.0 million and $3.9 million for the three and six months ended June 30, 2023, respectively, compared to $1.6 million and $3.1 million for the same periods in 2022. The increase in interest expense for the three and six months ended June 30, 2023, compared to the same periods in 2022, primarily reflects rising interest rates. Currently, we have $50.0 million in principal debt outstanding. Interest expense reflects interest owed under the Loan Agreement, as well as amortization of associated debt issuance costs and debt discounts using the effective interest method and accrual for an end of term charge. See Note 4 on Debt in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q for additional information about the Loan Agreement.

Other Income and (Expense), Net

Net other expense was $11,000 for the three months ended June 30, 2023 and net other income was $28,000 for the six months ended June 30, 2023, compared to net other income of $1.1 million for the three and six months ended June 30, 2022. Net other income and expense primarily reflects bank charges related to our cash operating accounts and marketable securities portfolio and foreign currency transaction adjustments.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2023, we had cash, restricted cash, cash equivalents, and marketable securities of $400.2 million, compared to $173.1 million at December 31, 2022. The increase in cash, restricted cash, cash equivalents and marketable securities during the six months ended June 30, 2023 was primarily the net result of the receipt of net cash proceeds of $213.3 million from our underwritten public offering completed in January 2023 and receipt of cash proceeds from exercise of outstanding warrants of $77.6 million, partially offset by cash being used for operations.

On January 10, 2023, we completed an underwritten public offering of 68,007,741 shares of our common stock and a pre-funded warrant to purchase 25,000,000 shares of our common stock, or the 2023 pre-funded warrant. The net cash proceeds from this offering are $213.3 million, after deducting the underwriting discount and other offering expenses paid by us, and excludes any future proceeds from the exercise of the 2023 pre-funded warrant, which has not been exercised. See Note 6 on Stockholders’ Equity in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q for additional information about the underwritten public offering completed in January 2023.

From January 1, 2023 through June 30, 2023, we have received $54.1 million in cash proceeds from the exercise of warrants we issued in 2020, covering 41,635,576 shares of our common stock. From January 1, 2023 through June 30, 2023, we have received $23.5 million in cash proceeds from the exercise of warrants we issued in 2022, covering 16,190,474 shares of our common stock.

As of June 30, 2023, we had a long-term principal debt balance of $50.0 million under the Loan Agreement with Hercules and SVB. In June 2022, we entered into a second amendment to the Loan Agreement with Hercules and SVB. Under the second amendment, the aggregate principal amount available to us increased from $75.0 million to $125.0 million. As of June 30, 2023, a total of $55.0 million is available to be drawn in a series of tranches under the Loan Agreement, subject to certain terms and conditions. Of this amount, $30.0 million is available subject to our achievement of certain clinical and regulatory milestones and

satisfaction of certain capitalization and other requirements, and the remaining $25.0 million is available subject to approval by an investment committee comprised of Hercules and SVB. See Note 4 on Debt in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q for additional information on the second amendment.

We have an investment policy to invest our cash in liquid, investment grade securities, such as interest-bearing money market funds, certificates of deposit, U.S. Treasury securities, municipal securities, government and agency securities, commercial paper and corporate notes. 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 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.

On September 4, 2020, we entered into an At Market Issuance Sales Agreement, or the 2020 Sales Agreement, with B. Riley Securities, Inc., or B. Riley Securities, pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $100.0 million in such quantities and on such minimum price terms as we set from time to time through B. Riley Securities as our sales agent. We pay B. Riley Securities 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 Securities under the 2020 Sales Agreement. We did not sell any shares of our common stock pursuant to the 2020 Sales Agreement during the six months ended June 30, 2023. Approximately $79.1 million of our common stock remained available for issuance under the 2020 Sales Agreement as of June 30, 2023. The 2020 Sales Agreement will expire upon the earlier of: (a) the sale of all common stock subject to the 2020 Sales Agreement, or (b) September 4, 2023.

Financing Strategy

We may, from time to time, consider additional funding through a combination of new collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. We will continue to manage our capital structure and consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

Future Funding Requirements

Based on our current operating plan and our expectations regarding the timing of the potential acceptance and approval of our NDA by the FDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with lower risk MDS who have failed to respond to or have lost response to or are ineligible for ESAs, we believe that our existing cash, cash equivalents, restricted cash and current and noncurrent marketable securities will be sufficient to fund our projected operating requirements through the end of the third quarter of 2025, which includes estimated revenues potential U.S. commercial launch of imetelstat in lower risk MDS in the first half of 2024 and the revised timing expectations for interim and final analyses in IMpactMF. In the absence of potential additional proceeds from exercises of currently remaining warrants and potential drawdowns under the Loan Agreement, we will require substantial additional funding to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, as well as conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications, and our need for additional funds may arise sooner than planned. We cannot predict with any certainty whether and to what extent the outstanding remaining warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all.

In addition, our ability to commercialize imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities which we may be unable to do in a timely manner or at all.

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; whether we will obtain regulatory approval for imetelstat in any indication we pursue, including lower risk MDS; or whether we will be able to effectively commercialize imetelstat, if at all. 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. In addition, our plans and timing expectations could be further delayed or interrupted by the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues. Further, 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 scope, progress, timing, magnitude 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 similar international regulatory authorities;

- the scope, progress, duration, results and costs of current clinical trials, including IMerge Phase 3, IMpactMF, IMproveMF and IMpress, and any potential future clinical trials of imetelstat, as well as our recently opened expanded access program and non-clinical studies and assessments of imetelstat;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in IMpactMF, IMproveMF, IMpress, or any potential future clinical trials of imetelstat, whether as a result of the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, such as obtaining and maintaining regulatory clearances and approvals to continue clinical development of imetelstat in current and potential future clinical trials, as well as to commence potential commercialization of imetelstat in the U.S. 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 achieve any meaningful reduction in manufacturing costs;
- the costs of multiple third-party vendors and service providers, including our CROs and third-party manufacturers, to pursue the development, manufacturing and potential commercialization of imetelstat;
- our ability to establish, enforce and maintain collaborative or other strategic arrangements for the research, development, clinical testing and manufacturing of imetelstat on favorable terms, if at all;
- our efforts to enhance operational, financial and management processes and systems that will be required for future development and commercialization of imetelstat, and our ability to successfully recruit and retain additional key personnel to support the development and potential future commercialization of imetelstat;
- our ability to successfully market and sell imetelstat, if imetelstat receives future regulatory approval or clearance, in the U.S. and other countries, and the associated costs;
- the costs and timing necessary to build a sales force in the U.S. and potentially other countries to market and sell imetelstat, should it receive regulatory approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator;
- the sales price for imetelstat, if any;
- the availability of coverage and adequate third-party reimbursement for imetelstat, if any;
- the extent to which we acquire or in-license other drugs and technologies, or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions, or to which we out-license imetelstat;
- the extent to which we are able to enter into strategic partnerships, collaborations and alliances or licensing arrangements with third parties including for the commercialization and marketing of imetelstat in certain global regions;
- the success of any collaborations that we may enter into with third parties;
- expenses associated with settlement of the pending securities class action lawsuits, as well as any other potential litigation;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation;
- our level of indebtedness and associated debt service obligations;
- the costs of maintaining and operating facilities in California and New Jersey, telecommunications and administrative oversight, as well as higher expenses for travel;
- macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, the prospects of a recession, bank failure and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, that may reduce our ability to access debt capital or financing on preferable terms, which may adversely affect future capital requirements and forecasts;

- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities; and
- the amount of proceeds, if any, of cash exercises of our currently outstanding warrants.

Until we can generate a sufficient amount of revenue from imetelstat to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, which may not be possible. Availability of such financing sources may be negatively impacted by any further delays in reporting results from IMpactMF or investors' perception of top-line results from IMerge Phase 3, despite our interpretation of such data being positive, as well as macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects or a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues.

Additional financing through public or private debt or equity financings, including pursuant to the 2020 Sales Agreement with B. Riley Securities, Inc., or B. Riley, the remaining tranches of up to $55.0 million available under the Loan Agreement, which are subject to the achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche; capital lease transactions or other financing sources, may not be available on acceptable terms, or at all. We may be unable to raise equity capital, or may be forced to do so 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 debt and equity markets to proposed financings has been substantially affected by uncertainty in the general economic, market and political climate due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, and may in the future be affected by other factors which are unpredictable and over which we have no control. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, which could reduce or eliminate our ability to raise additional funds through financings, and could negatively impact the terms upon which we may raise those funds. Similarly, these macroeconomic conditions have created extreme volatility and disruption in the capital markets and is expected to have further global economic consequences. If the equity and credit markets deteriorate, including as a result of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development and potential commercialization of imetelstat may be further delayed, altered or abandoned, which might cause us to cease operations.

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. Due to uncertainty in the general economic, market and political climate, we may determine that it is necessary or appropriate to raise additional funds proactively to meet longer-term anticipated operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the 2020 Sales Agreement, your ownership interest as a stockholder may be diluted, and the terms may include liquidation or other preferences that materially and adversely affect your rights as a stockholder. In addition, we have borrowed, and in the future may borrow, additional capital from institutional and commercial banking sources to fund imetelstat development and our future growth, including pursuant to our Loan Agreement or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as the Loan Agreement, that include restrictive covenants, including covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Moreover, 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, future proceeds from potential cash exercises of currently outstanding warrants, potential future sales of our common stock, including under the 2020 Sales Agreement with B. Riley and potential future drawdowns, if available, of the remaining up to $55.0 million under the Loan Agreement (which are subject to the achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche), will be sufficient to fund our operating plans. While we did not hold cash deposits or securities at SVB, if other banks and financial institutions enter receivership, become insolvent or otherwise fail in the future in response to financial conditions affecting the banking system and financial markets or otherwise, our ability to access our existing cash, cash equivalents and marketable securities may be delayed or precluded, which could have a material adverse effect on our business, business prospects and financial position.

Cash Flows from Operating Activities

Net cash used in operations for the six months ended June 30, 2023 and 2022 was $76.0 million and $62.6 million, respectively. The increase in net cash used in operations for the six months ended June 30, 2023, compared to the same period in 2022, primarily

reflects higher payments to support ongoing clinical trials of imetelstat, commercial preparatory activities, and increases in headcount to support pre-approval and commercialization efforts.

Cash Flows from Investing Activities

Net cash used in investing activities was $223.2 million for the six months ended June 30, 2023 and net cash provided by investing activities was $33.2 million for the six months ended June 30, 2022. The increase in net cash used in investing activities for the six months ended June 30, 2023, compared to the same period in 2022, primarily reflects a higher rate of purchases than maturities of marketable securities in 2023 from the investment of net cash proceeds received from the underwritten public offering completed in January 2023 and warrant exercises in the first half of 2023.

Cash Flows from Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2023 and 2022 was $299.4 million and $70.6 million, respectively. Financing activities in 2023 primarily reflect the receipt of net cash proceeds from the underwritten public offering completed in January 2023 and warrant exercises in the first half of 2023.

Contractual Obligations

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Our contractual obligations primarily consist of our current and noncurrent debt obligations under the Loan Agreement with Hercules and SVB, as described above and in Note 4 on Debt in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q, and obligations under non-cancellable operating leases. The aggregate amount of our future operating lease payments was reported in our 2022 Form 10-K and there have been no changes to the contractual terms of our operating leases during the six months ended June 30, 2023.

In the normal course of business, we enter into agreements with CROs for clinical trials and third-party manufacturers for clinical supply manufacturing and with other vendors for non-clinical research studies, investigator-led trials and other services and products for operating purposes. We have not considered these payments to be contractual obligations since the contracts are generally cancellable at any time by us upon less than 180 days' prior written notice. We also have certain in-license agreements that require us to pay milestones to such third parties upon achievement of certain development, regulatory or commercial milestones. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones, which may not be achieved.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information specified under this item.

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 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

See Note 5 on Contingencies and Uncertainties in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q for information on legal proceedings.

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 2022 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 2022 Form 10-K.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this summary to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, are described below, and this summary is qualified in its entirety by that description. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below as part of your evaluation of an investment in our common stock.

- We are wholly dependent on the success of our sole product candidate, 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 or to commercialize imetelstat, on a timely basis or at all.
- Our failure to obtain regulatory approval for imetelstat in the U.S. would have a material adverse effect on our business that would likely cause us to cease operations.
- If imetelstat is approved for marketing and commercialization in lower risk MDS and we are unable to establish sales, marketing and distribution capabilities, or obtain coverage and adequate third-party payor reimbursement, we will be unable to successfully commercialize imetelstat.
- If we are not successful in commercializing imetelstat, we will not be able to achieve our projections for future revenue, if any.
- Any suspension of or delays in IMpactMF, including due to challenges in opening clinical sites or patient recruitment, enrollment and retention resulting from macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Any termination of IMpactMF would have a material adverse effect on our business, business prospects and the future of imetelstat.
- If IMpactMF fails to demonstrate safety and effectiveness to the satisfaction of the FDA or international regulatory authorities or does not otherwise produce positive results, we would incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of imetelstat in patients with relapsed/refractory MF which would have a material adverse effect on our business, business prospects and the future of imetelstat.

- Imetelstat may continue to 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.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier stage clinical trials and non-clinical studies may not be predictive of future results.
- We rely on third parties to conduct our clinical trials and their failure to perform could have a material adverse effect on our business that might cause us to cease operations.
- We rely on third parties to manufacture and supply imetelstat, and may be unable to ensure that we have adequate quantities of imetelstat that meet specifications that may be approved or required by regulatory authorities, and timelines necessary for current and potential future clinical trials and potential commercial uses.
- Regulatory inspections of third-party manufacturers may identify deficiencies in manufacturing processes or facilities which could impact the ability of third-party manufacturers to produce and deliver products, including imetelstat.
- If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat for an adequate amount of time, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to imetelstat, and our ability to successfully commercialize imetelstat may be adversely affected.
- If competitors develop products, product candidates or technologies that are superior to or more cost-effective than imetelstat, this would significantly impact the development and commercial viability of imetelstat; severely and adversely affect our financial results, business and business prospects and the future of imetelstat; and might cause us to cease operations.
- Our failure to obtain additional capital would force us to further delay, reduce or eliminate development of imetelstat in current and any potential future clinical trials of imetelstat, and our potential future imetelstat commercialization efforts, any of which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.
- We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.
- We and certain of our officers have been named as defendants in pending securities class action lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome.
- We are subject to legal and contractual obligations related to privacy, data protection and information security. Our actual or perceived failure, or that of third parties upon which we rely, to comply with such obligations or changes in such obligations may adversely affect our business, operations and financial performance.
- Additionally, if our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences.

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 or to commercialize imetelstat, on a timely basis or at all.*

Imetelstat is our sole product candidate, upon whose success we are wholly dependent. We do not currently have any other products or product candidates. Our ability to develop imetelstat and launch it commercially is subject to significant risks and uncertainties, including, obtaining regulatory approval from the FDA and EMA for commercializing imetelstat in lower risk MDS, as well as, among other things, our ability to:

- obtain acceptance for filing from the FDA of our imetelstat NDA and submit an MAA to the EMA in lower risk MDS that is validated for filing;
- obtain from the FDA and EMA their respective determinations that the regulatory submissions are sufficient to support regulatory approval to commercialize imetelstat in lower risk MDS, without the requirement for additional pre-approval clinical trials or further testing or development commitments, if at all, any of which could result in increased costs to us, and delay or limit our ability to generate revenue;

- obtain sufficient safety and efficacy data from IMpactMF to support any application for regulatory approval in relapsed/refractory MF, without clinically meaningful safety issues, side effects or dose-limiting toxicities related to imetelstat that may negatively impact its benefit-risk profile;
- 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;
- obtain additional capital in order to enable us to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, as well as to conduct the regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications;
- develop clinical plans for, and successfully commence, conduct and complete potential future clinical trials of imetelstat;
- generate sufficient safety and efficacy data from ongoing and potential future clinical trials of imetelstat that provide a positive benefit-risk profile to support the continued and future development of imetelstat;
- obtain and maintain required regulatory clearances and approvals to enable continued clinical development, as well as potential commercialization, of imetelstat;
- enter into and maintain arrangements with third parties to provide services needed to further research and develop imetelstat, including maintaining the agreements with our contract research organizations, or CROs, or to manufacture imetelstat, in each case at commercially reasonable costs;
- recruit and retain sufficient qualified and experienced personnel to support the development and potential commercialization of imetelstat in the U.S., including to enroll, conduct and complete current and potential future clinical trials of imetelstat, and to provide internal capabilities for sales, marketing, distribution and other functions to support the potential commercialization of imetelstat in the U.S.;
- enter into and maintain arrangements with third parties to provide services needed to support the potential commercialization of imetelstat for territories outside of the U.S. in compliance with applicable laws;
- achieve acceptance of imetelstat, if approved, by patients and the relevant medical communities;
- compete effectively with other approved treatments in lower risk MDS;
- obtain appropriate coverage and reimbursement levels for the cost of imetelstat from governmental authorities, private health insurers and other third-party payors; and
- obtain, maintain and enforce adequate intellectual property and regulatory exclusivity for imetelstat both in the U.S. and globally.

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 and/or commercialization of imetelstat, which would severely harm our business, prospects and our ability to raise additional capital, and might cause us to cease operations.

Our current and potential future clinical trials of imetelstat could be interrupted, delayed, terminated or abandoned for a variety of reasons, including due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.*

Currently, the active clinical trials of imetelstat are IMpactMF, IMproveMF and IMpress. In addition, we have extended IMerge Phase 3 to allow remaining patients to continue to receive treatment of either imetelstat or placebo, and such patients are also being followed for survival and disease progression, as well as safety. In June 2023, we opened an expanded access program, sometimes called compassionate use, whereby imetelstat could be used outside of a clinical trial for lower risk MDS patients with serious or life-threatening conditions who have exhausted their treatment options and are not eligible for, or able to participate in, a clinical trial.

The conduct and completion of IMpactMF, IMproveMF and IMpress could be interrupted, delayed or abandoned for a variety of reasons, including due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues. In addition, we may also experience clinical trial failures or delays related to:

- overcoming patient recruitment, enrollment and retention challenges and operational delays related to opening new clinical sites, and conducting and completing IMpactMF, IMproveMF and IMpress, while also competing with clinical trials for other investigational drugs in the same patient population;
- clinical sites electing to terminate their participation in any of our clinical trials, which would likely have a detrimental effect on patient enrollment;

- difficulties in patient recruitment and enrollment in IMpactMF, IMproveMF and IMpress;
- any inability to successfully retain patients in IMpactMF in order to complete the planned interim and final analyses for IMpactMF;
- a higher number of patients being required for clinical trials, or higher than expected patient drop out rates;
- obtaining and/or maintaining regulatory clearances in the U.S. 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, prevent us from, or result in substantial delays in, conducting or completing IMpactMF, IMproveMF and IMpress, or commencing potential future clinical trials of imetelstat;
- maintaining the investigational new drug applications, or INDs, and equivalent submissions in other countries for imetelstat without such INDs and/or equivalent submissions in other countries being placed on full or partial clinical hold, suspended or subject to other requirements by the FDA or other similar international regulatory authorities;
- contracting with a sufficient number of clinical trial sites to conduct current and potential future clinical trials, and ensuring that such contracts contain all necessary terms and conditions required by applicable laws, including providing for valid mechanisms to engage in cross-border data transfers, as well as identifying, recruiting and training suitable clinical investigators, while also competing with other clinical trials in MF and other oncology indications;
- obtaining or accessing necessary clinical data in accordance with appropriate clinical or quality practices and regulatory requirements, in a timely and accurate manner to ensure complete data sets;
- responding to safety findings, recommendations or conclusions by the internal data safety review committees, independent data monitoring committees and/or hepatic expert committees of current and potential future clinical trials of imetelstat based on emerging data occurring during such clinical trials, such as significant systemic or organ toxicities, including severe cytopenias, hepatotoxicity, fatal bleeding with or without any associated thrombocytopenia, or reduced platelet count, patient injury or death, or other safety issues, resulting in an unacceptable benefit-risk profile;
- use of trial endpoints that inherently require prolonged periods of clinical observation or analysis of the resulting data to determine trial outcomes;
- manufacturing sufficient quantities that meet our specifications and timelines of imetelstat, or other clinical trial materials, in a manner that meets the quality standards of the FDA and other similar international regulatory authorities, and responding to any disruptions to drug supply, clinical trial materials or quality issues that may arise, including as a result of temporary or permanent shut down of contract manufacturing facilities due to violations of good manufacturing practices, or GMP, regulations or other applicable requirements; infections or cross-contaminations of product candidates in the manufacturing process; or capacity limitations;
- ensuring the ability to manufacture and supply imetelstat at acceptable costs for potential future clinical trials of imetelstat and potential commercial uses;
- obtaining sufficient quantities of any study-related treatments, materials (including best available therapy, or BAT, comparator products, placebo or combination therapies) or ancillary supplies;
- obtaining acceptance by regulatory authorities of any manufacturing changes for imetelstat, 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, physician investigators, vendors and other third parties located in the U.S. or jurisdictions in other countries, including our CROs, laboratory service providers and clinical trial sites, on all aspects of clinical development and collaborating with them successfully;
- third-party clinical investigators or our CROs losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials according to our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or regulatory requirements, or not performing data collection or analyses in a timely or accurate manner;
- third-party contractors becoming debarred, disqualified or suspended or otherwise penalized by the FDA or other similar international regulatory authorities for violations of applicable regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of any applications for regulatory approval;
- obtaining timely review and clearances by regulatory authorities for any clinical protocol amendments or modifications to our manufacturing process which may be sought for current 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,

prevent us from conducting or completing IMpactMF, IMproveMF or IMpress, or commencing potential future clinical trials of imetelstat; and

- obtaining institutional review board or ethics committee approvals for clinical trial protocols or protocol amendments, including any future refinements to the trial designs we may seek for IMpactMF, IMproveMF or IMpress, or as a result of changes in regulatory requirements and policies, which could, for example, prevent us from conducting or completing IMpactMF, IMproveMF or IMpress, and commencing potential future clinical trials of imetelstat.

We could also encounter delays if a clinical trial is suspended or terminated. Clinical trials may be suspended or terminated due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial site by the FDA or similar international regulatory authorities resulting in the imposition of a clinical hold;
- safety issues or adverse side effects;
- failure to demonstrate a benefit from using imetelstat; or
- changes in governmental regulations or administrative actions.

Failures or delays with respect to any of the aforementioned events could adversely affect our ability to conduct or complete IMpactMF, IMproveMF or IMpress, or to commence, conduct and complete potential future clinical trials of imetelstat, 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.

Further difficulties retaining patients in IMerge Phase 3 and enrolling or retaining patients in IMpactMF, IMproveMF and the investigator-led clinical trial IMpress, whether as a result of the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, or for any other reasons, could further delay or otherwise adversely affect our clinical development and commercialization activities, which would cause our business and business prospects to be severely harmed.*

The timely completion of a clinical trial in accordance with its protocol depends, among other things, on the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. Further challenges in screening, enrolling and retaining patients in IMpactMF, IMproveMF and IMpress, as well as treating and following the remaining patients in IMerge Phase 3, whether as a result of the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, or for any other reasons, may further delay our conduct of such trials, or cause them to be discontinued. For example, we have clinical trial sites in Ukraine, Russia and nearby European countries, and have experienced, and may continue to experience, delays and suspensions in clinical trial activities at clinical sites in Ukraine and Russia due to the current civil or political unrest conditions, including delays in clinical site initiations, patient screening and enrollment, as well as constraints on available sites and site personnel.

Although we reported positive top-line results from IMerge Phase 3 in January 2023, the trial has been extended to allow remaining patients to continue to receive treatment of either imetelstat or placebo, which allows us to continue to assess the longer-term durability of transfusion independence, as well as survival, disease progression and safety. Such assessments would be precluded or adversely affected if we experience difficulties in retaining such patients, whether due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, or for any other reasons. The retention of patients in IMerge Phase 3 and the enrollment and retention of patients in IMpactMF, IMproveMF and IMpress, depend on many factors, such as:

- our ability to identify and screen patients who meet 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, and patients' willingness and ability to travel to trial sites for treatment or monitoring;
- the design of the trial;
- our ability to recruit and retain clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions of the potential advantages of imetelstat, both in relation to other available therapies, including new drugs that have been approved or 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;

- our ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- the risk that disease progression will result in death or clinical deterioration before the patient can enroll in a clinical trial of imetelstat, or before sufficient data has been collected from such patient, such that any data collected from the patient does not contribute in a meaningful way to the interpretation of the results of the clinical trial in which the patient is enrolled; 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, progressive disease, site restrictions, alternate treatments being approved for the indication, or personal issues.

In addition, IMpactMF, IMproveMF and IMpress have competed, and will continue to 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. This competition reduces the number of clinical sites and hospital staff available to participate in IMpactMF, IMproveMF and IMpress, as well as the number and type of patients available to enroll or remain in current and potential future 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 IMpactMF, IMproveMF or IMpress, based on efficacy and safety results reported to date and that may be reported in the future.

Furthermore, if imetelstat is approved for commercialization, we will need to complete substantial preparations to be ready for any potential future commercialization of imetelstat. The development of an in-house marketing and sales force or entering into an arrangement with a third party for the commercialization of imetelstat outside of the U.S. will require significant capital expenditures, management resources and time, and may have an adverse effect on the timely completion of IMpactMF, IMproveMF and IMpress.

Delays caused by the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, or other factors in patient enrollment, or the inability to retain or treat patients, have resulted in and may in the future result in further increased costs due to extended timelines and other factors, and may lead to incomplete data sets, or adversely affect the timing or outcome of current and potential future clinical trials of imetelstat which could delay or prevent the commencement, conduct or completion of these trials and adversely affect the clinical development, as well as the timing or outcome of the potential commercialization of imetelstat. Such additional occurrences would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.

Imetelstat may continue to 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 continue to 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, such as IMerge Phase 3, IMpactMF, IMproveMF and IMpress, as well as our recently opened expanded access program. In this regard, adverse events and dose-limiting toxicities observed in previous and ongoing 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, as well as reversible Grade 4 febrile neutropenia;
- bleeding events, with or without thrombocytopenia, including reversible Grade 3/4 bleeding events;
- hepatotoxicity and liver function test abnormalities, as well as hepatic failure;
- gastrointestinal events;
- infections;
- muscular and joint pain;
- fatigue;
- headache; and
- infusion-related reactions.

If patients in any clinical trials of imetelstat, including IMerge Phase 3, IMpactMF, IMproveMF, IMpress, our recently opened expanded access program or any potential future clinical trials of imetelstat, experience similar or more severe adverse events, or new or unusual adverse events, or if the FDA or other similar international 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 similar international regulatory authorities may again place one or more of the INDs for imetelstat on clinical hold, as occurred in March 2014. If this were to occur, there would be a significant delay in, or possible termination of, such clinical trial or all the imetelstat clinical trials and any potential commercialization efforts, which might cause us to cease operations. For example, we are aware of a case in our IMpactMF clinical trial of a patient with myelofibrosis associated with underlying progressive bone marrow failure, who died from febrile neutropenia, pulmonary hemorrhage and bilateral pneumonia, which, at the time of reporting, the investigator related to imetelstat. If such toxicities or other safety issues in any clinical trial of imetelstat are determined by us, the FDA or similar international regulatory authorities 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 similar international regulatory authorities and if any such information supplied by us, or by our former collaboration partner, is not deemed acceptable, current clinical trials of imetelstat could be suspended, terminated, or placed on clinical hold by the FDA or similar international regulatory authorities;
- the ability to retain enrolled patients in our 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.

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 IMerge Phase 3, IMpactMF, IMproveMF and IMpress continue to receive imetelstat treatment, and patients in our recently opened expanded access program will continue to receive imetelstat treatment, additional or more severe toxicities or safety issues, including additional non-serious or serious adverse events and dose-limiting toxicities, may be observed as patient treatment continues and more data become available. In addition, because additional data are being generated from these trials, 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.

The occurrence of any of the aforementioned events could interrupt, further delay, or halt, any development, and as a result, impact or preclude the potential commercialization of imetelstat, as well as increase costs to develop imetelstat, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat, any of which might cause us to cease operations.

The design of a clinical trial can determine whether its results will support regulatory approval of a product, and flaws in the trial design may not become apparent until the clinical trial is well advanced or during the approval process after the trial is completed.

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of imetelstat clinical trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results of clinical trials with smaller sample sizes less reliable than trials with a larger number of patients. As a result, there may be less certainty that imetelstat will achieve a statistically significant effect in any future clinical trials.

For example, we shortened the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable an earlier clinical cut-off date for the primary analysis in IMerge Phase 3. Although we reported positive top-line results from IMerge Phase 3 in January 2023, our decision to shorten the follow-up period after the last patient has been enrolled may result in further clinical responses that may have occurred after the 12-month clinical cut-off date being excluded from the primary analysis. The exclusion of this additional data from the primary analysis could reduce the overall efficacy results of the trial, including durability of transfusion independence, which could limit or prevent marketing approval of imetelstat in lower risk MDS by the FDA or similar international regulatory authorities, cause them not to approve imetelstat at all or require additional clinical trials or further testing prior to granting any regulatory approval to market imetelstat in lower risk MDS.

Moreover, with respect to the trial design for IMpactMF, the FDA urged us to consider adding a third dosing arm to the trial to assess a lower dose and/or a more frequent dosing schedule that might improve the trial's chance of success by identifying a less toxic regimen and/or more effective spleen response, one of the trial's secondary endpoints. Based on data from IMbark, our Phase 2 clinical trial in relapsed/refractory MF, we believe that testing a lower dose regimen would likely result in a lower median OS, which is the trial's primary endpoint, in the imetelstat treatment arm. Existing data also suggest that lowering the dose would not result in a clinically meaningful reduction in toxicity, and for these reasons we therefore determined not to add a third dosing arm to the trial design, and the FDA did not object to our proposed imetelstat dose and schedule of 9.4 mg/kg every three weeks. Our belief may ultimately be incorrect. Therefore, our failure to add a third dosing arm could result in a failure to maintain regulatory clearance from the FDA and similar international regulatory authorities, could result in the trial's failure, or could otherwise delay, limit or prevent marketing approval of imetelstat in relapsed/refractory MF by the FDA or similar international regulatory authorities.

Results and data we disclosed from prior non-clinical studies and clinical trials may not predict success in later clinical trials, and we cannot assure you that any ongoing or future clinical trials of imetelstat will lead to similar results and data that could potentially enable us to obtain any regulatory approvals.*

Success in non-clinical testing and early clinical trials, including Phase 2 clinical trials, such as IMbark, does not ensure that later clinical trials will be successful, nor does it predict final clinical trial results. In addition, even though we reported positive top-line results from IMerge Phase 3 in January 2023, this does not ensure that any other clinical trials of imetelstat, including IMpactMF, IMproveMF and IMpress, 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. Imetelstat 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. Many 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.

In IMbark, we reported a median overall survival of 19.9 months and 28.1 months for the 4.7 mg/kg and 9.4 mg/kg dosing arms, respectively, in relapsed/refractory MF patients. In general, Phase 3 clinical trials with larger numbers of patients or longer durations of therapy may fail to replicate efficacy and safety results observed in earlier clinical trials, such as IMbark, and if this were to occur with IMpactMF, this would adversely affect future development prospects of imetelstat, and as a result, impact the potential commercialization of imetelstat in relapsed/refractory MF, which would substantially impair our ability to raise additional capital.

Furthermore, non-clinical and clinical data are often susceptible to varying interpretations and analyses. In some instances, there can be significant variability between different clinical trials of imetelstat due to numerous factors, including changes in trial procedures set forth in trial protocols, differences in the size and type of patient populations, and changes in and adherence to the dosing regimens. For example, complete and partial remissions were observed in an investigator-sponsored pilot study of imetelstat conducted at Mayo Clinic in MF patients, or 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 relapsed/refractory 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 IMpactMF, and similar results, including potential improvement in survival, if any, with respect to any patient population or patient population subgroup, may not be observed in IMpactMF. Likewise, although the statistical analyses comparing IMbark data to closely matched real world data, or RWD, published in the September 2021 issue of the Annals of Hematology, suggest potentially favorable OS in relapsed/refractory MF patients treated with imetelstat, compared to BAT 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 and any conclusions from such analyses should be considered carefully and with caution, and should not be relied upon as demonstrative or otherwise predictive or indicative of any current or potential future clinical trial results of imetelstat in relapsed/refractory MF, including IMpactMF.

Failure to achieve results supporting a positive benefit-risk profile in current or potential future imetelstat clinical trials would interrupt, further delay, or halt, any development, and as a result, potential commercialization of imetelstat, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat.

Interim, "snapshot," "top-line," and preliminary data or statistical analyses from clinical trials that we announce or publish from time-to-time may change as more patient data become available, may be more positive than the final data, and are subject to audit and verification procedures that could result in material changes in the final data. Thus, such preliminary data should be considered carefully and with caution and not relied upon as indicative of future clinical results.

From time-to-time, preliminary or interim safety and efficacy data from previous and current imetelstat clinical trials have been reported or announced by us, clinical investigators or our former collaboration partner. Preliminary data is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As such, preliminary or interim results may not be reproduced in any current or 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. Additional or updated safety and efficacy data from current or potential future clinical trials of imetelstat may result in a benefit-risk profile that does not justify the continued development of imetelstat in a particular patient population, or at all. Any data reported from IMpactMF may materially differ from and be less positive than data previously reported from IMbark. Thus, reported data should be considered carefully and with caution, and not relied upon as indicative of future clinical results. Such additional data could result in a lower benefit-risk profile than initially expected, which could hinder the potential success of IMpactMF, IMproveMF or IMpress, or cause us to abandon further development of imetelstat entirely.

In January 2023, we announced positive top-line results from IMerge Phase 3 and in June 2023, we reported additional and new data from IMerge Phase 3 at the American Society of Clinical Oncology Annual Meeting and the European Hematology Association Annual Congress. Such top-line results and data may differ from future results of the same study, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. As a result, top-line results and subsequently reported data, including from IMerge Phase 3, should be viewed with caution. Moreover, as remaining patients in IMerge Phase 3 continue to be treated and followed under the extension phase of the trial and longer-term outcomes are assessed, these additional and more mature data may alter the benefit-risk profile of imetelstat. Material adverse differences in future results, compared to preliminary, interim or top-line data, could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, including the potential commercialization 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, our sole product candidate, and 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 myeloid hematologic malignancies, including MDS and MF, may be further delayed or abandoned, even after significant resources have been expended on it. Examples of such situations include:

- in September 2012, the discontinuation of our Phase 2 clinical trial of imetelstat in metastatic breast cancer;
- in April 2013, the discontinuation of our development of imetelstat in solid tumors with short telomeres;
- in March 2014, the full clinical hold placed by the FDA on imetelstat clinical trials;
- in the third quarter of 2016, closure of the 4.7 mg/kg dosing arm in IMbark to new patient enrollment and suspension of 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;
- in the third quarter of 2017, expansion of IMerge Phase 2 to enroll additional lower risk MDS patients in a target patient population; and
- in September 2018, our former collaboration partner’s decision to terminate its imetelstat collaboration agreement with us.

Further delay, suspension or abandonment of our development of imetelstat in myeloid hematologic malignancies, including with respect to our IMpactMF, IMproveMF and IMpress clinical trials, could have a material adverse effect on the future of imetelstat and our business prospects, including the potential commercialization of imetelstat in indications other than lower risk MDS.

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 we contract with 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 CROs to support our imetelstat clinical development activities, and any failure by our CROs to perform their contractual obligations, or disputes with our CROs about the quality of their performance or other matters, could further delay or halt our imetelstat clinical development activities, including current or future imetelstat clinical trials. 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 rely on third parties to conduct our imetelstat clinical trials, including IMerge Phase 3, IMpactMF and IMproveMF, we remain responsible for ensuring that each clinical trial is conducted in accordance with its investigational plan and protocol, and applicable laws. Moreover, the FDA and similar international regulatory authorities require us to comply with GCP regulations and standards 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 the rights, integrity and confidentiality of patients participating in clinical trials are protected, including being adequately informed of the potential risks. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, or similar international regulatory authorities, may require us to perform additional clinical trials before approving any application for approval. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or other applicable regulations. In addition, our clinical trials must be conducted with imetelstat

produced under applicable GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would further delay the process for any regulatory approval. Our ability to comply with these regulations and standards may be 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. Any failures by us or third parties noted above would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat, including the potential commercialization of imetelstat, any of which might cause us to cease operations.

We also are required to register imetelstat clinical trials that we sponsor and post the results of certain completed clinical trials on certain government-sponsored databases, such as ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the execution of clinical trials and the subsequent compilation and analysis of the data produced, including the interim and final analyses for IMpactMF, 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, GCP or GMP requirements, or for any other reason, we may need to enter into new arrangements with alternative third parties, which would cause delay, and 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, including the potential commercialization of imetelstat, and might cause us to cease operations.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding CROs, investigators and other third parties involves additional costs and delays because of the time it takes to finalize a contract with a new CRO and for their commencement of work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our CROs, investigators and other third parties, we and any of these third parties may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, business prospects and the future of imetelstat.

In addition, certain principal investigators for our clinical trials serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected conduct of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of any applications for approval by the FDA and may ultimately lead to the denial of approval of imetelstat.

We will not control the conduct of current or any potential future investigator-led clinical trials, and data from such trials could show marginal efficacy and/or clinically relevant safety concerns related to imetelstat resulting in an unfavorable benefit-to-risk assessment that could impact our ongoing clinical trials or development program for imetelstat.

We will not control the design or administration of the investigator-led clinical trial, IMpress, or any potential future investigator-led trials, nor the submission, approval or maintenance of any IND or international equivalent filings required to conduct these clinical trials. In addition, we will not have control over the timing and reporting of the data from any such investigator-led clinical trials. A delay in the timely completion of or reporting of data from any potential future investigator-led clinical trial could have a material adverse effect on our ability to further develop imetelstat or to advance imetelstat to subsequent clinical trials.

Investigator-led clinical trials may be conducted under less rigorous clinical standards than those used in company-sponsored clinical trials. Accordingly, regulatory authorities may closely scrutinize the data collected from these investigator-led clinical trials. In addition, any investigator-led clinical trials could show marginal efficacy and/or clinically relevant safety concerns that could delay the further clinical development or marketing approval of imetelstat for any indication. To the extent that the results of any investigator-led clinical trials raise safety or other concerns regarding imetelstat, regulatory authorities may question the results of such investigator-led clinical trials, or question the results of company-sponsored trials, IMerge Phase 3, IMpactMF, and IMproveMF. Safety concerns arising from future investigator-led clinical trials could result in partial or full clinical holds being placed on the imetelstat INDs by the FDA or other similar international regulatory authorities, as occurred in March 2014, which would further delay or prevent us from advancing imetelstat into further clinical development and cause us to discontinue our development of imetelstat, which would severely harm our business and prospects, including the potential commercialization of imetelstat, and could potentially cause us to cease operations.

RISKS RELATED TO REGULATORY APPROVAL AND COMMERCIALIZATION OF IMETELSTAT

Our inability to obtain and maintain regulatory clearances and approvals to continue the clinical development of, and to potentially commercialize, imetelstat, would severely and adversely affect imetelstat's future value, and our business and business prospects, and might cause us to cease operations.

Federal, state and local governments in the U.S. 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 or failure to maintain regulatory clearances and approvals, or limitations in the scope of such clearances or approvals, could:

- impede or halt our activities and plans for clinical development and commercialization;
- 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.

In addition, with respect to the trial design for IMpactMF, the FDA urged us to consider adding a third dosing arm to the trial to assess a lower dose and/or a more frequent dosing schedule that might improve the trial's chance of success by identifying a less toxic regimen and/or more effective spleen response, one of the trial's secondary endpoints. Based on data from IMbark, we believe that testing a lower dose regimen would likely result in a lower median OS, which is the trial's primary endpoint, in the imetelstat treatment arm. Existing data also suggest that lowering the dose would not result in a clinically meaningful reduction in toxicity, and for these reasons we therefore determined not to add a third dosing arm to the trial design and the FDA did not object to our proposed imetelstat dose and schedule of 9.4 mg/kg every three weeks. Our belief may ultimately be incorrect. Therefore, our failure to add a third dosing arm could result in a failure to maintain regulatory clearance from the FDA and similar international regulatory authorities, could result in the trial's failure, or could otherwise delay, limit or prevent marketing approval of imetelstat for relapsed/refractory MF by the FDA or similar international regulatory authorities.

Furthermore, in IMerge Phase 3 we shortened the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable an earlier clinical cut-off date for the primary analysis. Although we reported positive top-line results from IMerge Phase 3 in January 2023, our decision to shorten the follow-up period after the last patient has been enrolled may result in further clinical responses that may have occurred after the 12-month clinical cut-off date being excluded from the primary analysis. The exclusion of this future data from the primary analysis could reduce the overall efficacy results, including durability of transfusion independence, which could otherwise delay, limit or prevent marketing approval of imetelstat in lower risk MDS by the FDA or similar international regulatory authorities or require additional clinical trials and further testing prior to granting any regulatory approval to market imetelstat in lower risk MDS.

Even though we reported positive top-line results from IMerge Phase 3 in January 2023, those results are not necessarily predictive of imetelstat activity in other indications and for other pivotal trials that may be needed to support any application to the FDA or similar international regulatory authorities for such other indications, such as from IMpactMF. We may therefore fail to further develop or commercialize imetelstat, which would severely and adversely affect our business and business prospects, and might cause us to cease operations.

If we are unable to successfully obtain regulatory approval for and commercialize imetelstat, or experience significant delays in doing so, our business will be materially harmed.*

The process of obtaining marketing approvals, both in the U.S. and in other countries, is lengthy, expensive and uncertain. It may take many years to obtain approval, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Of the large number of drugs in development, only a small percentage complete the regulatory approval process and are successfully commercialized. In addition, the lengthy review process as well as the unpredictability of future clinical trial results may result in a delay in obtaining, or our failure to obtain, regulatory approval for imetelstat in lower risk MDS, relapsed/refractory MF, or any other indication, which would significantly harm our business, business prospects, including the potential commercialization of imetelstat, and the future value of imetelstat and might cause us to cease operations.

Securing marketing approval requires the submission of extensive non-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy, as well as information about the product manufacturing process and any inspections of manufacturing facilities conducted by regulatory authorities through the filing of an NDA in the U.S. and an MAA in Europe. In June 2023, we announced our submission to the FDA of an NDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with lower risk MDS who have failed to respond or have lost response to or are ineligible for ESAs. There can be no assurance that the NDA submission will be accepted by the FDA. If the

FDA determines after an initial review of the NDA that the data included in the application is insufficient and not ready for formal consideration, we could receive a "refuse to file" notice. The FDA also has substantial discretion in the approval process.

While we reported positive top-line results from IMerge Phase 3 in lower risk MDS, and while we believe that these results and our assessment of the positive benefit-risk profile of imetelstat, combined with data from our Phase 2 clinical trials, are supportive of our NDA submission and the planned MAA submission for imetelstat in lower risk MDS, regulatory authorities in those jurisdictions may disagree with our interpretation of the data and may require additional clinical testing before we can obtain regulatory approval and begin commercialization of imetelstat, if at all, any of which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. There is no guarantee that we will obtain regulatory approval or be able to commence commercialization on the timeline we are planning or at all.

Imetelstat must receive all relevant regulatory approvals before it may be marketed in the U.S. or other countries. Regulatory authorities have substantial discretion in the approval process and can delay, limit or deny approval of imetelstat or require us to conduct additional non-clinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design or implementation of our clinical trials, including our statistical analysis of trial results;
- failure to demonstrate to the FDA or similar international regulatory authorities that imetelstat's efficacy results provide sufficient evidence of overall clinical benefit;
- unfavorable benefit-to-risk assessment, in the case of marginal efficacy and/or clinically relevant safety concerns, for any proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to imetelstat;
- disagreement with our interpretation of data from non-clinical studies or clinical trials, including disagreement from any advisory committee convened in connection with the NDA review;
- failure to collect data from clinical trials of imetelstat meeting the level of integrity or statistical or clinical significance required by the FDA or similar international regulatory authorities, or a determination such data is not sufficient to support the submission of an NDA, MAA, or other submission, or to obtain regulatory approval in the U.S., the EU or elsewhere;
- deficiencies in our clinical trial operations or the clinical trial operations of trial sites, including as a result of FDA or EMA bioresearch monitoring inspections in conjunction with NDA or MAA review;
- identification of critical issues as a result of a pre-approval health authority inspection that could negatively impact the integrity of data in an NDA or MAA and lead to a rejection by the FDA and similar international health authorities;
- errors or deficiencies in the conduct of the imetelstat program prior to its transition to us by our former collaborator, and/or in the transition of the imetelstat program to us by our former collaborator;
- unwillingness or inability by our former collaborator to provide information requested by the FDA or similar international regulatory authorities regarding the time period when our former collaborator was responsible for the imetelstat program;
- a determination by the FDA or similar international regulatory authorities that the appropriate indication for commercial use of imetelstat is narrower or more restrictive than anticipated;
- failure to satisfy the requirement to develop a risk evaluation and mitigation strategy, or REMS, for the U.S. and a risk management plan for the EU including post-marketing studies, as a potential condition to approval;
- disagreement regarding the formulation, labeling and/or the specifications for imetelstat;
- a determination by the FDA or similar international regulatory authorities that the manufacturing processes, test procedures and specifications applicable to the manufacture of imetelstat, or the facilities of the third-party manufacturers with which we contract for clinical and commercial supplies of imetelstat are inadequate, or failure by such third-party manufacturers to maintain compliance with the regulatory and other requirements established by the FDA or similar international regulatory authorities, including as a result of pre-approval inspections conducted in conjunction with NDA or MAA review;
- the failure of the quality or stability of imetelstat to meet acceptable regulatory standards;
- the FDA or similar international regulatory authorities may lack resources or be delayed in conducting pre-approval inspections due to lack of resources or other reasons;
- we or any third-party service providers may be unable to demonstrate compliance with GMP, and/or GCP, to the satisfaction of the FDA or similar international regulatory authorities;
- changes in regulatory policies or approval processes, or potential reduction of unmet medical need with the entry of competitive therapies to the market, could render our clinical efficacy or safety data insufficient for approval; or

- political factors surrounding the approval process, such as government shutdowns, political instability or global pandemics and other health crises.

Furthermore, in recent years, there has been increased public and political scrutiny on the FDA and similar international regulatory authorities with respect to the approval process for new drugs, and as a result regulatory authorities may apply more stringent regulatory standards, especially regarding drug safety, when reviewing regulatory submissions for new drugs.

Even if we believe we have complied with all of the regulatory requirements to receive marketing approval for imetelstat, we may not obtain marketing approval for reasons that we cannot currently predict. If we fail to obtain regulatory approval for imetelstat, we will have no commercialized products and correspondingly no revenue.

Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render imetelstat not commercially viable, which would harm imetelstat's future value and our business and business prospects. In addition, obtaining regulatory approval is a lengthy, expensive and uncertain process. For example, following the result of a referendum in 2016, the United Kingdom, or U.K., left the EU on January 31, 2020, commonly referred to as Brexit, and its withdrawal from the EU was completed on December 31, 2020. The withdrawal of the U.K. from the EU has resulted in uncertainty in relation to the regulatory process in the U.K., and for Europe could potentially result in a delay in the review of regulatory submissions which 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 EU or the U.K. Such regulatory changes in the U.K. or elsewhere could adversely affect and/or delay our ability to obtain approval of, and market and sell, imetelstat in the U.S. or other countries.

Regulatory authorities may also not approve the labeling claims that are necessary or desirable for the successful commercialization of a drug, such as imetelstat. For example, future regulatory clearances, if any, that we might obtain for imetelstat may be limited to fewer or narrower indications than we might request, or may be granted subject to the performance of post-marketing studies, which may impose further requirements or restrictions on the distribution or use of imetelstat, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria, and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for imetelstat and affect reimbursement by third-party payors. Future regulatory clearances, if any, may be limited to a smaller patient population, or may require a different drug formulation or a different manufacturing process, than we might in the future decide to seek.

In addition, failure by our former collaborator to comply with applicable regulatory guidelines prior to our assumption of sponsorship of the imetelstat program 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 NDAs.

Any delay in obtaining or failure to obtain required approvals of imetelstat, or limitations on any regulatory approval that we might receive in the future, if any, 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 and ability to raise additional capital, the price of our common stock, our business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat, and might cause us to cease operations.

If imetelstat is approved for commercialization and we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to commercialize imetelstat, we will be unable to successfully commercialize imetelstat if and when it is approved.

We will need to complete substantial preparations to be ready for any potential future commercialization of imetelstat, and currently we are in the process of establishing sales, marketing or distribution capabilities. As a company, we have no experience in selling and marketing products. To advance imetelstat to potential marketing approval, we will be required to complete our commercialization preparatory activities, and continue to incur related expenses, before we obtain any marketing approval. These activities will include, among other things, the development of an in-house marketing and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain qualified marketing and sales personnel. If we are unable to adequately prepare for the potential future commercialization of imetelstat, we may not be able to generate product revenue if marketing authorization is obtained.

There are risks involved with both establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of imetelstat for which we recruit a sales and marketing force and establish distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which would be costly. Even if imetelstat is approved in lower risk MDS and we are able to establish our own sales and marketing capabilities, imetelstat will be a newly-marketed drug. As a result, we will be required to expend significant time and resources to train sales personnel in commercializing imetelstat. If we are unable to effectively train sales personnel and equip them with compliant and effective materials, our efforts to successfully commercialize imetelstat could be adversely affected, which would negatively impact our business, business prospects and the future value of imetelstat.

Factors that may inhibit our efforts to commercialize imetelstat on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, distribution, coverage or reimbursement, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with compliant and effective materials, including medical and sales literature to help them educate physicians regarding the indications we are targeting and imetelstat, if approved;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe imetelstat;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability to price imetelstat at a sufficient price point to ensure an adequate and attractive level of profitability;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization;
- our inability to maintain existing supply arrangements, or to establish new supply arrangements with third-party suppliers and contract manufacturers to ensure sufficient commercial supplies;
- our inability to obtain and maintain patent protection, trade secret protection and regulatory exclusivity, both in the U.S. and in other countries;
- lack of an acceptable safety profile following any regulatory approval; and
- our inability to compete effectively with other therapies.

If we enter into arrangements with third parties to perform commercialization services like sales, marketing and distribution, we will be reliant on the efforts of such third parties, and our sales revenue from sales of imetelstat or the profitability from such sales to us are likely to be lower than if we were to market and sell imetelstat ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize imetelstat or may be unable to do so on terms that are favorable to us. In entering into third-party commercialization arrangements, any revenue we receive will depend upon the efforts of the third parties, and we cannot assure you that such third parties will establish adequate commercialization capabilities or devote the necessary resources and attention to commercialize imetelstat effectively. We also face competition in our search for third parties to assist us with the commercialization efforts of imetelstat.

Our inability to successfully establish commercialization capabilities for imetelstat, if we receive regulatory approval to do so, would severely and adversely affect our financial results, business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat.

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 U.S. 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 similar international regulatory authorities. Coverage and reimbursement may impact the demand for, or the price of

imetelstat, if 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.

Although orphan drug designation has been granted to imetelstat for the treatment of MF and MDS in the U.S. and in the EU, 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 EMA granted orphan drug designation in December 2015 to imetelstat for the treatment of MF and in July 2020 for the treatment of MDS. 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 for certain reasons, including 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. Failure to maintain orphan designation status in the EU at the time of submitting the MAA, or failure to complete the agreed pediatric plan, would lead to the loss of the additional two-year exclusivity period.

Even if we maintain orphan drug exclusivity for imetelstat, the exclusivity may not effectively protect imetelstat from all 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 it 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 designations received for imetelstat for MDS and MF, does not guarantee marketing approval and may not lead to a faster development, regulatory review or approval process.

In October 2017, the FDA granted Fast Track designation to imetelstat for the treatment of adult patients with transfusion-dependent low red blood cell counts, or anemia, due to non-del(5q) lower risk MDS and who are refractory or resistant to treatment with an ESA. In September 2019, the FDA granted Fast Track designation to imetelstat for the treatment of adult patients with relapsed/refractory MF.

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 of the sponsor's NDA. 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 any imetelstat NDA will be approved or that any approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track designation for any indication if it believes that the designation is no longer supported by data emerging from the imetelstat clinical development program.

The Innovation Passport designation from the United Kingdom regulatory authorities does not guarantee marketing approval and may not lead to a faster development, regulatory review or approval process.

In October 2021, we gained access to the Innovative Licensing and Access Pathway, or ILAP, through the receipt of an Innovation Passport for imetelstat to treat lower risk MDS. The ILAP is a new program sponsored by the Medicines and Healthcare products Regulatory Agency, or MHRA, in the U.K., post-Brexit. The objective of this new licensing and access pathway is to reduce the time to market and enable earlier patient access for innovative medicines. The Innovation Passport is the first prescribed entry point in the ILAP process. Key benefits of being within ILAP include a potential 150-day accelerated assessment and rolling review of an MAA, as well as opportunities for frequent interactions with the review staff at the MHRA and its partner agencies to discuss imetelstat's development, regulatory and reimbursement plans.

Although the goal of ILAP and the Innovation Passport is to reduce the time to market and enable earlier patient access, it does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that any imetelstat MAA will be approved or that any approval will be granted within any particular timeframe. Despite receiving Innovation Passport designation, we may decide to delay or forego the commercialization of imetelstat in the U.K.

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;
- medical information;
- 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.

In addition, if imetelstat causes serious or unexpected side effects or is associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of imetelstat;
- we may be required to recall imetelstat, seek to change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- regulatory authorities may require revisions to the labeling of imetelstat, including limitations on approved uses or the addition of further warnings, contraindications or other safety information, or may impose restrictions on distribution in the form of REMS in connection with approval, if any;
- we may experience manufacturing delays and supply disruptions if regulatory inspectors identify regulatory noncompliance by third party manufacturers requiring remediation;
- imetelstat may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- the FDA or similar international regulatory authorities may refuse to approve pending applications or supplements to approved applications filed by us, or may suspend or revoke license approvals; or
- we may be required to change or stop ongoing clinical trials of imetelstat, which would negatively impact the development of imetelstat for other potential indications.

Any of these events could prevent us from achieving or maintaining market acceptance for imetelstat or could substantially increase the costs and expenses of commercializing imetelstat, which in turn could delay or prevent us from generating any revenues from the sale of the imetelstat.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce regulations prohibiting the promotion of any drug product for off-label uses. If we were found to have improperly promoted off-label use of imetelstat, we would be subject to significant civil, criminal and administrative penalties, which would inhibit our ability to commercialize imetelstat and generate revenue, require us to expend significant time and resources in response, and generate negative publicity. Enforcement actions include, among others:

- adverse regulatory inspection findings;
- fines, warning letters, or untitled letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing imetelstat;
- restrictions on, or prohibitions against, importation or exportation of imetelstat;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for imetelstat;

- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

The imposition of any of these penalties or other commercial limitations would severely and adversely affect our financial results, business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat, and might cause us to cease operations.

If, in the future, we seek regulatory approval to market imetelstat internationally, we may experience a variety of risks that would materially adversely affect our business.

If, in the future, we seek regulatory approval of imetelstat outside of the U.S., and if the necessary approvals are obtained, we will be subject to additional risks related to operating in countries outside of the U.S., including:

- foreign regulatory approvals, if any, may take longer and be more costly to obtain than approvals in the U.S., due to differing regulatory requirements in foreign countries, such as the lack of pathways for accelerated drug approval;
- regulatory authorities outside of the U.S. may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of regulatory authorities outside of the U.S. may significantly change in a manner rendering our clinical data insufficient for potential approval;
- the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues;
- we may experience unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- risks of potential noncompliance with legal requirements applicable to privacy, data protection, information security and other matters;
- risks of potential noncompliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- increased taxes outside of the U.S., including withholding of payroll taxes;
- significant foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of the U.S.;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable regulations outside of the U.S.;
- challenges enforcing our contractual and intellectual property rights, especially in those countries outside of the U.S. that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

We are also subject to numerous regulatory requirements outside of the U.S. governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in jurisdictions outside of the U.S. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the U.S. and vice versa.

In Europe, the Clinical Trials Regulation, which came into effect in January 2022, introduced substantial changes in how clinical trials are authorized in the European Economic Area, or EEA, enabling sponsors to submit a single application to run a clinical trial in several European countries. The objectives of the new regulation include consistent rules for conducting trials throughout the EU, consistent data standards and adverse events listing, and consistent information on the authorization status. Information on the conduct and results of each clinical trial carried out in the EU will be made publicly available. Commencing in January 2023, clinical trial sponsors will need to use the Clinical Trials Information System, or CTIS, to apply to start a new clinical trial in the EEA; and from January 2025, clinical trials in the EEA will need to comply with the Clinical Trials Regulation.

In addition, a new pan-European clinical trial data information database has been created that will be complementary to the database established for pharmacovigilance (Regulation (EC) No 726/2004 with respect to centrally authorized medicinal products). In addition, Commission Implementing Regulation (EU) No 520/2012 outlines the practical implications for marketing authorization holders, national competent authorities, and the EMA. Also, Commission Delegated Regulation (EU) No 357/2014 on post-authorization efficacy studies specifies the situations in which such studies may be required. Post-authorization efficacy studies may be required where concerns relating to some aspects of efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed, or where the understanding of the disease, the clinical methodology or the use of the medicinal product under real-life conditions indicate that previous efficacy evaluations might have to be revised significantly.

Brexit is also expected to disrupt the operation of pre- and post-authorization clinical trial infrastructure. The rules around GMP and pharmacovigilance in the U.K. currently remain similar to the EU requirements. However, the Falsified Medicines Directive will not apply in Great Britain though it is likely that the U.K. will implement a procedure to minimize the risk of falsified medicines.

Uncertainty in the regulatory framework and future legislation could lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Changes to existing regulations may add considerably to the time from clinical development to marketing authorization and commercialization of products in the EU and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

Demand for compassionate use of imetelstat could strain our resources, delay our drug development activities, negatively impact our regulatory approval or commercial activities, and result in losses.*

We are developing imetelstat to treat life-threatening hematologic malignancies for which there are currently limited therapeutic options. We recently opened an expanded access program for the use of imetelstat in lower risk MDS patients. We are a small company with limited resources, and any unanticipated trials or access programs resulting from requests for access could deplete our drug supply, increase our capital expenditures, reduce the availability of potentially eligible clinical trial participants, and otherwise divert our resources from our primary goals.

In addition, legislation referred to as “Right to Try” laws have been introduced at the local and national levels, which are intended to give patients access to unapproved therapies. New and emerging legislation regarding expanded access to unapproved drugs for life-threatening illnesses could negatively impact our business in the future. Either activism or legislation related to requests for access may require us to initiate an unanticipated expanded access program or to make imetelstat more widely available sooner than anticipated.

Patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and generally have exhausted all other available therapies. The risk for serious adverse events, including those which may be unrelated to imetelstat, in this patient population is high and could have a negative impact on the safety profile of imetelstat, which could cause significant delays or an inability to successfully commercialize imetelstat and could materially harm our business. We have recently initiated an expanded access program, and we could experience adverse publicity or other disruptions related to potential participants in such program. Similarly, we could experience adverse publicity or other disruptions if we were to restructure or pause our expanded access program after initiating such a program or after the provision of imetelstat through compassionate access to an individual patient or patients.

If we fail to comply with federal, state and international 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, including federal and state fraud and abuse laws, including anti-kickback and false claims laws; data privacy and security laws, including the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH; and transparency laws related to payments and/or other transfers of value made to physicians, other healthcare professionals and teaching hospitals. 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 imetelstat, if marketing approval is obtained. For details regarding the restrictions under applicable federal and state healthcare laws and regulations that may affect our

ability to operate see Item 1 “Business—Government Regulation— Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations” in our 2022 Form 10-K.

Federal and state enforcement bodies have 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, our ability to operate our business and our results of operations could be adversely affected by:

- the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement and 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.

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.

RISKS RELATED TO MANUFACTURING IMETELSTAT

Failure by us to establish and/or maintain 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 delay in our ability to obtain regulatory approvals of imetelstat, and affect our ability to commercialize imetelstat, and our business and business prospects could be severely harmed, and we could cease operations.*

The manufacture of imetelstat must comply with applicable regulatory standards for current and potential future clinical trials and potential commercial uses. The process of manufacturing imetelstat is complex and remains subject to several risks, including:

- the ability to scale-up and attain sufficient production yields with appropriate quality control and quality assurance to meet the needs of our clinical trials and potential future market demand, and to establish commercial supply agreements;
- reliance on third-party manufacturers and suppliers, whose efforts we do not control;
- supply chain issues, including the timely availability and shelf life requirements of raw materials and other supplies, any of which may be impacted by a number of factors, including the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, and pandemics or other health crises;
- shortage of qualified personnel; and
- regulatory acceptance 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 and/or maintain a manufacturing infrastructure and supply chain capable of providing imetelstat for IMerge Phase 3, IMpactMF, IMproveMF and IMpress or our recently opened expanded access program, and potential future commercial uses, which would delay or result in a cessation of such current or potential future clinical trials of imetelstat and cause potential reputational harm. Occurrence of any such events 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 or complete current or potential future clinical trials of imetelstat or to commercialize imetelstat in the future.*

Our imetelstat manufacturing supply chain relies, and will continue to rely, solely upon third-party manufacturers 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 have established arrangements with third parties for the manufacture of imetelstat, our manufacturing supply chain is highly specialized, and as such we are reliant upon a small group of third-party manufacturers to supply starting materials, drug substance and drug product. Failure by such third-party manufacturers to perform in a timely manner and in compliance with all regulatory requirements, 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. In this regard, recent FDA inspections of one of our third-party manufacturers identified certain deficiencies in the manufacturer's processes and facilities which, while not directly related to the production of imetelstat, could impact the manufacturer's ability to produce and deliver products, including imetelstat, if not remediated by the manufacturer, and could lead to delays or shortages in drug supply, or the inability to manufacture or ship drug supply necessary for non-clinical and clinical activities and commercialization. In addition, we may not be able to obtain imetelstat from third-party manufacturers on acceptable terms, or at all. We expect to rely on third-party manufacturers to produce and deliver sufficient quantities of imetelstat and other materials to support clinical trials and potential commercialization on a timely basis and to comply with applicable regulatory requirements. We do 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 contract with suitable third-party manufacturers, including for potential commercial supply of imetelstat, because the number of potential manufacturers is limited;
- delays and disruptions experienced by third-party manufacturers that adversely impact the ability of such parties to fulfill their contractual obligations to us;
- capacity limitations and scheduling constraints experienced by third-party manufacturers due to scheduling and other commitments, and queued manufacturing activities in contracted facilities;
- potential shortages of available manufacturing capacity or consumable manufacturing supplies at third-party manufacturers;
- requirements by regulatory authorities to validate and qualify significant activities for any current or replacement manufacturer, which could involve new testing and compliance inspections;
- the inability to execute timely contracts with third-party manufacturers and suppliers on acceptable terms, or at all;
- the inability of third-party manufacturers to timely formulate and manufacture imetelstat or to produce or ship imetelstat in the quantities or of the quality required to meet clinical and commercial needs;
- the possible mislabeling by third-party manufacturers of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or comparator not being properly identified;
- 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 imetelstat to meet commercial needs;
- compliance by third-party manufacturers with GMP standards mandated by the FDA and state agencies and other government regulations corresponding to similar international regulatory authorities, including any deficiencies identified during regulatory inspections, such as those identified in a recent FDA inspection of one of our third-party manufacturers;
- breach or termination of manufacturing or supply contracts;
- inadequate storage or maintenance at contracted facilities resulting in theft or spoilage; 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 or ship drug supply necessary for non-clinical and clinical activities, and commercialization. For example, manufacturing delays could adversely impact the conduct or completion of imetelstat clinical trials, such as IMerge Phase 3, IMpactMF, IMproveMF and IMpress, as well as our recently opened expanded access program, or commencement of potential future clinical trials of imetelstat, or preclude or delay potential future commercial sales, which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat and cause reputational harm.

In addition, third-party manufacturers and/or any other manufacturers 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 manufacturers 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 enter into suitable commercial supply agreements, or 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 or reduced gross margins, if any, for us, which would materially and adversely affect our financial results, business and business prospects, and the future of imetelstat.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

Our failure to obtain additional capital would force us to further delay, reduce or eliminate development of imetelstat in current and any potential future clinical trials of imetelstat, and our potential future imetelstat commercialization efforts, any of 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. As of June 30, 2023, we had approximately $400.2 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities. Based on our current operating plan and our expectations regarding the timing of the potential acceptance and approval of our NDA by the FDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with lower risk MDS who have failed to respond to or have lost response to or are ineligible for ESAs, we believe that our existing cash, cash equivalents, restricted cash and current and noncurrent marketable securities will be sufficient to fund our projected operating requirements through the end of the third quarter of 2025, which includes estimated revenues a potential U.S. commercial launch of imetelstat in lower risk MDS in the first half of 2024, and the revised timing expectations for interim and final analyses in IMpactMF. In the absence of potential additional proceeds from exercises of remaining outstanding warrants and potential drawdowns under the Loan Agreement, we will require substantial additional funding to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, as well as conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications, and our need for additional funds may arise sooner than planned.

We cannot predict with any certainty whether and to what extent the remaining outstanding warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all. For example, holders of our outstanding warrants may not exercise any portion of a warrant if, after giving effect to such exercise, the holder would own more than 9.99% of our outstanding common stock immediately after exercise, which percentage may be changed at the holder's election upon 61 days' notice to us subject to the terms of the warrants. In addition, in the event that a registration statement registering the issuance of the shares of common stock underlying our purchase warrants is not effective or available for the issuance of such shares to such holder at the time of exercise, a holder of our purchase warrants may only exercise such purchase warrants through a “cashless exercise,” in which case, the holder would receive upon such exercise, the net number of shares of common stock determined according to the formula set forth in the purchase warrant, and we would not receive any proceeds from the exercise of such purchase warrants. As a result, we may not receive our anticipated proceeds from certain of our outstanding warrants. In addition, drawdowns under the Loan Agreement are subject to our achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements to our existing capital resources, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche. Even if we receive the future proceeds in full from the potential cash exercise of outstanding warrants and potential drawdowns under the Loan Agreement, we may still require additional funding. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development, including conducting and completing IMpactMF, IMproveMF and IMpress, or commencing, conducting or completing potential future clinical trials of imetelstat, or pursuing potential commercialization of imetelstat, which would severely harm our business and we might cease operations. In addition, our ability to commercialize imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities which we may be unable to do in a timely manner or at all.

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; whether we will obtain regulatory approval for imetelstat in any indication we pursue, including in lower risk MDS; or whether we will be able to effectively commercialize imetelstat, if at all. 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. In addition, our plans and timing expectations could be further delayed or interrupted by the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues. Further, 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 scope, progress, timing, magnitude 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 similar international regulatory authorities;
- the scope, progress, duration, results and costs of current clinical trials, including IMerge Phase 3, IMpactMF, IMproveMF and IMpress, and any potential future clinical trials of imetelstat, as well as our recently opened expanded access program and non-clinical studies and assessments of imetelstat;

- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in IMpactMF, IMproveMF, IMpress, or any potential future clinical trials of imetelstat, whether as a result of the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, such as obtaining and maintaining regulatory clearances and approvals to continue clinical development of imetelstat in current and potential future clinical trials, as well as to commence potential commercialization of imetelstat in the U.S. 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 achieve any meaningful reduction in manufacturing costs;
- the costs of multiple third-party vendors and service providers, including our CROs and third-party manufacturers, to pursue the development, manufacturing and potential commercialization of imetelstat;
- our ability to establish, enforce and maintain collaborative or other strategic arrangements for the research, development, clinical testing and manufacturing of imetelstat on favorable terms, if at all;
- our efforts to enhance operational, financial and management processes and systems that will be required for future development and commercialization of imetelstat, and our ability to successfully recruit and retain additional key personnel to support the development and potential future commercialization of imetelstat;
- our ability to successfully market and sell imetelstat, if imetelstat receives future regulatory approval or clearance, in the U.S. and other countries, and the associated costs;
- the costs and timing necessary to build a sales force in the U.S. and potentially other countries to market and sell imetelstat, should it receive regulatory approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator;
- the sales price for imetelstat, if any;
- the availability of coverage and adequate third-party reimbursement for imetelstat, if any;
- the extent to which we acquire or in-license other drugs and technologies, or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions, or to which we out-license imetelstat;
- the extent to which we are able to enter into strategic partnerships, collaborations and alliances or licensing arrangements with third parties including for the commercialization and marketing of imetelstat in certain global regions;
- the success of any collaborations that we may enter into with third parties;
- expenses associated with settlement of the pending securities class action lawsuits, as well as any other potential litigation;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation;
- our level of indebtedness and associated debt service obligations;
- the costs of maintaining and operating facilities in California and New Jersey, telecommunications and administrative oversight, as well as higher expenses for travel;
- macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, that may reduce our ability to access debt capital or financing on preferable terms, which may adversely affect future capital requirements and forecasts;
- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities; and
- the amount of proceeds, if any, of cash exercises of our currently outstanding warrants.

Until we can generate a sufficient amount of revenue from imetelstat to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, which may not be possible. Availability of such financing sources may be negatively impacted by any further delays in reporting results from IMpactMF or investors' perception of top-line results from IMerge Phase 3, despite our interpretation of such data being positive, as well as macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank

failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues.

Additional financing through public or private debt or equity financings, including pursuant to the 2020 Sales Agreement with B. Riley Securities, Inc., or B. Riley, the remaining tranches of up to $55.0 million available under the Loan Agreement, which are subject to the achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche; capital lease transactions or other financing sources, may not be available on acceptable terms, or at all. We may be unable to raise equity capital, or may be forced to do so 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 debt and equity markets to proposed financings has been substantially affected by uncertainty in the general economic, market and political climate due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, and may in the future be affected by other factors which are unpredictable and over which we have no control. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, which could reduce or eliminate our ability to raise additional funds through financings, and could negatively impact the terms upon which we may raise those funds. Similarly, these macroeconomic conditions have created extreme volatility and disruption in the capital markets and is expected to have further global economic consequences. If the equity and credit markets deteriorate, including as a result of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development and potential commercialization of imetelstat may be further delayed, altered or abandoned, which might cause us to cease operations.

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. Due to uncertainty in the general economic, market and political climate, we may determine that it is necessary or appropriate to raise additional funds proactively to meet longer-term anticipated operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the 2020 Sales Agreement, your ownership interest as a stockholder may be diluted, and the terms may include liquidation or other preferences that materially and adversely affect your rights as a stockholder. In addition, we have borrowed, and in the future may borrow, additional capital from institutional and commercial banking sources to fund imetelstat development and our future growth, including pursuant to our Loan Agreement or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as the Loan Agreement, that include restrictive covenants, including covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Moreover, 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, future proceeds from potential cash exercises of currently outstanding warrants, potential future sales of our common stock, including under the 2020 Sales Agreement with B. Riley and potential future drawdowns, if available, of the remaining up to $55.0 million under the Loan Agreement (which are subject to the achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche), will be sufficient to fund our operating plans. While we did not hold cash deposits or securities at SVB, if other banks and financial institutions enter receivership, become insolvent or otherwise fail in the future in response to financial conditions affecting the banking system and financial markets or otherwise, our ability to access our existing cash, cash equivalents and marketable securities may be delayed or precluded, which could have a material adverse effect on our business, business prospects and financial position.

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

Although in the past we have received license and other payments under former license and collaboration agreements, we do not currently have any material revenue-generating license or collaboration agreements, have no products approved for commercialization and have never generated any revenue from product sales. In addition, we are incurring and have incurred operating losses every year since our operations began in 1990, except for one. As of June 30, 2023, our accumulated deficit was approximately $1.5 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. Our license agreements related to our hTERT technology have expired or been terminated due to expiration of the underlying hTERT patents, and will not generate any further revenues. We have no ongoing collaborations related to imetelstat and have no current plans to enter into any corporate collaboration, partnership or license agreements that result in revenues, although we may seek a collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat, especially outside the U.S., and to provide funding for such activities.

We also expect to experience increased negative cash flow for the foreseeable future as we fund our operations and imetelstat clinical development activities and research programs continue, and we prepare for potential commercialization of imetelstat. 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.

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

Our net operating loss carryforwards attributable to tax years beginning before January 1, 2018 could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, federal net operating losses incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50-percentage-point cumulative 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 and development 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 in, or other future changes could 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. At the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

RISKS RELATED TO OUR INDEBTEDNESS

Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

As of June 30, 2023, the total outstanding principal amount under the Loan Agreement was $50.0 million. The tranches for the remaining $55.0 million available to us under the Loan Agreement are as follows: (a) the first remaining tranche of $10.0 million is available from January 1, 2023 until December 15, 2023, subject to the achievement of certain clinical and regulatory milestones, and satisfaction of certain other requirements; (b) the second remaining tranche of $20.0 million is available from September 15, 2023 until September 15, 2024, subject to the achievement of certain clinical and regulatory milestones, and satisfaction of certain capitalization requirements; and (c) the final remaining tranche of $25.0 million is available through December 31, 2024, subject to approval by an investment committee comprised of Hercules and SVB. Without the achievement of the required clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, we will not be eligible to draw funds under the first two remaining tranches. If we do not receive investment committee approval, we will not be eligible to draw funds under the final remaining tranche under the Loan Agreement. In addition, before we would consider drawing down any of the remaining tranches under the Loan Agreement, if available, we must first satisfy ourselves that we will have access to future alternate sources of capital, such as from the equity capital markets or debt capital markets, in order to repay any additional principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired. As a result, our development and potential commercialization of imetelstat and other research and development programs could be significantly delayed, which would materially adversely affect our business, business prospects, financial condition and operating results.

All obligations under the Loan Agreement are secured by substantially all of our existing property and assets, excluding intellectual property, which is subject to a negative pledge. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing the outstanding debt obligations at maturity. If we are able to draw down any of the remaining tranches under the Loan Agreement, our indebtedness will increase, which would further increase our risk of being unable to pay off or refinance our outstanding debt obligations at maturity. Our indebtedness could also have important negative consequences, including:

- we will need to repay the indebtedness by making payments of interest and principal, which will reduce the amount of cash available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the obligations of our affirmative and restrictive covenants in the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules and SVB could seek to enforce their security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

The terms of the Loan Agreement place restrictions on our operating and financial flexibility.

The Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiaries to, among other things:

- dispose of certain assets;
- change our line of business;
- engage in mergers, acquisitions or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make contributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

The Loan Agreement also contains financial covenants. Beginning June 1, 2022 and prior to receiving potential regulatory approval for imetelstat, if any, we are required to maintain a minimum cash balance in an amount equal to the greater of 50% of the outstanding principal amount under the Loan Agreement or $30.0 million. Under the Loan Agreement, if we enter into certain licensing transactions, this cash covenant requirement would increase to $35.0 million. After the potential regulatory approval for imetelstat, if any, the minimum cash requirement may be satisfied through one of the following three options, as elected by us: (a) maintaining a cash balance in an amount not less than 40% of the outstanding principal amount under the Loan Agreement; (b) maintaining a cash balance in an amount not less than 25% of the outstanding principal amount under the Loan Agreement, if our market cap is or exceeds $750.0 million; or (c) maintaining six month net product revenues of at least 70% of net product revenues forecasted by us, should any potential regulatory approval for imetelstat be obtained. The breach of any of these restrictive covenants or any other terms of the Loan Agreement would accelerate our obligation to repay our indebtedness under the Loan Agreement, which could have a material adverse effect on our business, business prospects and financial position.

We may not have cash available in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the state of the capital and lending markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Failure to satisfy our current and future debt obligations under the Loan Agreement could result in an event of default. In addition, the Loan Agreement includes customary affirmative and negative covenants and other events of default, the occurrence and continuance of which provide Hercules and SVB with the right to demand immediate repayment of all principal and unpaid interest under the Loan Agreement, and to exercise remedies against us and the collateral securing the Loan Agreement. These events of default include, among other things:

- insolvency, liquidation, bankruptcy or similar events;
- failure to observe any covenant or secured obligation under the Loan Agreement, which failure, in most cases, is not cured within 15 days;
- occurrence of an event that could reasonably be expected to have a material adverse effect on our business, operations, properties, assets or financial condition;
- material misrepresentations;
- occurrence of any default under any other agreement involving indebtedness in excess of specified amounts, or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect on us; and
- certain money judgments being entered against us or any portion of our assets are attached or seized.

In the event of default, Hercules and SVB could accelerate all of the amounts due under the Loan Agreement. Under such circumstances, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate imetelstat development or potential commercialization efforts or grant to others rights to develop and market imetelstat. Hercules and SVB could also exercise their rights to take possession and dispose of the collateral securing the Loan Agreement, which collateral includes

substantially all of our property other than intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat for an adequate amount of time, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to imetelstat, and our ability to successfully commercialize imetelstat may be adversely affected.

Protection of our proprietary technology is critically important to our business. 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. Our success will depend in part on our ability to obtain, maintain, enforce, and extend our patents and maintain trade secrets, both in the U.S. and in other countries.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and in other countries. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing imetelstat or our technology and/or limit the duration of the patent protection for imetelstat and our technology. 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 imetelstat and/or our technologies will be adversely affected, and we may not be able to further develop or potentially commercialize imetelstat.

While we have method-of-use patents that protect the use of imetelstat for the treatment of certain diseases, this type of patent does not prevent a generic competitor from making and marketing a product that is identical to imetelstat for an indication that is outside the scope of our approved use after our composition of matter patents or their patent term extensions have expired. Moreover, even if competitors do not actively promote their product for our approved indications, physicians may prescribe or use these generic products “off-label,” which would result in decreased sales for us.

Loss or impairment of our intellectual property rights related to imetelstat might further delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval, and might further delay or preclude any future development or commercialization of imetelstat by us. Furthermore, 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.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The U.S. Patent and Trademark Office, or the Patent Office, and various governmental patent agencies in other countries require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the Patent Office and various governmental patent agencies in other countries over the lifetime of our owned and licensed patents and/or patent applications and any patent rights we may own or license in the future. Maintaining such compliance may be impacted by macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. For example, we have issued patents and pending patent applications in Ukraine and Russia, and if we are unable to submit responses to governmental patent agencies or make payments related to such patents and patent applications in a timely manner due to the military conflict in the region, these patents or patent applications may be irrevocably lost. In such an event, potential competitors might be able to enter the market with imetelstat or similar products, and this circumstance could harm our financial condition, business and business prospects and the future of imetelstat. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us or jointly owned with us, any of the foregoing could expose us to liability to the applicable patent owner or patent co-owner.

Patent terms may be inadequate to protect our competitive position on imetelstat for an adequate amount of time.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after its first effective nonprovisional filing date. Given the amount of time required for the development, testing and regulatory review of imetelstat, patents protecting imetelstat (e.g., patents claiming imetelstat and/or components thereof, methods of use, or methods of making) might expire

before imetelstat is commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to imetelstat.

In the U.S., the Hatch-Waxman Act permits one patent per approved product to receive a patent term extension of up to five years beyond its normal expiration. The length of the patent term extension is typically calculated as one half of the clinical trial period plus the entire period of time during the review of the NDA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. Only one of our imetelstat U.S. patents may be eligible for patent term extension under the Hatch-Waxman Act. We plan to apply to the Patent Office for patent term extension of one or more patent(s). Once the Patent Office and the FDA determine the extension period for each proposed eligible patent, we will select the one patent to be extended. Currently, communication of patent term extension approval and the length of the granted extension period by the Patent Office may occur up to five years from filing of an application for patent term extension. Accordingly, we will decide on the specific patent to be extended only after such communication from the Patent Office.

Similar extensions are also available in certain countries and territories outside the U.S., such as in Japan, and in Europe as Supplementary Protection Certificates, or SPCs. If we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the Patent Office in the U.S., and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. Should we seek a patent term extension, we may not be granted any such patent term extension and/or the applicable time period of such patent term extension could be less than five years. Moreover, in some countries, including the U.S., the scope of protection for claims under such patent term extensions, if any, does not extend to the full scope of the claims but is limited to the product composition as approved and, for a method of treatment patent, is limited to the approved indication. Thus, for example, if we do not receive a patent term extension for our U.S. composition of matter patent for imetelstat, as approved by the regulatory authorities, our U.S. composition of matter patent will expire in December 2025. If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

If regulatory approval of imetelstat occurs after a patent has expired in a country that does not allow interim patent term extensions, as is the case in many countries and territories including Europe, we will be unable to obtain any patent term extension of that expired patent, and the duration of our patent rights may be limited. If we do not receive marketing approval and submit a request for an SPC before our patents expire in the European Economic Area, or EEA, where we have imetelstat composition of matter patents, our imetelstat composition of matter patents will expire in September 2024. In all other countries outside the U.S. and the EEA where we have imetelstat composition of matter patents, either: (a) extension of patent term is not available, and the patents will expire in September 2024, or (b) we may not have marketing authorization in those countries in sufficient time to file an extension of patent term before our composition of matter patents expire in September 2024. If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

Also, there are regulations for the listing of patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. If we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If imetelstat is approved for commercial sale and an appropriate patent covering imetelstat is not listed in the Orange Book or is subsequently removed from the Orange Book, a manufacturer of generic drugs would not be required to provide advance notice to us of any abbreviated NDA filed with the FDA to obtain permission to sell a generic version of imetelstat. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Changes in U.S. or international 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 U.S. 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.

The U.S. has enacted and implemented wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act, or the AIA, signed into law on September 16, 2011. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on actions by Congress, the federal courts, and the Patent Office, the 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 or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our existing patents or patents that we may obtain in the future. 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.

As a result of the AIA, in March 2013, the U.S. transitioned to a first-inventor-to-file system under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, 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, we are not able to be certain upon filing a patent application that the persons or entities that we name as inventors or applicants in our patent applications were the first to invent the inventions disclosed therein, or the first to file patent applications for these inventions. 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 our former collaboration partner and assigned to us, for the future development, commercialization and manufacture of imetelstat. As a result, if we are not the first inventor-to-file, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be significant to the future success 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.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. The impact of the withdrawal of the U.K. from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain SPCs of imetelstat based on our U.K. patents and our ability to establish and maintain European trademarks in the U.K. In 2012, the European Patent Package, or EU Patent Package, was approved and included regulations with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. The EU Patent Package was ratified in February 2023 and currently covers 17 EU states. As of June 1, 2023, all European patents, including those issued prior to ratification, will by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions and also be at risk of central revocation at the UPC in participating UPC states. Under the EU Patent Package, patent holders are permitted to “opt out” of the UPC on a patent-by-patent basis during an initial seven year transitional period after June 1, 2023, the date the EU Patent Package came into effect. Owners of European patent applications who receive notice of grant after the EU Patent Package came into effect could, for the UPC contracting states, either obtain a Unitary Patent or 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 and pending applications. 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.

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

Our patents or those patent rights we have licensed, including patent rights that we may seek with respect to inventions made by past or future collaborators, 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, 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. We may not be able to obtain from our past or future collaborators the information needed to support our patent rights which could result in the loss of important 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, 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 U.S. 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 not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending and enforcing patents for imetelstat and our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. are less extensive than those in the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover imetelstat and our technologies. There can be no assurance that we will obtain or maintain patent rights inside or outside the U.S. under any future license agreements. In addition, the laws of some countries outside the U.S. do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with imetelstat and our technologies and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions outside the U.S. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, many countries outside the U.S. have compulsory licensing laws under which a patent owner must grant licenses to third parties. Proceedings to enforce our patent rights, even if obtained, in jurisdictions outside the U.S. could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. While we intend to protect our intellectual property rights in major markets for imetelstat, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market imetelstat. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own and potentially develop in the future.

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. 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. 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.

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 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. 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, while our past collaboration agreements have terminated, we are still subject to indemnification obligations to certain collaborators, including with respect to claims of third-party patent infringement.

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. 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, manufacturing 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 any material 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 current and 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 are seeking registered trademarks for a commercial trade name for imetelstat in the U.S. and jurisdictions outside of the U.S. and failure to secure such registrations could adversely affect our business.*

We are seeking registration of trademarks for a potential commercial trade name for imetelstat in the U.S. and other jurisdictions outside of the U.S. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. We intend to maintain our trademark registration in all countries but failure to maintain such registrations could adversely affect our business. If our United States application which forms the basis for our international registration, or IR, for our commercial trade name is refused, withdrawn, or abandoned within the first 5 years of our IR we will lose our IR registrations which could adversely affect our business. Moreover, any name we propose to use for imetelstat in the U.S. and Europe must be approved by the FDA and the EMA respectively, regardless of whether we have registered it, or applied to register it, as a trademark. Both the FDA and the EMA typically conduct a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or the EMA rejects all of our proposed proprietary product names, we may be required to expend additional time and resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA and the EMA.

We may become involved in disputes with past or future collaborator(s) 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 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 are not able to protect or license rights to these inventions. In addition, clinical trial investigators, scientific consultants and research collaborators generally have contractual rights to publish data and other proprietary information, subject to review by 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 our past or future collaborators, 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 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. However, 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.

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 need to recruit, maintain, motivate and integrate additional personnel with expertise and experience in clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing, regulatory affairs, medical affairs, legal affairs, market access, pricing, commercial operations, sales, and marketing, 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. The substantial risks and uncertainties related to our development and potential commercialization of imetelstat and the risks and uncertainties regarding our future business viability could have an adverse impact on our ability to retain and recruit qualified personnel. We may also face higher than expected personnel costs in order to attract new personnel due to shortages in qualified applicants, or to maintain our current management and personnel due to the increased number of opportunities in the biotechnology sector. If we are unable to successfully retain, motivate and incentivize our existing personnel, or to attract, assimilate and retain other highly qualified personnel in the future on acceptable terms, our ability to further develop and potentially commercialize imetelstat will be impaired, and our business and the price of our common stock would be adversely impacted.

In addition, our personnel are currently performing their duties in multiple jurisdictions, and if we are unable or fail to comply with employment, tax, benefits and other laws in such jurisdictions, we may face penalties, fines or litigation.

Our future financial performance and our ability to develop, manufacture and commercialize imetelstat will depend, in part, on our ability to effectively manage any future growth. Our management may have to divert financial and other resources, as well as devote a substantial amount of time, to managing growth activities, such as enhancing operational, financial and management processes and systems. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure and ability to comply with applicable legal and regulatory requirements and regulations, operational mistakes or shortcomings, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and could delay the execution of our business plans or disrupt our current operations. Our ineffective performance in managing any such future growth would negatively impact our business prospects.

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 a workforce in multiple countries, jurisdictions and locations. For example, in September 2021, we established a subsidiary in the U.K., and in February 2023, we established a subsidiary in the Netherlands. Our business needs and the expansion of our workforce may require us to establish additional business offices or entities in additional jurisdictions outside of the U.S., including additional subsidiaries, or to retain third parties to manage employment-related matters in new countries, jurisdictions and locations. Because the legal and regulatory requirements related to the operation and maintenance of such entities, and the employment of personnel in such countries, jurisdictions and regions is multi-national and complex, we may be unable to effectively operate and maintain such entities, or be unable to attract and retain ex-U.S. personnel, which could lead to significant costs and could delay the execution of our business plans or disrupt our current and future operations. If we fail to achieve key development goals, our abilities to grow as a company, and to further develop and potentially commercialize imetelstat, could be prevented or hindered, and our business and business prospects would be severely harmed, which might cause us to cease operations.

Notwithstanding our research and discovery efforts, we expect imetelstat to remain 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.

Other than imetelstat, we do not currently have any other product candidates. While we have initiated a discovery program to identify a lead compound as a potential next generation oral telomerase inhibitor, our discovery efforts are at an early stage and may not be successful. In this regard, internal discovery efforts to identify new product candidates require substantial technical, financial and human resources, and the outcome of those efforts are uncertain and unpredictable. In addition, these discovery efforts may initially show promise in identifying a potential product candidate, yet fail to yield a product candidate for clinical development for a

number of reasons, including where the research methodology used may not be successful in identifying a potential product candidate, or where a potential product candidate may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profile or other characteristics suggesting that it is unlikely to be an effective product. Furthermore, in addition to research and development risks, any potential lead compounds identified during discovery may not be patentable, and therefore unsuitable for further development. Likewise, our research efforts to evaluate imetelstat in lymphoid hematologic malignancies may not be successful. In any event, notwithstanding our research and discovery efforts, we remain and expect to continue remain 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. Similarly, if we are unable to discover and develop new product candidates or to develop imetelstat in lymphoid hematologic malignancies through our research and discovery efforts, our business and business prospects would be harmed.

If we seek to establish potential future collaborative arrangements for imetelstat, we may be unable to establish such collaborative arrangements on acceptable terms, or at all, and 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 in the U.S. We may seek a collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat, especially outside the U.S., 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. Our ability to seek and establish potential collaborative arrangements may be impacted by delays in reporting any results from IMpactMF, as well as the period of the patent term for our intellectual property portfolio and market exclusivity for imetelstat. We may not be able to establish 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, or 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, given the significant risks and uncertainties regarding the future imetelstat development program, potential collaborative partners may be reluctant 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 collaborative partner or partners on favorable terms, if at all. If we are unable to negotiate collaborative arrangements, we may have to:

- delay or curtail the additional development of imetelstat;
- further delay or abandon the potential commercialization of imetelstat outside of the U.S.;
- 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 additional capital than our current resources.

In the absence of future proceeds from potential cash exercises of remaining outstanding warrants and potential drawdowns under the Loan Agreement, we will require substantial additional funding to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, as well as for our recently opened expanded access program, and conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications, and our need for additional funds may arise sooner than planned. However, we cannot predict with any certainty whether and to what extent the remaining outstanding warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all. In addition, if we elect to increase our expenditures to fund imetelstat development or commercialization activities outside the U.S., 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 are unable to raise additional capital if and when needed, we will not be able to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, as well as to conduct the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications to 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 U.S.

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 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 for commercialization activities, 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 have established subsidiaries in the United Kingdom and the Netherlands, which exposes us to additional costs and risks.*

The wholly-owned subsidiaries we have established in the U.K. and the Netherlands subject us to certain additional costs and risks associated with doing business outside the U.S., including:

- the increased complexity and costs inherent in managing international operations in geographically disparate locations;
- challenges of complying with diverse regulatory, financial and legal requirements, which are subject to change at any time;
- potentially adverse tax consequences, including changes in applicable tax laws and regulations;
- potentially costly trade laws, tariffs, export quotas, custom duties or other trade restrictions, and any changes to them;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- liabilities for activities of, or related to, our international operations;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- natural disasters, political and economic instability, including terrorism and civil and political unrest, outbreak of health epidemics, including any resurgence of COVID-19, and the resulting global economic and social impacts;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.; and
- compliance with the United Kingdom Bribery Act 2010, or UK Bribery Act, and similar antibribery and anticorruption laws in the Netherlands and other jurisdictions, and the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, including by failing to maintain accurate information and control over sales and distributors' activities.

In addition, our international operations in the U.K. and the Netherlands expose us to fluctuations in currency exchange rates between the British pound, the Euro and the U.S. dollar. Given the volatility of currency exchange rates, there is no assurance that we will be able to effectively manage currency transaction and/or conversion risks. To date, we have not entered into derivative instruments to offset the impact of foreign exchange fluctuations, which fluctuations could have an adverse effect on our financial condition and results of operations.

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, or claims related to data protection.

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, including if the use of imetelstat is alleged to have injured patients, such as 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 of our current or potential future clinical trials of imetelstat. In addition, 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. We may be unable to obtain or maintain clinical trial insurance in all of the jurisdictions where we conduct current or potential future clinical trials. In addition, business liability, product liability and cybersecurity 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, cybersecurity or other insurance for our business activities in the future on acceptable terms or with adequate coverage against potential liabilities would have a material adverse effect on our business, and could cause us to cease our development of imetelstat.

We and certain of our officers have been named as defendants in pending securities class action lawsuits and shareholder derivative lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome.*

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.

Between January 23, 2020 and March 5, 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed on March 19, 2020. The other two lawsuits, filed in the U.S. District Court, or the Court, for the Northern District of California, or the Northern District, were consolidated by the Court on May 14, 2020, and on August 20, 2020, the lead plaintiffs filed a consolidated class action complaint. The consolidated class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to IMbark during the period from March 19, 2018, to September 26, 2018. The consolidated class action complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose facts related to the alleged failure of IMbark to meet the two primary endpoints of the trial, spleen response rate and Total Symptom Score, and that our stock price dropped when such information was disclosed. The plaintiffs in the consolidated class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On October 22, 2020, lead plaintiffs filed an amended consolidated class action complaint. We filed a motion to dismiss the amended consolidated class action complaint on November 23, 2020. On April 12, 2021, the Court granted in part and denied in part our motion to dismiss. Our answer to the amended consolidated class action complaint was filed on May 13, 2021. On September 30, 2021, lead plaintiffs filed their motion for class certification, and on April 2, 2022, the Court granted the lead plaintiffs' motion for class certification. On September 2, 2022, the parties agreed to a settlement and entered into a Stipulation and Agreement of Settlement, or the Stipulation, which is subject to court approval. On October 13, 2022, the Court preliminarily approved the parties' settlement, and permitted notice to be distributed to the class members. On March 30, 2023, the Court held a hearing on the motion for final approval of the settlement and plan of allocation and ordered supplemental notice to be sent to all of the class members. A second final approval hearing is scheduled for August 24, 2023. Final approval by the Court of the settlement is subject to a number of conditions and contingencies out of our control. There can be no guarantee that all of these conditions and contingencies will occur. Should a material condition or contingency to the settlement fail to occur, one or both of the parties to the settlement may exercise their right to terminate the settlement agreement.

Between April 23, 2020 and June 8, 2021, seven shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former members of our board. Of these actions, or the Derivative Lawsuits, two were filed in the Northern District, two were filed in the Court of Chancery of the State of Delaware, or the Chancery Court, two were filed in the U.S. District Court for the District of Delaware, or the District of Delaware, and one was filed in the Superior Court of California for the County of San Mateo, or the San Mateo Superior Court, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and/or violations of Section 14 of the Exchange Act, based on the same underlying facts as the consolidated class action lawsuit described above. The plaintiffs seek damages, corporate governance reforms, equitable relief, restitution, and an award of reasonable costs, including attorneys' fees. The status of the seven Derivative Lawsuits is currently as follows:

- On July 2, 2021, we filed a motion to dismiss the consolidated shareholder derivative actions filed in the Chancery Court, or the Chancery Court Derivative Lawsuits. On September 1, 2021, the plaintiffs filed a consolidated amended complaint in the Chancery Court Derivative Lawsuits. On October 12, 2021, we filed our motion to dismiss the consolidated amended complaint. The Court of Chancery of the State of Delaware heard oral argument on the motion on February 15, 2022, and, on June 22, 2022, issued an order staying its decision on our motion to dismiss until after final resolution of the consolidated securities class action lawsuit described above. On December 21, 2022, the parties in the Chancery Court Derivative Lawsuits entered into a Stipulation of Settlement, or the Derivative Stipulation, that, subject to final approval by the Chancery Court, will resolve the Chancery Court Derivative Lawsuits. On May 17, 2023, following a hearing, the Chancery Court entered an order approving the Derivative Stipulation and dismissing the Chancery Court Derivative Lawsuits with prejudice;
- The consolidated shareholder derivative actions filed in the District of Delaware have been stayed pending the ruling on our motion to dismiss the Chancery Court Derivative Lawsuits. On December 21, 2022, the parties in the consolidated District of Delaware derivative actions entered into the Derivative Stipulation, that, subject to final approval by the Chancery Court, will resolve the consolidated District of Delaware derivative actions. On May 30, 2023, the parties in the consolidated District of Delaware derivative actions, pursuant to the Derivative Stipulation, sought dismissal of the consolidated District of Delaware derivative actions with prejudice, which the Court granted on May 31, 2023;
- The consolidated shareholder derivative actions filed in the Northern District were initially stayed through the ruling on our motion to dismiss in the consolidated securities class action lawsuit described above and then subsequently were stayed through the ruling on the lead plaintiffs' motion for class certification in the securities consolidated class action lawsuit. Subsequent to the grant of class certification in the consolidated class action lawsuit, on May 3, 2022, the Northern District entered an order providing plaintiffs until June 7, 2022, to file an amended complaint. On June 7, 2022, plaintiffs filed an amended shareholder derivative complaint. On July 6, 2022, the Northern District entered an order staying the consolidated shareholder derivative actions filed in the Northern District until the earlier of either a public announcement of a settlement in the consolidated securities class action lawsuit or a final, non-appealable judgment in the consolidated securities class action lawsuit. On December 21, 2022, the parties in the consolidated derivative actions in the Northern District entered into the Derivative Stipulation, that, subject to final approval by the Chancery Court, will resolve the consolidated derivative actions in the Northern District. On May 30, 2023, the parties in the consolidated derivative actions in the Northern District, pursuant to the Derivative Stipulation, sought dismissal of the consolidated derivative actions in the Northern District with prejudice, which the Court granted the same day; and

- Our motion to dismiss the shareholder derivative action pursuant to the forum selection clause in our amended and restated bylaws was filed in the San Mateo Superior Court on August 5, 2021. At the hearing on the motion to dismiss on November 2, 2021, the court granted our motion to dismiss and stayed the case until April 19, 2022. At the case management conference on April 19, 2022, the court continued the stay until June 14, 2022. At the case management conference on June 14, 2022, the court continued the stay until December 13, 2022. On December 13, 2022, the court dismissed the action without prejudice.

It is possible that additional lawsuits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Such lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we have and may continue to incur substantial legal fees and costs in connection with such lawsuits. As discussed in Note 5 on Commitments and Contingencies in Notes to Condensed Consolidated Financial Statements of this quarterly report on Form 10-Q, we recorded our portion of the settlement amounts for the Stipulation and the Derivative Stipulation on our consolidated statements of operations for the year ended December 31, 2022, as well as corresponding liabilities on our consolidated balance sheet as of December 31, 2022. We currently are not able to estimate the possible additional costs to us, if any, from these matters, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages or legal costs that we may be required to pay. 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 the pending lawsuits and any potential future lawsuits, and we may not prevail in such lawsuits. Additionally, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage.

We have not established any reserve for any potential liability relating to the pending lawsuits or any potential future lawsuits, other than for the total settlement amount under the Stipulation. 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 the pending lawsuits, 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. We may become involved in performance or other disputes with the CROs we have retained to support our imetelstat clinical development activities, or with other third parties such as service providers, vendors, manufacturers, 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 or potentially commercialize imetelstat. 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.

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 securities.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

RISKS RELATED TO COMPETITIVE FACTORS

If competitors develop products, product candidates or technologies that are superior to or more cost-effective than imetelstat, this would 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 characterized by intense and dynamic competition with rapidly advancing technologies and a strong emphasis on proprietary products. While we believe our proprietary oligonucleotide chemistry; experience with the biological mechanisms related to imetelstat, telomeres and telomerase; clinical data to date indicating potential disease-modifying activity with imetelstat treatment; and knowledge and expertise around the development of potential treatments for myeloid hematologic malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Imetelstat will compete, if approved, with other products and therapies that currently exist, are being developed or will in the future be developed, some of which we may not currently be aware of.

If approved for commercial sale for the treatment of lower risk MDS, imetelstat would compete against a number of currently existing therapies, including ESAs and other hematopoietic growth factors that are indicated for anemia; immunomodulators, such as Revlimid (lenalidomide) by Celgene Corporation, a Bristol-Myers Squibb Corporation, or Celgene; hypomethylating agents, such as Vidaza (azacitidine) by Celgene and manufacturers of generic azacitidine; Dacogen (decitabine) by Otsuka America Pharmaceutical, Inc. and other manufacturers in the U.S. and Janssen-Cilag NV in the EU; Inqovi (oral combination of decitabine and cedazuridine) by Astex Pharmaceuticals, Inc., or Astex; and Reblozyl (luspatercept), a TGF-beta inhibitor, by Acceleron Pharma, Inc., or Acceleron (acquired by Merck & Co., Inc., or Merck, in November 2021), in collaboration with Celgene. Bristol-Myers Squibb Company, or BMS, has announced that the FDA accepted the supplemental Biologics License Application, or sBLA, for luspatercept for Priority Review in first-line LR-MDS and set a Prescription Drug User Fee Act (PDUFA) review date of August 28, 2023. The announcement also stated that the EMA had validated the equivalent Type II Variation Application, indicating that the EMA's centralized review can also begin.

Roxadustat, a hypoxia-inducible factor prolyl hydroxylase inhibitor, by FibroGen, Inc. reported that their Phase 3 trial did not meet its primary end-point. Other therapies currently in Phase 3 development in lower risk MDS, some of which may obtain regulatory approval earlier than imetelstat include Onureg (oral azacitidine) by BMS; and Hengqu (hetrombopag), an oral nonpeptide thrombopoietin receptor agonist, by Jiangsu Hengrui Pharmaceuticals Co., Ltd.

In addition, there are multiple Phase 1 and Phase 2 clinical trials of other agents being developed for lower risk MDS, including but not limited to: HuMax-IL8 (BMS-986253), an anti-IL-8 monoclonal antibody, by BMS; LB-100, a PP2A inhibitor, by Lixte Biotechnology Holdings, Inc.; bemcentinib, an AXL inhibitor, by BerGenBio ASA; H3B-8800, a spliceosome inhibitor, by H3 Biomedicine, Inc.; KER-050, a TGF-beta inhibitor, by Keros Therapeutics, Inc., or Keros Therapeutics; TP-0184, an inhibitor of ALK2 or ACVR1 kinase, by Sumitomo Dainippon Pharma Oncology, Inc; ilginatinib (NS-018), a JAK2 inhibitor, by NS Pharma, Inc., a U.S. subsidiary of Nippon Shinyaku Co., Ltd., or NS Pharma; RVT-2001, a SF3B1 modulator, by Roivant Sciences, Ltd.; sabatolimab (MBG453), a TIM-3 inhibitor, by Novartis AG; a lower dose of ASTX727, an oral formulation of decitabine and cedazuridine, referred to as ASTX727 LD, by Astex; ASTX030, an oral formulation of azacitidine and cedazuridine, by Astex; R289, an oral inhibitor of interleukin receptor-associated kinases 1 and 4, or IRAK1/4, by Rigel Pharmaceuticals, Inc.; a combination treatment regimen of luspatercept and lenalidomide by BMS; HuMax-IL8 (BMS-986253), an anti-IL-8 monoclonal antibody, by BMS; etavopivat, an oral, small molecule activator of erythrocyte pyruvate kinase (PKR) by Forma Therapeutics, Inc., a Novo Nordisk Company; canakinumab, an interleukin antagonist, by Novartis AG; briquilimab (JSP191), an unconjugated, aglycosylated, anti-c-Kit antibody, by Jasper Therapeutics, Inc.; and AG946, a next-generation pyruvate kinase-R (PKR) activator, by Agios Pharmaceuticals, Inc.

If approved for commercial sale for the treatment of MF, imetelstat would compete against currently approved JAK inhibitors: Jakafi (ruxolitinib) by Incyte Corporation, or Incyte, and Inrebic (fedratinib) by Celgene, as well as a kinase inhibitor, Vonjo (pacritinib), by CTI Biopharma Corp., which was approved in February 2022 for the treatment of adults with Intermediate or High-Risk primary or secondary myelofibrosis with a platelet count below 50×10^9/L. 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; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include ESAs, androgens, danazol, corticosteroids, thalidomide and lenalidomide.

Other therapies currently in Phase 3 development in MF, some of which may obtain regulatory approval earlier than imetelstat, include momelotinib, a JAK inhibitor, by GlaxoSmithKline plc; or momelotinib plus AZD5153, a BET inhibitor by GlaxoSmithKline plc which has a PDUFA date of September 16, 2023 for approval in the U.S.; pelabresib (CPI-0610), a BET inhibitor, by MorphoSys AG; navitoclax, a BCLXL, BCL-2 and BCLW inhibitor, by AbbVie, Inc.; XPOVIO (selinexor), a nuclear export inhibitor, by Karyopharm Therapeutics, Inc.; development of parsaclisib, a PI3K delta inhibitor, by Incyte has been discontinued in both the front-line and JAKi treated MF Phase 3 trials. Other approaches for MF currently under investigation that could compete with imetelstat in the future include luspatercept; zinpentraxin alfa (RG6354, formerly PRM-151), an anti-fibrosis antibody, by F. Hoffmann-La Roche, Ltd.; LCL-161, an inhibitor of apoptosis protein (IAP), by Novartis; ABBV-744, a BET inhibitor, by AbbVie, Inc.; KRT-232, an inhibitor of MDM2, by Kartos Therapeutics, Inc.; GB2064, a LOXL2 inhibitor, by Galecto Biotech; elraglusib (9-ING-41), a glycogen synthase kinase-3 beta inhibitor, by Actuate Therapeutics, Inc.; TL-895, an oral tyrosine kinase inhibitor, by Telios Pharma,

Inc.; IMG-7289, a LSD1 inhibitor, by Imago Biosciences, Inc.; APG-1252, a dual BCL-2/BCL-XL inhibitor, by Ascentage Pharma; ilginatinib (NS-018), a JAK2 inhibitor by NS Pharma; DISC-0974, a monoclonal antibody against hemojuvelin (HJV) by DISC Management Inc.; KER-050 in combination with ruxolitinib, by Keros Therapeutics; CK0804, an allogeneic T-regulatory cell agent, by Cellenkos, Inc. in collaboration with Incyte; TP-3654, PIM kinase inhibitor by Sumitomo Pharma Co., Ltd.; and a mutated-CALR vaccine, a peptide-based vaccine, from the Icahn School of Medicine at Mount Sinai.

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 myeloid hematologic 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.

Many of our competitors, either alone or with their strategic partners, could have substantially greater financial, technical and human resources than we do and significantly greater experience in obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. We believe that the commercial success of imetelstat is subject to a number of factors, including:

- product efficacy and safety;
- method of product administration;
- cost of manufacturing;
- the timing and scope of regulatory consents;
- status of coverage and level of reimbursement;
- level of generic competition;
- 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 healthcare community, which can be very slow to adopt or unreceptive to new technologies and products.

Even if approved for marketing, imetelstat may not achieve market acceptance, or the potential worldwide or U.S. revenue we believe may be possible, 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, if any;
- the country and/or regions within which imetelstat is approved, if any;
- 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 willingness of medical professionals to prescribe, and patients to use, imetelstat, or to continue to use imetelstat;
- the publication of unfavorable safety or efficacy data concerning imetelstat by third parties or us;

- restrictions on use of imetelstat in combination with other products;
- the label and promotional claims allowed by the FDA or similar international regulatory authorities for imetelstat, if any, including usage for only certain indications and any limitations or warnings about the prevalence or severity of any side effects;
- the timing of market introduction of imetelstat as well as competitive products, including sequencing of available products;
- the effectiveness of sales, marketing and distribution support for imetelstat;
- the extent to which imetelstat is approved for inclusion on National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology and formularies in hospitals and managed care organizations;
- the pricing of imetelstat, both in absolute terms and relative to alternative treatments;
- 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 therapeutic or economic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for myeloid hematologic malignancies. Third-party payors may decide that any potential benefit that imetelstat may provide to clinical outcomes in myeloid hematologic malignancies is not adequate to justify the costs of treatment with imetelstat. If the healthcare community does not accept imetelstat for any of the foregoing reasons, or for any other reasons, 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.

If the market opportunities for imetelstat are smaller than we believe, our potential revenue may be adversely affected, and our business may suffer.

Our initial focus for imetelstat development has been on the lead indications, lower risk MDS and relapsed/refractory MF. The addressable patient populations, if imetelstat is approved in those indications, are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new information from us or others may change the estimated incidence or prevalence of those indications.

Any regulatory approval of imetelstat would be limited to the therapeutic indications examined in our clinical trials and as determined by the FDA and similar international regulatory authorities, which would not permit us to market imetelstat for any other indications not expressly approved by those regulatory authorities. Additionally, the potentially addressable patient population for imetelstat may not ultimately be amenable to treatment with imetelstat. Even if we receive regulatory approval for imetelstat, such approval could be conditioned upon label restrictions that materially limit the addressable patient population.

Our market opportunity may also be limited by the pricing we are able to achieve for imetelstat, if approved, the quality and expiration of our intellectual property rights and licenses, duration of imetelstat treatment in an indication and future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunities for imetelstat that we or any potential future collaborative partners develop could be significantly diminished which would have a material adverse impact on our business and business prospects.

The adoption of health policy changes and healthcare reform in the U.S. may adversely affect our business and financial results.

In the U.S. and some jurisdictions outside the U.S., there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could impact our business. Generally, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing, including specialty drug pricing practices, in light of the rising cost of prescription drugs and biologics. Specifically, there have been 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 and biologics. In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Furthermore, the Inflation Reduction Act of 2022, or the IRA, signed into law by President Biden on August 16, 2022, includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government. Some of the specific provisions under the IRA that could impact us include:

- Requirement that the federal government negotiate prices for certain high-expenditure, single-source drugs covered under Medicare Part B and D with the highest total spending, beginning in 2026; and
- Requirement that drug companies pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries, beginning in 2023.

While the Medicare drug price negotiation program is currently subject to legal challenges, the IRA is expected to have a significant impact on the pharmaceutical industry. Furthermore, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. HHS subsequently released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could affect pricing for imetelstat if it is approved.

Moreover, the U.S. and some jurisdictions in other countries are considering or have enacted legislative and regulatory proposals to contain healthcare costs, as well as to improve quality and expand access. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA was signed into law, which included a number of provisions of importance to the biopharmaceutical industry. There have been judicial and Congressional challenges to certain aspects of the ACA, and it is possible that the ACA will be subject to judicial or Congressional challenges in the future. In addition, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that may be charged for imetelstat.

If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. 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.

Our employees, independent contractors, principal investigators, clinical trial sites, contract research organizations, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, clinical trial sites, CROs, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the FDA’s or similar international regulatory authorities’ regulations, including those laws requiring the reporting of true, complete and accurate information; manufacturing standards; healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our non-clinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could adversely affect our business, financial condition, results of operations or prospects through:

- the imposition of civil, criminal and administrative penalties, damages and monetary fines;
- possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs;
- contractual damages;
- reputational harm;
- diminished potential profits and future earnings; and
- curtailment of our operations.

RISKS RELATED TO OUR COMMON STOCK AND FINANCIAL REPORTING

Historically, our stock price has been extremely volatile and your investment may suffer a decline in value.*

Historically, our stock price has been extremely volatile. Between July 1, 2014 and June 30, 2023, our stock has traded as high as $6.38 per share and as low as $0.89 per share. Between July 1, 2022 and June 30, 2023, the price has ranged between a high of $3.69 per share and a low of $1.67 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- announcements regarding the potential regulatory approval or non-approval of imetelstat and the timing thereof, specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review process;
- announcements regarding the research and development of imetelstat, or adverse efficacy or safety results of, further delays in the commencement, enrollment or conduct of, discontinuation of, or further modifications or refinements to any current clinical trials of imetelstat, including IMerge Phase 3, IMpactMF, IMproveMF and IMpress, as well as for our recently opened expanded access program or for potential future clinical trials of imetelstat, for any reason, or our inability, for any reason, to successfully continue the development of imetelstat;
- obtaining additional capital on commercially reasonable terms to further advance the imetelstat program, including through the completion of IMpactMF, IMproveMF and IMpress, and to conduct the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and other future indications;
- timeliness of preliminary, interim or final clinical trial data expected to be 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 U.S. to continue clinical development of imetelstat in relapsed/refractory MF, lower risk MDS or any additional myeloid hematologic malignancies in a timely manner or at all;
- changes in laws or regulations applicable to imetelstat, including but not limited to clinical trial requirements for approval;
- announcements regarding the safety of imetelstat and partial or full clinical holds placed on the imetelstat INDs by the FDA or similar international regulatory authorities, or other regulatory developments related to imetelstat;
- the successful completion of any clinical trials, regulatory approval and commercialization of imetelstat for one or more label expansion indications;
- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, potential future collaborative partners or our competitors;
- adverse developments concerning our manufacturers, including our inability to obtain adequate product supply for imetelstat or inability to do so at acceptable prices;
- our failure to launch and commercialize imetelstat on the timelines anticipated, or at all;
- the size and growth of our lead indications, lower risk MDS and relapsed/refractory MF;
- disputes or other developments relating to imetelstat proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the terms and timing of any future collaboration agreements for the development and potential commercialization of imetelstat that we may establish;
- announcements of significant acquisitions, strategic partnerships, collaborations, joint ventures or capital commitments by us or our competitors;
- our ability to acquire or in-license new product candidates to grow our pipeline;
- the demand in the market for our common stock;

- fluctuations in our operating results;
- increased or continuing operating losses;
- general domestic and international market conditions or market conditions relating to the biopharmaceutical and pharmaceutical industries, especially given the volatility caused by macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues;
- perceptions of the biotechnology and pharmaceutical industry by the public, legislature, regulators and the investment community;
- comments by securities analysts or other third parties, including blogs, articles and other media;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- large stockholders increasing or exiting their position in our common stock or an increase in the short interest in our common stock;
- changes in the market valuations of similar companies;
- announcements of or developments concerning pending and potential future litigation;
- actions instituted by activist shareholders or others;
- the issuance of common stock to partners, vendors or investors to raise additional capital or as a result of option or warrant exercises;
- other events or factors that are beyond our control; 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, including those resulting from the effects of macroeconomic conditions like pandemics or other health crises, civil or political unrest or military conflicts around the world, such as the military conflict between Ukraine and Russia, inflation, rising interest rates or prospects of a recession, could materially and adversely affect the market price of our common stock and the return on your investment in our securities.

In addition, as further discussed in the Risk Factor above entitled *"We and certain of our officers have been named as defendants in pending securities class action lawsuits and shareholder derivative lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome"*, we and one of our officers have been named as defendants in pending securities class action lawsuits. Such lawsuits have often been instituted against companies, including us, whose securities have experienced periods of volatility in market price. The pending lawsuits and any lawsuits 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 delays of IMpactMF, IMproveMF and IMpress, and/or could preclude or delay potential future clinical trials, or could preclude or delay commercialization efforts.

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

As of June 30, 2023, 521,942,104 shares of common stock were issued and outstanding, and we had reserved 134,662,133 shares of our common stock for future issuance pursuant to our stock option and equity incentive plans and outstanding warrants.

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 the 2020 Sales Agreement with B. Riley or upon the potential exercise of currently outstanding warrants, 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 stock options and shares of common stock reserved for issuance under our stock option and equity incentive plans and outstanding warrants, also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities, which could negatively affect the market price of our common stock and the return on stockholders' 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.

While the exclusive forum provisions in our bylaws do not apply to lawsuits brought to enforce a duty or liability created by the Exchange Act or the Securities Act of 1933, as amended, or any claim for which the federal courts have exclusive jurisdiction, these provisions may nonetheless 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. In addition, the terms of our Loan Agreement prevent us from paying dividends and any future debt agreements may continue to preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

RISKS RELATED TO INFORMATION TECHNOLOGY SYSTEMS, DATA SECURITY AND DATA PRIVACY

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations and actions; litigation; fines and penalties; a disruption of our business operations such as our clinical trials; reputational harm; loss of revenue and profits; and other adverse consequences.

In the ordinary course of our business, we (and third parties upon which we rely) may collect, receive, store, process, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose, or otherwise process (commonly known as processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data and participant study related data), intellectual property, and trade secrets (collectively, sensitive information). In addition, we rely on third-party service providers to establish and maintain appropriate information technology and data security protections over the information technology systems they provide us to operate our critical business systems, including cloud-based infrastructure and systems, employee email, and data storage and management systems. However, except for contractual duties and obligations, we have limited ability to control their safeguards and actions related to such matters, and these third parties may not have adequate information security measures in place. Furthermore, while we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. We may share or receive sensitive information with or from third parties. Most of our employees work remotely, resulting in risks to our information technology systems and data, as employees utilize network connections, computers, and devices outside our premises and networks, including working at home, while in transit and in public locations. Additionally, the prevalent use of mobile devices that access our sensitive information increases the risk of breaches.

Our information technology systems, including in our remote work environment, and those of the third parties upon which we rely, are potentially vulnerable to evolving threats. These threats are prevalent, continue to increase, and come from a variety of sources such as “hackers,” threat or internal bad actors, personnel (such as through theft, error or misuse), sophisticated nation states and nation-state-supported actors. These threats include, but are not limited to, social-engineering attacks, malicious code or malware, unauthorized intrusions, denial-of-service attacks, personnel misconduct or errors, ransomware attacks, supply-chain attacks, software bugs, computer viruses, server malfunctions, software, hardware or data center failures, loss of data or other information technology assets, natural disasters, terrorism, war, and telecommunication and electrical failures. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in operations, loss of data and income, reputational harm, and diversion of funds. If we were to experience such an attack, extortion payments might alleviate the negative impact of a ransomware attack, but we might be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks and attacks on clinical trial sites as well as regulatory and health authorities have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners’ supply chains, or of clinical trial sites and regulatory and health authorities, have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including those related to imetelstat) or the third-party information technology systems that support us and the services provided to us. Any of the aforementioned threats may result in unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive information, such as clinical trial data or information, intellectual property, proprietary business data and personal data. The costs to us to attempt to protect against such breaches could be significant, including potentially requiring us to modify our business (including non-clinical and clinical trial activities), and while we have implemented security measures designed to protect our information technology systems and to identify and remediate vulnerabilities, such measures may not be successful. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are sophisticated in nature, and may not be detected until after a security incident has occurred.

If we or third parties upon which we rely experience or are perceived to have experienced a breach, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), interruptions in our operations, including disruption of our imetelstat development program, interruptions or restrictions on processing sensitive data (which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the data), reputational harm, litigation (including class action claims), indemnification obligations, negative publicity, monetary fund diversions, financial loss, and other harms. In addition, such a breach may require notification of the breach to relevant stakeholders. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

Many of our contracts with relevant stakeholders include obligations relating to the safeguard of sensitive information, and a breach could lead to claims against us by such stakeholders. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities, damages, or claims relating to our data privacy and security obligations. 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.

We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations and actions; litigation; fines and penalties; disruptions to our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts.

In the ordinary course of business, we process personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. We are therefore subject to or affected by numerous data privacy and security obligations, such as various federal, state, local and foreign laws, regulations, guidances, industry standards, external and internal privacy and security policies, contracts, and other obligations governing the processing of personal data by us and on our behalf. These obligations may change, are subject to differing interpretations and may be inconsistent among jurisdictions or conflict. 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 us or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal data; 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 guidances is high and is likely to increase in the future. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (GDPR) (EU) 2016/679, or the EU GDPR, imposes strict requirements on the processing of personal data. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or the EEA, and the United Kingdom, or UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U.S. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health data. Additionally, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). While the CCPA contains limited exceptions for clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. It is anticipated that the California Privacy Rights Act of 2020, or CPRA, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of an enforcement action, and applies to personal information of business representatives and employees. Other states have also enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. If we become subject to new data privacy laws, at the state level or otherwise, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors).

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel or third parties whom we rely on fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor, including our clinical trial sites, to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar activities); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, our clinical trials if any); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize imetelstat; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. Moreover, clinical trial participants or research subjects about whom we or our vendors obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

GENERAL RISK FACTORS

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics, civil or political unrest or military conflicts around the world (such as the current military conflict between Ukraine and Russia), terrorism, insurrection or war, and other natural or man-made disasters or business interruptions. Furthermore, other events, such as the armed conflict between Russia and Ukraine, could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyberattacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business. There is a risk that one or more of our CROs, suppliers, and other contractors and consultants might not survive an economic downturn. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to develop and potentially commercialize imetelstat could be disrupted if our operations or those of our CROs and other contractors or consultants are affected by geopolitical events, man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our CROs, contractors and consultants, and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.*

New income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign sales and earnings. Any new taxes could adversely affect our domestic and international business operations and our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act, as modified by the CARES Act, significantly revised the Code, and recently enacted federal tax legislation made additional changes. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to such legislation may adversely affect us, and certain aspects of such legislation could be repealed or modified in the future, which could have an adverse effect on us. For example, the recently enacted Inflation Reduction Act of 2022, or the Inflation Reduction Act, includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. It is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the Inflation Reduction Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of earnings from other countries, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense.

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 the past, our independent registered public

accounting firm provided an opinion annually on the effectiveness of our internal control over financial reporting. As a smaller reporting company, we are no longer subject to this requirement.

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 assure you that material weaknesses or significant deficiencies will not exist or otherwise be discovered in the future, particularly in light of our increased reliance on personnel working remotely. 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.

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

		Incorporation by Reference			
Exhibit Number	**Description**	**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	May 18, 2012	000-20859
3.3	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	June 7, 2019	000-20859
3.4	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	May 13, 2021	000-20859
3.5	Certificate of Amendment of the Restated Certificate of Incorporation.	3.1	8-K	June 2, 2023	000-20859
10.1*	2018 Equity Incentive Plan, as amended.	10.1	8-K	June 2, 2023	000-20859
10.2+*	2018 Inducement Plan, as amended.				
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 3, 2023.				
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 3, 2023.				
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 3, 2023.**				
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 3, 2023.**				
101	The following materials from the Registrant's June 30, 2023 Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Condensed Consolidated Balance Sheets as of June 30, 2023 and December 31, 2022, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2023 and 2022, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2023 and 2022, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2023 and 2022 and (v) Notes to Condensed Consolidated Financial Statements.				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

\+ Filed herewith.

* Management contract or compensation plan or arrangement.

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

SIGNATURES

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 3, 2023

By: /s/ OLIVIA BLOOM

OLIVIA K. BLOOM

Executive Vice President, Finance, Chief Financial Officer and Treasurer (Duly Authorized Officer and Principal Financial and Accounting Officer)

GERON CORPORATION
2018 INDUCEMENT AWARD PLAN
ADOPTED BY THE BOARD OF DIRECTORS: DECEMBER 14, 2018
(WITH 3,000,000 SHARE RESERVE)
AMENDED AND RESTATED: JANUARY 29, 2019 (ADDED 5,000,000 SHARES)
AMENDED AND RESTATED: FEBRUARY 11, 2020 (ADDED 1,300,000 SHARES)
AMENDED AND RESTATED: FEBRUARY 1, 2021 (ADDED 800,000 SHARES)
AMENDED AND RESTATED: MAY 91, 2021 (ADDED 5,000,000 SHARES)
AMENDED AND RESTATED: FEBRUARY 2, 2022 (ADDED 1,000,000 SHARES)
AMENDED AND RESTATED: JULY 15, 2022 (ADDED 5,000,000 SHARES)
AMENDED AND RESTATED: JUNE 16, 2023 (ADDED 13,900,000 SHARES)

1. GENERAL.

a. Eligible Award Recipients. Awards may only be granted to Employees who satisfy the standards for inducement grants under Rule 5635(c)(4) of the Nasdaq Listing Rules. A person who previously served as an Employee or Director will not be eligible to receive Awards, other than following a bona fide period of non-employment.

b. Available Stock Awards. The Plan provides for the grant of the following types of Stock Awards: (i) Nonstatutory Stock Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards and (v) Other Stock Awards.

c. Purpose. The Plan, through the granting of Stock Awards, is intended to 1) help the Company and any Affiliate secure and retain the services of eligible Stock Award recipients, 2) provide an inducement material for such persons to enter into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules, 3) provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and 4) provide a means by which the eligible recipients may benefit from increases in value of the Common Stock. The Plan is also intended to provide long-term incentives that align the interests of our eligible Stock Award recipients with the interests of our stockholders.

2. ADMINISTRATION.

a. Administration by Board. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c). However, notwithstanding the foregoing or anything in the Plan to the contrary, the grant of Stock Awards will be approved by the Company's independent compensation committee or a majority of the Company's independent directors (as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the Nasdaq Listing Rules.

b. Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

i. To determine (A) who will be granted Stock Awards; (B) when and how each Stock Award will be granted; (C) what type of Stock Award will be granted; (D) the provisions of each Stock Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Stock Award; (E) the number of shares of Common Stock subject to, or the cash value of, a Stock Award; and (F) the Fair Market Value applicable to a Stock Award.

ii. To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Stock Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Stock Award fully effective.

iii. To settle all controversies regarding the Plan and Stock Awards granted under it.

iv. To accelerate, in whole or in part, the time at which a Stock Award may be exercised or vest (or the time at which cash or shares of Common Stock may be issued in settlement thereof).

v. To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or a Stock Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under his or her then-outstanding Stock Award without his or her written consent except as provided in subsection (viii) below.

vi. To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to certain nonqualified deferred compensation under Section 409A of the Code and/or to make the Plan or Stock Awards granted under the Plan exempt from or compliant with the

requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. Except as provided in the Plan (including Section 2(b)(viii)) or a Stock Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Stock Award without the Participant's written consent.

vii. To submit any amendment to the Plan for stockholder approval (to the extent the Board determines advisable or to the extent required pursuant to applicable laws or listing requirements), including, but not limited to, amendments to the Plan to comply with other applicable laws or listing requirements, provided, however, that any amendment provided in Section 9(a) relating to Capitalization Adjustments shall not require stockholder approval.

viii. To approve forms of Stock Award Agreements for use under the Plan and to amend the terms of any one or more Stock Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Stock Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion and applicable laws or listing requirements, including Rule 5635(c) of the Nasdaq Listing Rules; *provided, however,* that a Participant's rights under any Stock Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Stock Awards without the affected Participant's consent (A) to clarify the manner of exemption from, or to bring the Stock Award into compliance with, Section 409A of the Code; or (B) to comply with other applicable laws or listing requirements.

ix. Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Stock Awards.

x. To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Stock Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

c. Delegation to Committee. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated. However, notwithstanding the foregoing or anything in the Plan to the contrary, the grant of Stock Awards will be approved by the Company's independent compensation committee or a majority of the Company's independent directors (as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the Nasdaq Listing Rules.

d. Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

e. Repricing; Cancellation and Re-Grant of Stock Awards. Neither the Board nor any Committee will have the authority to (i) reduce the exercise, purchase or strike price of any outstanding Option or SAR under the Plan, or (ii) cancel any outstanding Option or SAR that has an exercise price or strike price greater than the then-current Fair Market Value of the Common Stock in exchange for cash or other Stock Awards under the Plan, unless the stockholders of the Company have approved such an action within 12 months prior to such an event.

f. Dividends and Dividend Equivalents. Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to a Stock Award, as determined by the Board and contained in the applicable Stock Award Agreement; *provided, however*, that (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested under the terms of such Stock Award Agreement, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be subject to all of the terms and conditions applicable to such shares under the terms of such Stock Award Agreement (including, but not limited to, any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to the Company on the date, if any, such shares are forfeited to or repurchased by the Company due to a failure to meet any vesting conditions under the terms of such Stock Award Agreement.

3. Shares Subject to the Plan.

a. Share Reserve.

i. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date will not exceed 35,000,000 shares (the "***Share Reserve***").

ii. For clarity, the Share Reserve in this Section 3(a) is a limitation on the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by Nasdaq Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

b. Reversion of Shares to the Share Reserve. If a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased or reacquired by the Company for any reason, including because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the Plan. Any shares reacquired or withheld by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award (including any shares subject to a Stock Award that are not delivered to a Participant because such Stock Award is exercised through a reduction of shares subject to such Stock Award (*i.e.*, "net exercised")) will again become available for issuance under the Plan.

c. Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. Eligibility.

a. Eligibility for Stock Awards. Stock Awards may be granted only to persons who are Employees described in Section 1(a), where the Stock Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. For clarity, Stock Awards may not be granted to (1) Directors, for service in such capacity, or (2) any individual who was previously an Employee or Director, other than following a bona fide period of non-employment. Notwithstanding the foregoing, Stock Awards may not be granted to Employees who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction) or (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from or alternatively comply with the distribution requirements of Section 409A of the Code.

b. Approval Requirements. All Stock Awards must be granted either by a majority of the Company's independent directors or by the Company's compensation committee comprised of independent directors within the meaning of Rule 5605(a)(2) of the Nasdaq Listing Rules.

5. Provisions Relating to Options and Stock Appreciation Rights.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be Nonstatutory Stock Options. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Stock Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Stock Award Agreement or otherwise) the substance of each of the following provisions:

a. Term. No Option or SAR will be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Stock Award Agreement.

b. Exercise Price. The exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Stock Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Stock Award if such Stock Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

c. Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any

combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or that otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

i. by cash, check, bank draft or money order payable to the Company;

ii. pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

iii. by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

iv. by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

v. in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Stock Award Agreement.

d. **Exercise and Payment of a SAR.** To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Award Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Stock Award Agreement evidencing such SAR.

e. **Transferability of Options and SARs.** The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board may determine. In the absence of such a determination by the Board to the contrary, the restrictions set forth in this Section 5(e) on the transferability of Options and SARs will apply. Notwithstanding the foregoing or anything in the Plan or a Stock Award Agreement to the contrary, no Option or SAR may be transferred to any financial institution without prior stockholder approval.

i. **Restrictions on Transfer.** An Option or SAR will not be transferable except by will or by the laws of descent and distribution (and pursuant to Sections 5(e)(ii) and 5(e)(iii) below) and will be exercisable during the lifetime of the Participant only by the Participant. Subject to the foregoing paragraph, the Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

ii. **Domestic Relations Orders.** Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulations Section 1.421-1(b)(2).

iii. **Beneficiary Designation.** Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, upon the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, upon the death of the Participant, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

f. **Vesting Generally.** The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual

Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

g. **Termination of Continuous Service.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date three months following such termination of Continuous Service (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR (as applicable) will terminate.

h. **Extension of Termination Date.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company or an Affiliate, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement. In addition, unless otherwise provided in a Participant's Stock Award Agreement, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of time (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement.

i. **Disability of Participant.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 24 months following such termination of Continuous Service (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR (as applicable) will terminate.

j. **Death of Participant.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company or an Affiliate, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Stock Award Agreement for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Participant's Option or SAR may be exercised (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within such period of time ending on the earlier of (i) the date 24 months following the date of death (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Stock Award Agreement. If, after the Participant's death, the Option or SAR (as applicable) is not exercised within the applicable time frame, the Option or SAR (as applicable) will terminate.

k. **Termination for Cause.** Except as explicitly provided otherwise in a Participant's Stock Award Agreement or other individual written agreement between the Participant and the Company or an Affiliate, if a Participant's Continuous Service is terminated for Cause, the Participant's Option or SAR will terminate immediately upon such termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the time of such termination of Continuous Service.

l. **Non-Exempt Employees.** If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six months following the date of grant of the Option or SAR (although the Stock Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's

retirement (as such term may be defined in the Participant's Stock Award Agreement, in another agreement between the Participant and the Company or an Affiliate, or, if no such definition, in accordance with the Company's or Affiliate's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. Provisions of Stock Awards Other than Options and SARs.

a. Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock underlying a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse, or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

i. Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company or (B) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

ii. Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

iii. Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

iv. Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement. Notwithstanding the foregoing or anything in the Plan or a Restricted Stock Award Agreement to the contrary, no Restricted Stock Award may be transferred to any financial institution without prior stockholder approval.

b. Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

i. Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

ii. Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

iii. Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

iv. Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

v. **Termination of Participant's Continuous Service.** Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

c. **Other Stock Awards.** Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (*e.g.*, options or stock appreciation rights with an exercise price or strike price less than 100% of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards granted under Section 5 and this Section 6. Subject to the provisions of the Plan (including, but not limited to, Section 2(f)), the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. Covenants of the Company.

a. **Availability of Shares.** The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

b. **Securities Law Compliance.** The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan the authority required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of a Stock Award or the subsequent issuance of cash or Common Stock pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

c. **No Obligation to Notify or Minimize Taxes.** The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising a Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

8. Miscellaneous.

a. **Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock issued pursuant to Stock Awards will constitute general funds of the Company.

b. **Corporate Action Constituting Grant of Stock Awards.** Corporate action constituting a grant by the Company of a Stock Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (*e.g.*, Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (*e.g.*, exercise price, vesting schedule or number of shares) that are inconsistent with those in the Stock Award Agreement or related grant documents as a result of a clerical error in the preparation of the Stock Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect terms in the Stock Award Agreement or related grant documents.

c. **Stockholder Rights.** No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to a Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Stock Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

d. **No Employment or Other Service Rights.** Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Stock Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause or (ii) as may be applicable after the grant of a Stock Award should the Employee recipient's service capacity change to that of a Consultant or Director, (1) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (2) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

e. **Change in Time Commitment.** In the event a Participant's regular level of time commitment in the performance of his or her services for the Company or any Affiliate is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee) after the date of grant of any Stock Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Stock Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Stock Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Stock Award that is so reduced or extended.

f. **Investment Assurances.** The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

g. **Withholding Obligations.** Unless prohibited by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to a Stock Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; *provided, however,* that no shares of Common Stock are withheld with a value exceeding the maximum amount of tax that may be required to be withheld by law (or such other amount as may be permitted while still avoiding classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from a Stock Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Stock Award Agreement.

h. **Electronic Delivery.** Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

i. **Deferrals.** To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company or an Affiliate. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

j. **Compliance with Section 409A of the Code.** Unless otherwise expressly provided for in a Stock Award Agreement, the Plan and Stock Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Stock Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. To the extent that the Board determines that any Stock Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Stock Award Agreement evidencing such Stock Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and, to the extent applicable, the Plan and Stock Award Agreements will be interpreted in accordance with the requirements of Section 409A of the Code. Notwithstanding anything to the contrary in this Plan (and unless the Stock Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded and a Participant holding a Stock Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount will be made upon a "separation from service" before a date that is six months following the date of such Participant's "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the Participant's death.

k. **Clawback/Recovery.** All Stock Awards granted under the Plan will be subject to recoupment in accordance with any clawback provisions in a Participant's employment agreement or other agreement with the Company or any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in a Stock Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

9. Adjustments upon Changes in Common Stock; Other Corporate Events.

a. **Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a) and (ii) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

b. **Dissolution or Liquidation.** Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, *provided, however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

c. **Corporate Transaction.** The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the Stock Award Agreement or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board may take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

i. arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

ii. arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

iii. accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction; *provided, however*, that the Board may require Participants to complete and deliver to the Company a notice of exercise before the effective date of a Corporate Transaction, which exercise is contingent upon the effectiveness of such Corporate Transaction;

iv. arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

v. cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

vi. make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be zero ($0) if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Common Stock in connection with the Corporate Transaction is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

d. **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. Termination or Suspension of the Plan.

a. The Board may suspend or terminate the Plan at any time. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

b. **No Impairment of Rights.** Suspension or termination of the Plan will not materially impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant or as otherwise permitted in the Plan.

11. Effective Date of Plan.
This Plan will become effective on the Effective Date.

12. Choice of Law.
The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. Definitions. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

a. "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

b. "***Board***" means the Board of Directors of the Company.

c. "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

d. "***Cause***" will have the meaning ascribed to such term in any written agreement between the Participant and the Company or an Affiliate defining such term and, in the absence of such agreement, such term will mean, with respect to a Participant and for purposes of the application of this Plan, the occurrence of any of the following events: (i) such Participant's conviction of, or plea of no contest with respect to, any crime involving fraud, dishonesty or moral turpitude; (ii) such Participant's attempted commission of or participation in a fraud or act of dishonesty against the Company or an Affiliate that results in (or might have reasonably resulted in) material harm to the business of the Company or an Affiliate; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or an Affiliate, or any statutory duty the Participant owes to the Company or an Affiliate; or (iv) such Participant's conduct that constitutes gross misconduct, insubordination, incompetence or habitual neglect of duties and that results in (or might have reasonably resulted in) material harm to the business of the Company or an Affiliate. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Stock Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or an Affiliate or such Participant for any other purpose.

e. "***Change in Control***" will be deemed to have occurred upon the first to occur of an event set forth in any one of the following paragraphs:

i. As a result of any merger or consolidation, the voting securities of the Company outstanding immediately prior thereto represent (either by remaining outstanding or by being converted into voting securities of the surviving or acquiring entity) less than 49% of the combined voting power of the voting securities of the Company or such surviving or acquiring entity outstanding immediately after such merger or consolidation;

ii. during any period of twenty-four consecutive calendar months, the individuals who at the beginning of such period constitute the Board, and any new directors whose election by such Board or nomination for election by stockholders was approved by a vote of at least two-thirds of the members of such Board who were either

directors on such Board at the beginning of the period or whose election or nomination for election as directors was previously so approved, for any reason cease to constitute at least a majority of the members thereof;

iii. any individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) shall become the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 20% of the then outstanding shares of Common Stock of the Company;

iv. any sale of all or substantially all of the assets of the Company; or

v. the complete liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Stock Award which provides for the deferral of compensation and is subject to Section 409A of the Code, the transaction or event with respect to such Stock Award must also constitute a "change in control event," as defined in Treasury Regulation §1.409A-3(i)(5) to the extent required by Section 409A.

The Committee shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the date of the occurrence of such Change in Control and any incidental matters relating thereto.

Notwithstanding the foregoing, a Change in Control shall not be deemed to occur solely because the threshold voting power of the Company's then outstanding securities in Section 13(e)(i) or (iii) is acquired by (A) a trustee or other fiduciary holding securities under one or more employee benefit plans maintained by the Company or any of its subsidiaries or (B) any corporation which, immediately prior to such acquisition, is owned directly or indirectly by the stockholders of the Company in the same proportion as their ownership of stock in the Company immediately prior to such acquisition.

For the avoidance of doubt, the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

Notwithstanding the foregoing or any other provision of this Plan, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Stock Awards subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply.

f. "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

g. "***Committee***" means a committee of one or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

h. "***Common Stock***" means the common stock of the Company.

i. "***Company***" means Geron Corporation, a Delaware corporation.

j. "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person. Consultants are not eligible to be granted Stock Awards under this Plan with respect to their service in such capacity.

k. "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided, however,* that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's or Affiliate's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

l. "***Corporate Transaction***" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

i. a sale, lease or other disposition of all or substantially all of the assets of the Company;

ii. a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

iii. a merger, consolidation or similar transaction in which the Company is not the surviving corporation; or

iv. a reverse merger, consolidation or similar transaction in which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

Notwithstanding the foregoing definition or any other provision of this Plan, the term Corporate Transaction will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

m. "***Director***" means a member of the Board. Directors are not eligible to be granted Stock Awards with respect to their service in such capacity under this Plan.

n. "***Disability***" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

o. "***Effective Date***" means the effective date of this Plan document, which is December 14, 2018, the date the Plan was approved by the Board.

p. "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

q. "***Entity***" means a corporation, partnership, limited liability company or other domestic or foreign entity.

r. "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

s. "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

i. If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

ii. Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

iii. In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

t. "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

u. "***Nonstatutory Stock Option***" means any option granted pursuant to Section 5 that does not qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

v. "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

w. "***Option***" means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

x. "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

y. "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

z. "***Other Stock Award***" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(c).

aa. "***Own,***" "***Owned,***" "***Owner,***" "***Ownership***" means a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

bb. "***Participant***" means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

cc. "***Plan***" means this Geron Corporation 2018 Inducement Award Plan.

dd. "***Restricted Stock Award***" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

ee. "***Restricted Stock Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

ff. "***Restricted Stock Unit Award***" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

gg. "***Restricted Stock Unit Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

hh. "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

ii. "***Rule 405***" means Rule 405 promulgated under the Securities Act.

jj. "***Securities Act***" means the Securities Act of 1933, as amended.

kk. "***Stock Appreciation Right***" or "***SAR***" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

ll. "***Stock Award***" means any right to receive Common Stock granted under the Plan, including a Nonstatutory Stock Option, a Stock Appreciation Right, a Restricted Stock Award, a Restricted Stock Unit Award or any Other Stock Award.

mm. "***Stock Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

nn. "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution.

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 3, 2023

/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 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 3, 2023

/s/ OLIVIA 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, 2023 (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 3, 2023

/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, 2023 (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 3, 2023

/s/ OLIVIA 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.