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 March 31, 2024

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 April 26, 2024:**
Common Stock, $0.001 par value	593,132,540 shares

GERON CORPORATION
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2024

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	MARCH 31, 2024	DECEMBER 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 189,761	$ 70,023
Restricted cash	1,119	1,115
Marketable securities	253,288	263,676
Interest and other receivables	1,629	1,655
Prepaid and other current assets	5,712	4,879
Total current assets	451,509	341,348
Noncurrent marketable securities	20,782	43,298
Property and equipment, net	1,681	1,177
Operating leases, right-of-use assets	3,392	3,556
Deposits and other assets	4,710	4,697
	$ 482,074	$ 394,076
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,992	$ 6,161
Accrued compensation and benefits	6,794	13,759
Operating lease liabilities	955	949
Debt	71,526	46,893
Accrued liabilities	33,891	40,308
Total current liabilities	123,158	108,070
Noncurrent operating lease liabilities	2,829	3,006
Noncurrent debt	11,219	35,051
Commitments and contingencies		
Stockholders' equity:		
Common stock	591	545
Additional paid-in capital	1,997,709	1,844,988
Accumulated deficit	(1,653,159)	(1,597,769)
Accumulated other comprehensive loss	(273)	185
Total stockholders' equity	344,868	247,949
	$ 482,074	$ 394,076

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2024	**2023**
Revenues:		
Royalties	$ 304	$ 21
Operating expenses:		
Research and development	29,373	27,219
General and administrative	27,065	12,894
Total operating expenses	56,438	40,113
Loss from operations	(56,134)	(40,092)
Interest income	4,239	3,853
Interest expense	(3,433)	(1,922)
Other income and (expense), net	(62)	39
Net loss	$ (55,390)	$ (38,122)
Basic and diluted net loss per share	$ (0.09)	$ (0.07)
Shares used in computing basic and diluted net loss per share	603,493,451	544,459,004

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2024	2023
Net loss	$ (55,390)	$ (38,122)
Net unrealized loss on marketable securities	(448)	75
Foreign currency translation adjustments	(10)	(16)
Comprehensive loss	$ (55,848)	$ (38,063)

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, 2023	544,912,215	$ 545	$ 1,844,988	$ (1,597,769)	$ 185	$ 247,949
Net loss	—	—	—	(55,390)	—	(55,390)
Other comprehensive income	—	—	—	—	(448)	(448)
Foreign currency translation adjustment	—	—	—	—	(10)	(10)
Issuance of common stock and pre-funded warrant to purchase common stock in public offering, net of issuance costs of $9,000	41,999,998	42	140,958	—	—	141,000
Issuance of common stock in connection with exercise of warrants	37,640	—	49	—	—	49
Stock-based compensation related to issuance of common stock and options in exchange for services	4,211,493	4	6,745	—	—	6,749
Issuance of common stock under equity plans	2,462	—	92	—	—	92
Stock-based compensation for equity-based awards to employees and directors	—	—	4,877	—	—	4,877
Balance at March 31, 2024	591,163,808	$ 591	$ 1,997,709	$ (1,653,159)	$ (273)	$ 344,868

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 loss	—	—	—	—	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

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (55,390)	$ (38,122)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111	99
Accretion and amortization on investments, net	(2,367)	(1,727)
Amortization of debt issuance costs/debt discounts	802	242
Stock-based compensation for services by non-employees	92	112
Stock-based compensation for employees and directors	4,877	2,961
Amortization of right-of-use assets	164	152
Changes in assets and liabilities:		
Current and noncurrent assets	(819)	1,915
Current and noncurrent liabilities	(9,723)	(11,997)
Net cash used in operating activities	(62,253)	(46,365)
Cash flows from investing activities:		
Purchases of property and equipment	(615)	(372)
Purchases of marketable securities	(65,618)	(241,611)
Proceeds from maturities of marketable securities	100,440	63,250
Net cash provided by (used in) investing activities	34,207	(178,733)
Cash flows from financing activities:		
Proceeds from issuances of common stock from equity plans	6,749	7,875
Proceeds from issuance of common stock from offering and pre-funded warrant, net of paid issuance costs	141,000	213,337
Proceeds from exercise of warrants	49	59,835
Net cash provided by financing activities	147,798	281,047
Effect of exchange rates on cash, cash equivalents and restricted cash	(10)	(16)
Net increase in cash, cash equivalents and restricted cash	119,742	55,933
Cash, cash equivalents and restricted cash at the beginning of the period	71,138	57,209
Cash, cash equivalents and restricted cash at the end of the period	$ 190,880	$ 113,142

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 months ended March 31, 2024 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, 2023, included in our Annual Report on Form 10-K for the year ended December 31, 2023, or the Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2023 has been derived from audited financial statements at that date.

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 March 31, 2024, none of these pre-funded warrants have been exercised. These pre-funded warrants, which represent an aggregate of 59,433,145 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 months ended March 31, 2024 and 2023, the diluted net loss per share calculation excludes potential dilutive securities of 84,430,455 and 107,971,822 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 and managed by CROs based upon the amount of work completed on each trial. Expenses are recorded based on contracted amounts agreed to with our CROs and through monthly reporting provided by CROs. We monitor activities conducted and managed by the CROs to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We record expense on the best information available at the time. However, additional information may become available to us which may require adjustments to research and development expenses in future periods.

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 months ended March 31, 2024 and 2023, which was allocated as follows:

	Three Months Ended March 31,	
(In thousands)	2024	2023
Research and development	$ 1,681	$ 1,306
General and administrative	3,196	1,655
Stock-based compensation expense included in operating expenses	$ 4,877	$ 2,961

As stock-based compensation expense recognized in our condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023 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 any remaining performance-based stock options on our condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023, as achievement of the specified strategic milestones associated with the remaining performance-based stock options 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 three months ended March 31, 2024 and 2023 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2024	2023
Dividend yield	0%	0%
Expected volatility range	82.94% to 86.68%	81.53% to 81.64%
Risk-free interest rate range	4.05% to 4.32%	3.42% to 4.10%
Expected term	6 years	6 years

Employee Stock Purchase Plan

The fair value of employees' stock purchase rights during the three months ended March 31, 2024 and 2023 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2024	2023
Dividend yield	0%	0%
Expected volatility range	59.46% to 79.05%	61.04% to 81.08%
Risk-free interest rate range	4.79% to 5.40%	0.09% to 4.76%
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 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 adopted ASU 2020-06 as of January 1, 2024, it did not have a material impact on our condensed consolidated financial statements.

New Accounting Pronouncements – Issued But Not Yet Adopted

In March 2024, the FASB issued ASU 2024-01, *Accounting for Application of Profits Interest and Similar Awards*, or ASU 2024-01. The key elements of ASU 2024-01 aim to account for profit interest awards as compensation to employees or nonemployees in return for goods and services effective for annual periods beginning after December 15, 2024, and interim periods with those annual periods. 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 March 31, 2024 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	$ 147,245	$ —	$ —	$ 147,245
Commercial Paper	1,498	—	—	1,498
	$ 148,743	$ —	$ —	$ 148,743
Restricted cash:				
Money market fund	$ 847	$ —	$ —	$ 847
Certificate of deposit	272	—	—	272
	$ 1,119	$ —	$ —	$ 1,119
Marketable securities:				
U.S. Treasury securities - due in 1 to 2 years	$ 29,938	$ 14	$ (2)	$ 29,950
Government-sponsored enterprise securities (due in less than one year)	63,652	14	(79)	63,587
Commercial paper (due in less than one year)	118,481	3	(157)	118,327
Corporate notes (due in less than one year)	41,458	5	(39)	41,424
Corporate notes (due in one to two years)	20,801	18	(37)	20,782
	$ 274,330	$ 54	$ (314)	$ 274,070

Cash equivalents, restricted cash and marketable securities by security type at December 31, 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	$ 16,815	$ —	$ —	$ 16,815
	$ 16,815	$ —	$ —	$ 16,815
Restricted cash:				
Money market fund	$ 843	$ —	$ —	$ 843
Certificate of deposit	272	—	—	272
	$ 1,115	$ —	$ —	$ 1,115
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 26,752	$ 95	$ —	$ 26,847
U.S. Treasury securities (due in one to two years)	2,877	17	—	2,894
Government-sponsored enterprise securities (due in less than one year)	86,250	43	(92)	86,201
Government-sponsored enterprise securities (due in one to two years)	13,598	72	—	13,670
Commercial paper (due in less than one year)	102,270	31	(33)	102,268
Corporate notes (due in less than one year)	48,409	14	(63)	48,360
Corporate notes (due in one to two years)	26,628	130	(24)	26,734
	$ 306,784	$ 402	$ (212)	$ 306,974

Cash equivalents and marketable securities with unrealized losses that have been in a continuous unrealized loss position for less than 12 months and 12 months or longer at March 31, 2024 and December 31, 2023 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 March 31, 2024:						
US Treasury Securities (due in less than one year)	$ 4,864	$ (2)	$ —	$ —	$ 4,864	$ (2)
Government-sponsored enterprise securities (due in less than one year)	38,097	(79)	—	—	38,097	(79)
Commercial paper (due in less than one year)	101,008	(157)	—	—	101,008	(157)
Corporate notes (due in less than one year)	24,559	(27)	4,957	(12)	29,516	(39)
Corporate notes (due in one to two years)	12,364	(37)	—	—	12,364	(37)
	$ 180,892	$ (302)	$ 4,957	$ (12)	$ 185,849	$ (314)
As of December 31, 2023:						
Government-sponsored enterprise securities (due in less than one year)	$ 69,377	$ (92)	$ —	$ —	$ 69,377	(92)
Commercial paper (due in less than one year)	58,622	(33)	—	—	58,622	(33)
Corporate notes (due in less than one year)	34,567	(63)	—	—	34,567	(63)
Corporate notes (due in one to two years)	3,952	(23)	—	—	3,952	(23)
	$ 166,518	$ (211)	$ —	$ —	$ 166,518	$ (211)

The gross unrealized losses related to U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper and corporate notes as of March 31, 2024 and December 31, 2023 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 months ended March 31, 2024 and 2023 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 March 31, 2024 and December 31, 2023 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 March 31, 2024:				
Money market funds[1][2]	$ 148,092	$ —	$ —	$ 148,092
Certificate of deposit[2]	272	—	—	272
U.S. Treasury securities[3]	—	29,950	—	29,950
Government-sponsored enterprise securities[3]	—	63,589	—	63,589
Commercial paper[3]	—	119,825	—	119,825
Corporate notes[3][4]	—	62,206	—	62,206
Total	$ 148,364	$ 275,570	$ —	$ 423,934
As of December 31, 2023:				
Money market funds[1][2]	$ 17,658	$ —	$ —	$ 17,658
Certificate of deposit[2]	272	—	—	272
U.S. Treasury securities[3][4]	—	29,742	—	29,742
Government-sponsored enterprise securities[3][4]	—	99,872	—	99,872
Commercial paper[3]	—	102,268	—	102,268
Corporate notes[3][4]	—	75,092	—	75,092
Total	$ 17,930	$ 306,974	$ —	$ 324,904

(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 March 31, 2024 and December 31, 2023:

(In thousands)	MARCH 31, 2024	DECEMBER 31, 2023
CRO and clinical trial costs	$ 19,695	$ 23,541
Manufacturing activities	10,593	14,629
Professional legal and accounting fees	1,061	556
Interest payable	896	768
Other	1,646	814
	$ 33,891	$ 40,308

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 $75.0 million 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 $75.0 million to $125.0 million, with such principal being available in a series of tranches, subject to certain terms and conditions. On December 14, 2023, we entered into a third amendment to the Original Loan Agreement, or as amended, the Loan Agreement. As of March 31, 2024, a total of $80.0 million has been drawn under the Loan Agreement.

On the effective date of the second amendment, we paid $100,000 as a facility charge that we recognized as a debt discount and are amortizing such cost to interest expense over the life of the loan using the effective interest rate method. Additional facility charges applied to future drawdowns will be treated similarly. We also incurred legal fees in connection with the second amendment, which we recognized as debt issuance costs and are amortizing such cost to interest expense over the life of the loan using the effective interest rate method.

Under the third amendment, the aggregate principal amount drawn down and remaining available to us under the Term Loan remains at $125.0 million, with such principal being available in a series of tranches, subject to certain terms and conditions. The third amendment also provides that (i) the fourth tranche of the Term Loan was increased from $10.0 million to $30.0 million, (ii) the commitment period for the fifth tranche of the Term Loan of $20.0 million, which is available subject to achievement of a regulatory milestone and satisfaction of certain capitalization requirements, was extended through December 15, 2024, (iii) the variable annual interest rate on the outstanding loans has been decreased to the greater of: (x) 9.0%, or (y) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0%; and (iv) the interest only period of the Term Loan has been extended through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. In connection with the third amendment, on the third amendment effective date, we borrowed and received the entire fourth tranche of the Term Loan in the amount of $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Loan Agreement is $80.0 million. On the effective date of the third amendment, we paid $300,000 as a facility charge that we recognized as a debt discount and are amortizing such cost to interest expense over the life of the loan using the effective interest rate method. Additional facility charges applied to future drawdowns will be treated similarly. We also incurred legal fees in connection with the third amendment, which we recognize as debt issuance costs and amortize such cost to interest expense over the life of the loan using the effective interest rate method. The third amendment of the Loan Agreement is not substantially different as compared to the Original Loan Agreement, and accordingly, we treated the amendment as a modification of the debt in accordance with ASC 470. On September 15, 2023, the third tranche of $20.0 million of the Term Loan expired and is no longer available for us, but was added to the fourth tranche as part of the third amendment to the Loan Agreement.

Under the Term Loan as amended, the Term Loan matures on April 1, 2025, or the Loan Maturity Date, and may be extended up to an additional six months upon the achievement of certain regulatory and financial milestones. The Term Loan bears interest at a floating rate per annum equal to the greater of either (i) 9.0% or (ii) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0% (8.5% as of December 31, 2023). The interest only period of the Term Loan is through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. Following the expiration of the interest-only period, we are required to repay the Term Loan in equal monthly amortization payments of principal and interest until the Loan Maturity Date. Upon full repayment of the Term Loan, we are also obligated to pay an end of term charge in an amount equal to 6.55% of the amount of the Term Loans actually borrowed. Such end of term charge is being accrued to interest expense over the term of the Term Loan using the effective interest rate method. At our option, upon at least five business days' prior written notice to Hercules, we may prepay all or any portion greater than or equal to $5.0 million of the outstanding loan by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest. There is no prepayment charge for prepayments of drawdowns under Tranche 1 or Tranche 2. Prepayments of drawdowns under Tranche 3, Tranche 4, Tranche 5 or Tranche 6 are subject to a prepayment charge of 1.5% of the prepayment amount, if the prepayment is made prior to June 30, 2025. Thereafter, any prepayment of Tranche 3, Tranche 4, Tranche 5 or Tranche 6 is not subject to a prepayment charge. We are in compliance with the covenants under the Loan Agreement as of March 31, 2024.

As of March 31, 2024, the net carrying value of the debt under the Loan Agreement was $82,745,000, which includes the principal amount of $80,000,000 less net unamortized debt discounts and issuance costs of $458,000 plus accrued end of term charge of $3,204,000. The carrying value of the debt approximates the fair value as of March 31, 2024. 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 March 31, 2024 (in thousands):

Remainder of 2024	$ 53,564
2025	39,262
Total	92,826
Less: amount representing interest	(7,587)
Less: unamortized debt discount and issuance costs	(458)
Less: unaccrued end of term charge	(2,036)
Less: current portion of debt	(71,526)
Noncurrent portion of debt	$ 11,219

5. CONTINGENCIES AND UNCERTAINTIES

Purported Securities Lawsuits

In 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, were consolidated by the court. In September 2022, the parties agreed to a settlement and entered into a Stipulation and Agreement of Settlement, which was subject to court approval. The court granted final approval of the settlement on September 28, 2023 and final judgment was entered on October 3, 2023.

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 directors' and officers', or D&O insurance coverage and, $7,000,000 in cash which was paid after final approval of the settlement by the court. The settlement does not constitute an admission of fault or wrongdoing by Geron or any of our officers. Our portion of the settlement amount was paid in the fourth quarter of 2023. There is no liability outstanding as of March 31, 2024 as the matter was fully settled during the year ended December 31, 2023.

In 2020 and 2021, seven shareholder derivative actions were filed in a number of courts, naming as defendants certain of our then current officers and certain of our then current and former members of our board. On December 21, 2022, the parties to the shareholder derivative action filed in the Delaware Court of Chancery entered into a stipulation of settlement, or the Derivative Stipulation, and on May 17, 2023, the Delaware Court of Chancery approved the Derivative Stipulation, and the case was dismissed with prejudice. Subsequently, each of the remaining derivative cases were dismissed with 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, we agreed to pay and/or to cause our insurance carriers to pay a total of $1,350,000, comprised of $525,000 in cash, which was payable under our available D&O insurance coverage and $825,000 in cash payable by us. The settlement does not constitute an admission of fault or wrongdoing by any of our officers or members of our board. 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. Accordingly, there are no outstanding amount to settle against this as of March 31, 2024.

While we have settled these lawsuits, it is possible that additional lawsuits might be filed, or allegations might be 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 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. 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 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. Expenses associated with any potential future lawsuits could be material to our consolidated financial statements if we do not prevail in the defense of such lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to any potential future lawsuits. 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 adopted two severance plans that apply to all of our employees who are not subject to performance improvement plans, one plan covering employees above the Vice President level, i.e., executives, and all other employees hired before January 1, 2022, and the other plan covering all non-executive employees hired on or after January 1, 2022. The severance plans provide for, among other benefits: (i) a severance payment upon a Change of Control Triggering Event and Separation from Service and (ii) 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 plans, 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 plans, (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 plans, a Non-Change of Control Triggering Event and Separation from Service is defined as an event where an employee is terminated by us without cause. Severance payments range from three to 18 months of base salary in connection with a Change of Control Triggering Event or from six weeks to 12 months of base salary in connection with a Non-Change of Control Triggering Event, as well as a pro-rata portion of the employee's annual target bonus, depending on the employee's position with us, payable in a lump sum payment, and monthly COBRA payments for the severance period. The severance plans also provide that they shall not supersede the provisions of any individual employment agreements entered into between us and our employees, and that the employees with such agreements will be entitled to whichever benefits are greater under the severance plan or their employment agreement. A copy of the severance plan covering our executive officers is filed as an exhibit to our annual report on Form 10-K. As March 31, 2024, all our executive officers have employment agreements with severance provisions and will receive the greater severance benefits of their agreements or those in the severance plan applicable to them.

6. STOCKHOLDERS' EQUITY

Registered Offering

On March 21, 2024, we completed an underwritten public offering of 41,999,998 shares of our common stock and a pre-funded warrant to purchase 8,002,668 shares of our common stock, or the 2024 pre-funded warrant. All of the securities were issued separately. The public offering price of the common stock was $3.00 per share. The public offering price of the 2024 pre-funded warrant was $2.99 per share. The 2024 pre-funded warrant has an exercise price of $0.001 per share and may be exercised at any time until the 2024 pre-funded warrant is exercised in full. As of March 31, 2024, none of the 2024 pre-funded warrant has been exercised. The net cash proceeds from the March 2024 offering were approximately $141.0 million, after deducting the underwriting discount and other offering expenses paid by us, and excluding any future proceeds from the exercise of the pre-funded warrant.

Upon the issuance of the 2024 pre-funded warrant, we evaluated the warrant terms 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 2024 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 2024 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 2024, warrants to purchase 37,640 shares of our common stock were exercised for net cash proceeds of approximately $49,000. 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. As of March 31, 2024, the following warrants remained outstanding:

- pre-funded warrants with an exercise price of $0.001 per share to purchase 59,433,145 shares of our common stock, which have no expiration date; and
- stock purchase warrants with an exercise price of $1.30 per share to purchase 2,436,861 shares of our common stock related to the public offering of our common stock in May 2020, which expire on December 31, 2025.

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, 2023 as filed with the SEC on February 28, 2024, or 2023 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 August 2023, our New Drug Application, or NDA, 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, was accepted by the United States, or U.S., Food and Drug Administration, or FDA, for review and assigned a Prescription Drug User Fee Act, or PDUFA, action date of June 16, 2024. In addition, the FDA held an advisory committee meeting as part of the NDA review on March 14, 2024 which voted 12 to 2 that the benefits of imetelstat outweigh its risks in this proposed indication. For more information, see "—Recent Developments" below. If imetelstat is approved for commercialization by the FDA, we anticipate commercial launch of imetelstat in transfusion-dependent lower-risk MDS in the U.S. could occur at the time of approval. In September 2023, we submitted a marketing authorization application, or MAA, in Europe that was validated for review by the European Medicines Agency, or EMA, for imetelstat for the same proposed indication as in the U.S. We expect a review of the MAA could be completed in early 2025, and subject to MAA review completion on that timing and ultimate approval of the MAA by the European Commission, we believe EU commercial launch of imetelstat would occur in 2025.

Our NDA and EMA submissions are based on positive data from the IMerge Phase 3 clinical trial. The trial met its primary endpoint of ≥ 8-week red blood cell transfusion independence rate and a key secondary endpoint of ≥ 24-week red blood cell transfusion independence rate, demonstrating highly statistically significant (i.e., $p<0.001$ for both) and clinically meaningful benefits with imetelstat treatment versus placebo. Furthermore, statistically significant and clinically meaningful efficacy results were observed in the trial across key MDS patient subtypes, including patients who were ringed sideroblast positive, or RS positive, and ringed sideroblast negative, or RS negative; patients with high (4-6 RBC units/8 weeks) and very high baseline transfusion burden (>6 RBC units/8 weeks); and patients classified as Low or Intermediate-1 risk according to the International Prognostic Scoring System, or IPSS. Consistent with prior imetelstat clinical experience, the most common Grade 3-4 adverse events were thrombocytopenia (62%) and neutropenia (68%) that were generally manageable and of short duration.

In addition to lower-risk MDS, we are developing imetelstat for the treatment of several myeloid hematologic malignancies. Our Phase 3 clinical trial IMpactMF evaluates 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, or R/R MF, with overall survival, or OS, as the primary endpoint. In November 2023, the trial reached 50% enrollment. Based on our current planning assumptions for enrollment and event (death) rates in the trial, we expect the interim analysis for OS in IMpactMF may occur in early 2026, and the final analysis may occur in early 2027.

We are also conducting a Phase 1 combination therapy clinical trial, named IMproveMF, in first-line Intermediate-1, Intermediate-2 or High-Risk myelofibrosis, or frontline MF, that currently is enrolling patients. Imetelstat is also being studied in

an investigator-led Phase 2 clinical trial, named IMpress, in Intermediate-2 or High-Risk myelodysplastic syndromes, or higher risk MDS, and acute myeloid leukemia, or AML, patients that are relapsed or refractory to hypomethylating agent, or HMA, treatment, in which the first patient was dosed in June 2023.

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 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.

Recent Developments

On March 14, 2024, the FDA convened its Oncologic Drugs Advisory Committee, or ODAC, to discuss our NDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with IPSS low-to intermediate-1 risk MDS who have failed to respond or have lost response to or are ineligible for ESAs. The ODAC discussed the efficacy of imetelstat in this proposed indication, based on the results of our IMerge Phase 3 clinical trial, considering the safety profile, and voted 12 to 2 that the benefits of imetelstat outweigh its risks in this proposed indication.

The FDA is not bound by the views or recommendations of its advisory committees, including the ODAC. Accordingly, notwithstanding the ODAC discussion and vote, the FDA may delay the approval of or ultimately determine not to approve our NDA for imetelstat for a variety of reasons, including due to their perception, evaluation, inspection or analysis of imetelstat's product quality, clinical data and outcomes, nonclinical data, safety risks, our or our third party vendors' compliance, or other considerations that are or may be important to the FDA's review of our NDA. For example, the FDA raised questions at the ODAC about the hazard ratio for the overall survival, or OS, data from our IMerge Phase 3 trial, and while we believe that the data to date adequately demonstrate that there is no survival detriment for these patients, the FDA could continue to raise questions and/or seek additional information about the OS data as part of its ongoing review that could influence its review. Moreover, while we have received comments from the FDA on our draft indication statement, or label, the FDA has not yet completed its review of the clinical, non-clinical and chemistry, manufacturing and controls, or CMC, portions of our NDA or scheduled any inspections of our contract manufacturers. Accordingly, while the PDUFA target action date for our NDA is June 16, 2024, there can be no assurance as to the timing or outcome of FDA's ultimate decision on our NDA. The FDA may deny approval of the NDA altogether, or may require additional testing or data before our NDA may be approved. In addition, the FDA may approve our NDA but limit imetelstat's use to certain patients or under specified conditions resulting in a narrower or more restrictive label than we expect, or could require costly post-approval commitments or requirements. Any such action by the FDA could severely and adversely affect our business and business prospects, including the potential commercialization of imetelstat, and might have a material adverse effect on our operations.

Financial Overview

Since our inception, we have primarily financed our operations through the sale of equity securities, draw downs on our debt facility, interest income on our marketable securities and payments we received under our prior collaborative and licensing arrangements. As of March 31, 2024, we had approximately $465.0 million in cash, cash equivalents, restricted cash and marketable securities and a long-term principal debt balance of $80.0 million.

Substantially all of our revenues to date have been payments under prior 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 March 31, 2024, we had an accumulated deficit of approximately $1.7 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. and European commercialization of imetelstat in lower-risk MDS.

On March 19, 2024, we entered into an underwriting agreement with Cowen and Company, LLC and and Stifel, Nicolaus & Company, Incorporated relating to the March 2024 public offering of 41,999,998 shares of our common stock and a pre-funded warrant to purchase 8,002,668 shares of our common stock. All of the securities were issued separately. The offering price of the common stock was $3.00 per share. The offering price of the pre-funded warrant was $2.99 per share. The pre-funded warrant has an exercise price of $0.001 per share and may be exercised at any time until it is exercised in full. As of March 31, 2024, the 2024 pre-funded warrant had not been exercised. The net cash proceeds from the March 2024 public offering were approximately $141.0 million, after deducting the underwriting discount and other offering expenses paid by us, and excluding any future proceeds from the exercise of the 2024 pre-funded warrant.

Based on our current operating plan and our assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower-risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of our outstanding warrants, and potential future drawdowns under the Loan Agreement (as defined below), will be sufficient to fund our projected operating requirements into the second quarter of 2026. Our ability to generate revenues from sales of imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner or at all. In addition, 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. Even if imetelstat is approved in lower-risk MDS and commercialized by us in the U.S. in that indication and we are able to drawdown the remaining tranches under the Loan Agreement in full, we will still require substantial additional funding to further advance the imetelstat program, including through the completion of our ongoing clinical trials and any potential future clinical trials, 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 indications we are pursuing or may in the future pursue, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

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 three months ended March 31, 2024, as compared to the critical accounting policies and estimates disclosed in our 2023 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.

Revenue based on sales of imetelstat is dependent on obtaining regulatory approval to commercialize imetelstat in the U.S. and other countries. We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in research and development efforts, including the 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.

Revenues

In connection with the divestiture of our 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 our divested intellectual property.

We recognized royalty revenues of $304,000 in the three months ended March 31, 2024 compared to $21,000 for the same period in 2023. Royalty revenues in 2024 and 2023 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. We expect royalty revenues for the full-year of 2024 to be lower than the full-year of 2023 as a result of reduced royalties from sales of cell-based research products from our divested stem cell assets.

Research and Development Expenses

During the three months ended March 31, 2024 and 2023, 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 months ended March 31, 2024 and 2023, 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 months ended March 31, 2024 and 2023 were as follows:

	Three Months Ended March 31,	
(In thousands)	2024	2023
	(Unaudited)	
Direct external expenses	$ 20,051	$ 17,764
Personnel-related expenses	8,790	7,699
All other expenses	532	1,756
Total research and development expenses	$ 29,373	$ 27,219

The increase in research and development expenses for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects the net result of higher manufacturing costs due to the timing of imetelstat manufacturing batches and increased personnel-related expenses for additional headcount. We expect research and development expenses to remain consistent in the future as we support IMpactMF, IMproveMF and IMpress, as well as the long-term treatment and follow-up of remaining patients in IMerge Phase 3. 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 $27.1 million for the three months ended March 31, 2024, compared to $12.9 million for the same period in 2023. The increase in general and administrative expenses for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects higher personnel-related expenses of approximately $11.9 million in preparation for commercial launch. We expect general and administrative expenses to increase in the future as the imetelstat program matures to prepare for the potential launch and commercialization of imetelstat continue.

Interest Income

Interest income was $4.2 million for the three months ended March 31, 2024,compared to $3.9 million for the same period in 2023. The increase in interest income for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects a larger marketable securities portfolio with the receipt of net cash proceeds from the underwritten offering completed in March 2024, 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 $3.4 million for the three months ended March 31, 2024, compared to $1.9 million for the same period in 2023. The increase in interest expense for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects rising interest rates. Currently, we have $80.0 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 $62,000 for the three months ended March 31, 2024 compared to income of $39,000 for the three months ended March 31, 2023. 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 March 31, 2024, we had cash, restricted cash, cash equivalents, and marketable securities of $465.0 million, compared to $378.1 million at December 31, 2023. The increase in cash, restricted cash, cash equivalents and marketable securities during the three months ended March 31, 2024 was primarily the net result of the receipt of net cash proceeds of $141.0 million from our underwritten offering completed in March 2024.

On March 21, 2024, we completed an underwritten public offering consisting of 41,999,998 shares of our common stock and a pre-funded warrant to purchase 8,002,668 shares of our common stock. All of the securities were issued separately. The offering price of the common stock was $3.00 per share. The offering price of the pre-funded warrant was $2.99 per share. The pre-funded warrant has an exercise price of $0.001 per share and may be exercised at any time until it is exercised in full. As of March 31, 2024, the 2024 pre-funded warrant had not been exercised. The net cash proceeds from this offering were approximately $141.0 million, after deducting the underwriting discount and other offering expenses paid by us, and excluding any future proceeds from the exercise of the pre-funded warrant. 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 offering completed in March 2024.

From January 1, 2024 through March 31, 2024, we received $49,000 in cash proceeds from the exercise of warrants we issued in 2020, covering 37,640 shares of our common stock. As of March 31, 2024, we had warrants remaining from our 2020 issuance covering 2,436,861 shares of our common stock, which if exercised in full for cash, would provide $3.2 million in cash proceeds.

As of March 31, 2024, we had a long-term principal debt balance of $80.0 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. On December 14, 2023, we entered into a third amendment to the Loan Agreement. After giving effect to the third amendment, the aggregate principal amount draw down and remaining available to us under the Loan Agreement remains at $125 million, with such principal being available in a series of tranches, subject to certain terms and conditions. The third amendment also provides that (i) the fourth tranche of the Loan Agreement was increased from $10.0 million to $30.0 million, (ii) the commitment period for the fifth tranche of the Loan Agreement of $20 million, which is available subject to achievement of a regulatory milestone and satisfaction of certain capitalization requirements, was extended through December 15, 2024, (iii) the variable annual interest rate on the outstanding loans has been

decreased to the greater of: (x) 9.0%, or (y) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0%; and (iv) the interest only period of the Term Loan has been extended through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. In connection with the third amendment, on the third amendment effective date, we borrowed and received the entire fourth tranche of the Term Loan in the amount of $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Amended Loan Agreement is $80.0 million. On September 15, 2023, the third tranche of $20.0 million of the Term Loan expired and is no longer available for us, but was added to the fourth tranche as part of the third amendment to the Loan Agreement.

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 November 1, 2023, we entered into an At Market Issuance Sales Agreement, or the 2023 Sales Agreement, with 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 have agreed to pay B. Riley Securities an aggregate commission equal to up to 3.0% of the gross proceeds of the sales under the agreement. To date, no sales of common stock have occurred under the 2023 Sales Agreement.

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 assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower-risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of outstanding warrants, and potential future drawdowns under the Loan Agreement, will be sufficient to fund our projected operating requirements into the second quarter of 2026. Our ability to generate revenues from sales of imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner or at all. In addition, 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. Our ability to drawdown any remaining tranches under the Loan Agreement is subject to our achievement of certain regulatory milestones and satisfaction of certain capitalization requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche. In addition, even if imetelstat is approved in lower-risk MDS and commercialized by us in the U.S. in that indication and we are able to drawdown the remaining tranches under the Loan Agreement in full, we will still require substantial additional funding to further advance the imetelstat program, including through the completion of our ongoing clinical trials and any potential future clinical trials, 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 indications we are pursuing or may pursue, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

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, if approved, 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 non-clinical and 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;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in our current or any potential future clinical trials of imetelstat;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, including with respect to our NDA and MAA submissions for imetelstat in lower-risk MDS;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing, developing, commercializing and marketing imetelstat, including with respect to third-party vendors and service providers and our ability to achieve any meaningful reduction in manufacturing costs, if imetelstat receives future regulatory approval or clearance, in the U.S., EU or other countries;
- 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 and conduct successful strategic partnerships, collaborations and alliances or licensing arrangements with third parties including for the commercialization and marketing of imetelstat in certain global regions;
- 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, as well as higher expenses for travel;
- macroeconomic or other global conditions that may reduce our ability to access equity or debt capital or other financing on preferable terms, which may adversely affect future capital requirements and forecasts; and
- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

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 or other 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 our ability to obtain FDA approval for and successfully commercialize imetelstat in lower-risk MDS, as well as 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 the other risks described in Part II, Item 1A, entitled "Risk Factors."

Additional financing through public or private debt or equity financings, including pursuant to the 2023 Sales Agreement with B. Riley Securities, the remaining tranches of up to $45.0 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, government shutdowns, 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, government shutdowns, 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 2023 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 revenues from potential sales of imetelstat, if approved, potential future sales of our common stock, including under the 2023 Sales Agreement, and potential future drawdowns, if available, of the remaining tranches under the Loan Agreement, will be sufficient to fund our operating plans. Moreover, 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 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 three months ended March 31, 2024 and 2023 was $62.3 million and $46.4 million, respectively. The increase in net cash used in operations for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects commercial preparatory activities, increases in headcount and higher payments to support ongoing clinical trials of imetelstat, to support pre-approval and commercialization efforts.

Cash Flows from Investing Activities

Net cash provided by investing activities was $34.2 million for the three months ended March 31, 2024 and net cash used in investing activities was $178.7 million for the three months ended March 31, 2023. The increase in net cash provided by investing activities for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects a higher rate of purchases than maturities of marketable securities in 2024, as well as decreased purchases of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 and 2023 was $147.8 million and $281.0 million, respectively. Financing activities in 2024 primarily reflect an underwriting offering of 41,999,998 shares of common stock and a pre-funded warrant to purchase 8,002,668 shares of common stock, resulting in net cash proceeds of $141.0 million completed in March 2024.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist of the following operational and manufacturing expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources and may consider additional funding through a combination of additional equity and debt financings, new collaborative arrangements, strategic alliances, or from other sources.

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 2023 Form 10-K and there have been no changes to the contractual terms of our operating leases during the three months ended March 31, 2024.

In the normal course of business, we enter into agreements with CROs for clinical trials and third-party manufacturers for clinical and commercial 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

During the three months ended March 31, 2024, there were no material changes to our quantitative and qualitative disclosures about market risk as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" of our 2023 Form 10-K,

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

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 under the heading "Risk Factors" below, and this summary is qualified in its entirety by that discussion. 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 consider carefully the risks and uncertainties described under the heading "Risk Factors" below.

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 may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could further delay or prevent the commencement and/or completion of clinical trials for imetelstat, delay or prevent its regulatory approval, or limit its commercial potential.
- If IMpactMF fails to demonstrate safety and effectiveness to the satisfaction of the FDA or international regulatory authorities, 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.
- Our clinical trials of imetelstat could be interrupted, delayed, terminated or abandoned for a variety of reasons which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.
- 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.

Risks Related to Regulatory Approval and Commercialization of Imetelstat

- If we are unable to obtain regulatory approval for and successfully commercialize imetelstat, including obtaining and maintaining licenses where required for us to sell imetelstat, or experience significant delays in doing so, our business will be materially harmed.
- If imetelstat is approved for marketing and commercialization and we are unable to establish and maintain effective sales, marketing and distribution capabilities, or obtain coverage and adequate third-party payor reimbursement, we will be unable to successfully commercialize imetelstat.
- Any regulatory approval that we may potentially receive for imetelstat could be subject to restrictions, and we may be subject to penalties or product withdrawal if we fail to comply with regulatory requirements or if we experience unanticipated problems with imetelstat.

Risks Related to Compliance with Healthcare Laws

- 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.

Risks Related to Manufacturing Imetelstat

- We rely on third parties to manufacture and supply imetelstat, and we 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, due to regulatory inspections of those third parties or otherwise.

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 and potential future commercialization of imetelstat, any of which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.
- We currently have no source of product revenue and may never become profitable.

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.

Risks Related to Protecting Our Intellectual Property

- If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat, our competitors could develop and commercialize products similar or identical to imetelstat, and our ability to successfully commercialize imetelstat may be adversely affected.

Risks Related to Competitive Factors

- If our 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.

Risks Related to Information Technology Systems, Data Security and Data Privacy

- 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.
- 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 Our Common Stock and Financial Reporting

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

RISK FACTORS

Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. You should carefully consider the following risk factors, together with the information contained in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission, or SEC, on February 28, 2024, including our consolidated financial statements and the related notes, and our other filings with the SEC, before deciding whether to invest in our common stock. 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.

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. Our ability to develop imetelstat and launch it commercially is subject to significant risks and uncertainties, including, among other things, our ability to:

- receive regulatory approval to commercialize imetelstat in lower-risk MDS from the FDA and European Commission, without the requirement for the conduct and completion of additional pre-approval clinical trials or further analyses, testing or development commitments, if at all, any of which could result in increased costs to us, and delay, limit or preclude our ability to generate revenue;

- generate sufficient safety and efficacy data from the IMpactMF clinical trial 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 when needed in order to enable us to further advance the imetelstat program;
- obtain and maintain required regulatory clearances and approvals to enable continued clinical development, as well as potential commercialization, of imetelstat;
- enter into and maintain commercially reasonable arrangements with third parties to provide services needed to further research and develop, and to potentially commercialize, imetelstat, including maintaining the agreements with our contract research organizations, or CROs, and third-party manufacturers;
- recruit and retain sufficient qualified and experienced personnel to support the development and 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 and relapsed/refractory MF if imetelstat is approved in those indications;
- 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 these 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 planned 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 clinical trials of imetelstat could be interrupted, delayed, terminated or abandoned for a variety of reasons which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.

The conduct and completion of our clinical trials could be interrupted, delayed or abandoned for a variety of reasons, including as a result of clinical trial failures, suspensions, terminations or delays related to:

- patient recruitment, enrollment and retention challenges and operational delays, including in connection with opening new clinical sites, while also competing with clinical trials for other investigational drugs in the same patient population;
- use of trial endpoints such as overall survival, that inherently require prolonged periods of clinical observation or analysis of the resulting data to determine trial outcomes, including the need for a certain number of events, or deaths, to occur in IMpactMF prior to the interim or final analysis in that trial of overall survival;
- obtaining and/or maintaining regulatory clearances in the U.S. or other countries to commence, conduct or modify current or potential future clinical trials of imetelstat, in a timely manner, or at all;
- investigational new drug applications, or INDs, and equivalent submissions in other countries for imetelstat 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;
- 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 data safety review committees, independent data monitoring committees and/or expert committees of current and potential future clinical trials of imetelstat based on emerging data occurring during such clinical trials;
- manufacturing sufficient quantities that meet our specifications, cost and quality requirements, and timelines for 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;
- the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, 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;
- 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 other countries, including our CROs, laboratory service providers and clinical trial sites, on all aspects of clinical development and collaborating with them successfully; and
- third-party clinical contractors, including investigators or our CROs not performing our clinical trials according to our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements, or not performing data collection or analyses in a timely or accurate manner.

Failures or delays with respect to any of these events could adversely affect our ability to conduct or complete the clinical trials being conducted by us or our investigators, 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.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could further delay or prevent the commencement and/or completion of clinical trials for imetelstat, delay or prevent its regulatory approval, or limit its commercial potential.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events affecting its safety or efficacy that could interrupt, further delay or halt current or potential future clinical trials of imetelstat, as well as our 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;
- bleeding events, with or without thrombocytopenia, including Grade 3/4 bleeding events;
- febrile neutropenia;
- hepatotoxicity and liver function test abnormalities, as well as hepatic failure;
- gastrointestinal events;
- infection events, with or without neutropenia, including Grade 3/4 infection events;
- muscular and joint pain;
- fatigue;
- headache; and
- infusion-related reactions.

If patients in any clinical trials of imetelstat or our expanded access program 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 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 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, one or more of 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 is not available or, if available, 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;
- additional, unexpected clinical trials or non-clinical studies may be required to be conducted; or
- imetelstat may not receive or maintain any regulatory authorizations, including for commercial use.

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 ongoing clinical trials and in our expanded access program continue to receive imetelstat treatment, additional or more severe toxicities or safety issues may be observed, and 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.

The occurrence of any of these events could interrupt, further delay, or halt, any development, and as a result, impact or preclude the potential regulatory approval and 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.

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.

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 clinical 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.

Further, 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 will be successful. Later stage clinical trials of imetelstat may fail to show an acceptable 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 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 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.

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, 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 overall survival 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. 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, prevent potential regulatory approval and 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.

Further, preliminary data are 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. 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 and/or potential regulatory approval 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.

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. 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 in an adverse manner, including with respect to overall survival. 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.

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 or investigator-sponsored 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. 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, 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 regulatory 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.

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.

Switching or adding CROs, investigators, vendors 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. Although we carefully manage our relationships with our CROs, investigators, vendors 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 do 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-risk assessment that could materially and adversely impact our ongoing clinical trials, our imetelstat development program as a whole, and/or the prospect for approval for imetelstat.

We do 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 do 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, limit or preclude the further clinical development or marketing approval of imetelstat in any indication, including lower-risk MDS. 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 any of our clinical trials. 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, would delay or preclude any marketing approvals for imetelstat and could cause us to discontinue our development of imetelstat, any of 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, halt or increase the costs of our activities and plans for clinical development and commercialization;
- significantly harm the commercial potential of imetelstat;
- diminish any competitive advantages that may have been available to us; or
- delay or preclude any revenue we may receive from the future commercialization of imetelstat, if any.

The occurrence of any such event would significantly harm our business, business prospects, including any potential commercialization of imetelstat, and the future value of imetelstat and might cause us to cease operations.

If we are unable to obtain regulatory approval for and successfully commercialize imetelstat, or experience significant delays in doing so, our business will be severely 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 to the satisfaction of such regulatory authorities 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. Although the FDA has accepted for standard review our 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, and the EMA has validated our MAA for imetelstat for the same proposed indication, there can be no assurance that we will receive regulatory approval by the FDA or the European Commission for the commercialization of imetelstat in a timely manner or at all. Further, because non-clinical and clinical data are often susceptible to varying interpretations and analyses, regulatory authorities, including the FDA and EMA, may disagree with our interpretation of the data and may require additional clinical testing and/or further analyses from completed clinical or non-clinical trials 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. For example, in connection with the anticipated FDA oncology drug advisory committee meeting concerning the NDA for imetelstat in lower-risk MDS, the FDA will release its review of our data, which may differ, perhaps materially, from our interpretation of our data. Additionally, many sponsors experience volatility in the stock price surrounding the advisory committee's discussion and vote, even though FDA is not obligated to follow the advisory committee's input.

On March 14, 2024, the FDA convened its Oncologic Drugs Advisory Committee, or ODAC, to discuss our NDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with IPSS low-to intermediate-1 risk MDS who have failed to respond or have lost response to or are ineligible for ESAs. The ODAC discussed the efficacy of imetelstat in this proposed indication, based on the results of our IMerge Phase 3 clinical trial, considering the safety profile, and voted 12 to 2 that the benefits of imetelstat outweigh its risks in this proposed indication.

The FDA is not bound by the views or recommendations of its advisory committees, including the ODAC. Accordingly, notwithstanding the ODAC discussion and vote, the FDA may delay the approval of or ultimately determine not to approve our NDA for imetelstat for a variety of reasons, including due to their perception, evaluation, inspection or analysis of imetelstat's product quality, clinical data and outcomes, nonclinical data, safety risks, our or our third party vendors' compliance, or other considerations that are or may be important to the FDA's review of our NDA. For example, the FDA raised questions at the ODAC about the hazard ratio for the OS data from our IMerge Phase 3 trial, and while we believe that the data to date adequately demonstrate that there is no survival detriment to these patients, the FDA could continue to raise questions and/or seek additional information about the OS data as part of its ongoing review that could influence its review. Moreover, while we have received comments from the FDA on our label, the FDA has not yet completed its review of the clinical, non-clinical and CMC portions of our NDA or scheduled any inspections of our contract manufacturers. Accordingly, while the PDUFA target action date for our NDA is June 16, 2024, there can be no assurance as to the timing or outcome of FDA's ultimate decision on our NDA. The FDA may deny approval of the NDA altogether, or may require additional testing or data before our NDA may be approved. In addition, the FDA may approve our NDA but limit imetelstat's use to certain patients or under specified conditions resulting in a narrower or more restrictive label than we expect, or could require costly post-approval commitments or requirements. Any such action by the FDA could severely and adversely affect our business and business prospects, including the potential commercialization of imetelstat, and might have a material adverse effect on our operations.

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.

Any of these events may result in a failure to further develop, obtain regulatory approval for or commercialize imetelstat, which would severely and adversely affect our business and business prospects, and might cause us to cease operations.

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 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.

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;
- rejection by the FDA of foreign data included in the NDA and the non-applicability of this data to the U.S. population and U.S. medical practice;
- 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, European Commission, or similar international health authorities;
- a determination by the FDA, EMA, 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;
- the failure of the quality or stability of imetelstat to meet acceptable regulatory standards;
- the FDA, EMA, the competent authorities of the individual EU Member States 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, GCP, or other applicable regulatory and other requirements to the satisfaction of the FDA, the competent authorities of the individual EU Member States or similar international regulatory authorities; or
- 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.

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.

Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that increase our costs or render imetelstat not commercially viable, which would harm imetelstat's future value and our business and business prospects.

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, although we believe that imetelstat could demonstrate disease-modifying properties, the indications we are pursuing with the FDA and EMA for the MDS population do not include disease-modifying claims, and 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, or to provide information if requested by regulatory authorities, 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, including the NDA for imetelstat in lower-risk MDS.

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.

Any regulatory approval that we may potentially receive for imetelstat could be subject to restrictions, and we may be subject to penalties or product withdrawal if we fail to comply with regulatory requirements or if we experience unanticipated problems with imetelstat.

Any regulatory approval that we may potentially receive for imetelstat could be subject to restrictions or conditions of approval that may require potentially costly post-marketing clinical trials or surveillance to monitor safety and efficacy of the drug candidate. In addition, imetelstat and the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities related to imetelstat will be subject to continual requirements of, and review by, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, current Good Manufacturing Practice (cGMP) requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding promotional interactions with healthcare professionals.

Failure to comply with these regulatory requirements or later discovery of previously unknown problems with imetelstat, or our manufacturers, or manufacturing processes for imetelstat, may result in actions such as restrictions on imetelstat manufacturing, distribution or use; restrictions on labeling or marketing; requirements to conduct post-marketing studies or clinical trials; warning letters, withdrawal of imetelstat from the market; refusal to approve our pending regulatory applications, or any supplements to approved applications that we might submit; recalls; suspension or termination of ongoing clinical trials; fines, restitutions or disgorgement of profits or revenues; refusal to permit the import or export of imetelstat; product seizure or detentions; injunctions or the imposition of civil or criminal penalties; and adverse publicity.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We also cannot predict the likelihood, nature, or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad.

If we are unable to fulfill any potential post approval commitments that may be applied to the approval and commercialization of imetelstat by any regulatory authority, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies,there may be a negative impact to our business and continued regulatory approval of imetelstat. Under such circumstances, we or our respective clinical investigators may be subject to the actions listed above, including losing marketing approval for imetelstat, which would severely and adversely affect 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 and maintain effective 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 need to complete substantial preparations to be ready for any potential future commercialization of imetelstat, and we are in the process of establishing sales, marketing and distribution capabilities. As a company, we have no experience in selling and marketing products. To advance imetelstat to potential marketing approval and commercialization, we will be required to complete our commercialization preparatory activities, including obtaining and maintaining state licenses where required for us to sell imetelstat, and continue to incur related expenses, before we obtain any marketing approval. These activities include, among other things, the development of an in-house marketing and sales force, which will continue to 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. 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.

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 and maintain effective 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 we do not obtain acceptable prices or adequate reimbursement for imetelstat, 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. The Inflation Reduction Act of 2022, or the Inflation Reduction Act, includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government, which may ultimately have a negative effect on the pricing for imetelstat, should it receive regulatory approval. However, the Medicare drug pricing negotiation program provisions of the law are currently subject to legal challenges. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the U.S. 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 European Commission 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 the European Commission 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, or failure to agree to and complete any agreed upon pediatric plan, would lead to the inability to obtain or the loss of such regulatory exclusivity.

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 the European Commission can subsequently approve a different drug with the same active moiety for the same condition, if the FDA or the European Commission 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.

Although imetelstat has received Fast Track designation by the FDA for MDS and MF, this 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.

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, including equivalent penalties or commercial limitations imposed by foreign regulatory authorities, 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.

We are seeking regulatory approval to market imetelstat in Europe, and as a result, we may experience additional risks related to marketing outside of the U.S. that would materially adversely affect our business.

We are seeking regulatory approval to market imetelstat in Europe, and may be subject to additional risks, including, if regulatory approval is obtained from the European Commission, risks related to operating outside of the U.S., such as:

- European Commission and other 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;

- EMA and other 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 EMA or other regulatory authorities outside of the U.S. may significantly change in a manner rendering our clinical data insufficient for potential approval;
- 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 and 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.;
- 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.

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.

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, and Transparency Laws and Regulations” in our 2023 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 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;
- 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 our clinical trials, our expanded access program, and potential future commercial uses, which would delay or result in a cessation of such current or potential future clinical trials, potential regulatory approvals and commercialization of imetelstat and cause financial and reputational harm.

If third parties that manufacture imetelstat fail to perform as needed, 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. 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:

- the inability to execute timely contracts with third-party manufacturers and suppliers on acceptable terms, or at all;
- 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;
- 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 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, including foreign governing 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, 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.

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 and potential future commercialization of imetelstat, 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 March 31, 2024, we had approximately $465.0 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities. Based on our current operating plan and our assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower-risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of outstanding warrants, and potential future drawdowns under the Loan Agreement, will be sufficient to fund our projected operating requirements into the second quarter of 2026. Our ability to generate revenues from sales of imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner or at all. In addition, 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. Our ability to drawdown any remaining tranches under the Loan Agreement is subject to our achievement of certain regulatory milestones and satisfaction of certain capitalization requirements, as well as approval by an investment committee comprised of Hercules and SVB, for the final $25.0 million tranche. In addition, even if imetelstat is approved in lower-risk MDS and commercialized by us in the U.S. in that indication and we are able to drawdown the remaining tranches under the Loan Agreement in

full, we will still require substantial additional funding to further advance the imetelstat program, including through the completion of our ongoing clinical trials and any potential future clinical trials, 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 indications we are pursuing or may pursue, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

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, if approved, 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 non-clinical and 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;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in our current or any potential future clinical trials of imetelstat;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, including with respect to our NDA and MAA submissions for imetelstat in lower-risk MDS;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing, developing, commercializing and marketing imetelstat, including with respect to third-party vendors and service providers and our ability to achieve any meaningful reduction in manufacturing costs, if imetelstat receives future regulatory approval or clearance, in the U.S., EU or other countries;
- 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 and conduct successful strategic partnerships, collaborations and alliances or licensing arrangements with third parties, including for the commercialization and marketing of imetelstat in certain global regions;
- 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, as well as higher expenses for travel;
- macroeconomic or other global conditions that may reduce our ability to access equity or debt capital or other financing on preferable terms, which may adversely affect future capital requirements and forecasts; and
- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

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 our clinical trials, regulatory developments, or the other risks described in this section.

Additional financing through public or private debt or equity financings, including pursuant to the 2023 Sales Agreement with B. Riley Securities, Inc., the remaining tranches of up to $45.0 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, government shutdowns, 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, government shutdowns, 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 2023 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 revenues from potential sales of imetelstat, if approved, potential future sales of our common stock, including under the 2023 Sales Agreement, and potential future drawdowns, if available, of the remaining tranches under the Loan Agreement, will be sufficient to fund our operating plans. Moreover, 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 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 March 31, 2024, our accumulated deficit was approximately $1.7 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 human telomerase reverse transcriptase, or 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. 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.

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 March 31, 2024, the total outstanding principal amount under the Loan Agreement was $80.0 million. The tranches for the remaining $45.0 million available to us under the Loan Agreement are as follows: (a) the first remaining tranche of $20.0 million is available until December 15, 2024, subject to the achievement of a certain regulatory milestone, and satisfaction of certain capitalization requirements; and (b) the second 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 regulatory milestone and satisfaction of certain capitalization and other requirements, we will not be eligible to draw funds under the first remaining tranche. If we do not receive investment committee approval, we will not be eligible to draw funds under the second 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 commercial revenues or 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.

All obligations under the Loan Agreement are secured by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge. Further, the terms of the Loan Agreement place restrictions on our operating and financial flexibility, and limit or prohibit our ability to dispose of certain assets, change our line of business, and engage in other significant transactions. 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.

In addition, we may borrow additional capital in the future to fund imetelstat development and our future growth, including pursuant to the Loan Agreement or potentially pursuant to new arrangements with different lenders. 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, including that we must maintain a minimum cash balance. 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 or to comply with certain covenants in the Loan Agreement could result in an event of default, the occurrence and continuance of which provide Hercules and SVB with the right to demand immediate repayment of all outstanding obligations 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, both in the U.S. and in other countries, 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, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications. Failure to respond to official actions within prescribed time limits, and nonpayment of fees, for example, maintenance fees, renewal fees, and annuity fees could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the jurisdiction. 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 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 U.S. patent 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.

In Europe and other countries, our composition of matter patent coverage expires in September 2024, and our method of treatment patent rights for MDS and MF expire in November 2033. Our method of treatment patents may be eligible for patent term extension under a Supplementary Protection Certificate, or SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation, upon receipt of drug product approval, such as, for example, our method of treatment patent for MDS. Since we do not expect to receive marketing approval and submit a request for an SPC before September 2024, our European composition of matter patent will expire in countries of the European Economic Area, or EEA, and we must rely on regulatory exclusivity and our method of treatment patents.

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 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.

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 certain EU states. As of June 1, 2023, all European patents, including those issued prior to ratification, by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions and are 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. 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.

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.

We may not be able to protect our intellectual property rights in the U.S or worldwide and 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 our U.S. patents and those we have licensed and may license from others, even those issued before March 16, 2013. 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, such as entities associated with hedge funds, to challenge the validity of certain patents. 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.

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 in jurisdictions outside the U.S. could result in substantial costs and divert our efforts and attention from other aspects of our business, and could put our patents at risk of being invalidated or interpreted narrowly.

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. Challenges to our patents through these procedures would be extremely expensive and time-consuming, even if the outcome was favorable to us. An adverse outcome in a patent dispute could severely harm our ability to further develop or commercialize imetelstat, or could otherwise have a material adverse effect on our business, and might cause us to cease operations, by:

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

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

The commercial success of imetelstat will depend upon our ability to research, develop, manufacture, market and sell imetelstat without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and many pharmaceutical companies, including potential competitors, have substantial patent portfolios. 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 and maintain such registrations could adversely affect our business.

We have secured a global trademark for a commercial trade name for imetelstat. During trademark registration proceedings, we may receive rejections or fail to maintain such registrations. 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. 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. Our product trademark is approved by the EMA and provisionally approved by the FDA. If the FDA or EMA should reject the trademark, 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, compliance, 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 the potential approval and 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.

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. and the EU. We may seek a collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat, especially in the EU and other regions 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 marketing approvals of imetelstat in lower-risk MDS in the U.S. and/or EU and in reporting 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.

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.

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 and costs 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;
- 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; and
- workforce uncertainty in countries where labor unrest is more common than in the U.S.

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 products. We may become subject to product liability claims or claims related to clinical trial conduct or the potential commercialization of imetelstat, if any, 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 product liability and clinical trial liability insurance, and we may not be able to maintain this type of insurance for the potential commercialization of imetelstat, if any, or 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 potential commercialization of imetelstat, 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.

In the past, we and certain of our officers have been named as defendants in securities class action lawsuits and shareholder derivative lawsuits. Potential similar or related lawsuits that may be filed in the future, 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. Any such lawsuits, or 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 activities. In 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, were consolidated by the Court. In September 2022, the parties agreed to a settlement and entered into a Stipulation and Agreement of Settlement, which was subject to court approval. The Court granted final approval of the settlement on September 28, 2023 and final judgment was entered on October 3, 2023. In 2020 and 2021, seven shareholder derivative actions were filed in a number of courts, naming as defendants certain of our then current officers and certain of our then current and former members of our board. On May 17, 2023, the Delaware Court of Chancery approved a settlement of the derivative case pending before it, and the case was dismissed with prejudice. Subsequently, each of the remaining derivative cases were dismissed with prejudice.

While we have settled these lawsuits, it is possible that additional lawsuits might be filed, or allegations might be 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 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. 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 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.

A decision adverse to our interests 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, 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 our 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; 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. For a description of the competition that imetelstat may face in our lead indications of lower-risk MDS and relapsed/refractory MF, see Item 1, "Business - Competition" in our 2023 Form 10-K.

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.

Competitors may develop more commercially desirable or affordable products than imetelstat, or achieve earlier or longer patent protection or product commercialization than we may be able to achieve with 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. 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 U.S. or international 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 countries 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, 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.

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 of 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 both in the U.S. and outside 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. For details regarding these legislative and regulatory changes and proposed changes regarding the healthcare system that may affect our ability to operate, see Item 1 “Business - Healthcare Reform” in our 2023 Form 10-K.

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.

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 or actions; litigation; fines and penalties; a disruption of our business operations, including 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) collect, receive, store, 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 or monitor third parties' 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. Most of our employees work remotely, resulting in increased 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 and while in transit and in public locations. Additionally, the prevalent use of mobile devices that access our sensitive information increases the risk of security incidents.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Our information technology systems, including in our remote work environment, and those of the third parties upon which we rely, have been in the past and may continue to be vulnerable to evolving threats. These threats are prevalent, continue to increase, and come from a variety of sources such as traditional "hackers," threat actors, ""hacktivist," organized criminal threats actors, 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, telecommunication and electrical failures and attacks enhanced or facilitated by artificial intelligence, or AI, and other similar threats. 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. For example, in February 2024, a service provider that processes clinical trial data experienced a security incident that resulted in certain of the service provider's information systems being unavailable for a limited period of time. Based on the service provider's forensic investigation findings that were shared with us, we believe that this incident did not have a material impact on us, our clinical trials or clinical trial participants. As another example, in March 2024, we learned about another security incident, involving another service provider, that processes personnel data for our limited number of UK personnel and directors of Geron UK Ltd. Following the service provider's forensic investigation, the service provider informed us that it did not determine the specific data involved or the incident's impact. While we believe that this incident did not have a material impact on us, out of an abundance of caution, we submitted a notification to the UK Information Commissioner's Office and notified potentially affected personnel and directors of the incident. Any of these or similar incidents or 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 security incidents could be significant, including potentially requiring us to modify our business, and while we have implemented security measures, policies and procedures designed to protect our information technology systems and to identify and remediate vulnerabilities, such measures may not be fully implemented, complied with or successful in protecting our systems and information. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. 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. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Unremediated high risk or critical vulnerabilities pose material risks to our business.

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, financial loss, and other harms. In addition, such a breach may require public

notification of the breach. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

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, industry standards, 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 or actions; litigation; fines and penalties; disruptions of 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, clinical trial participant data, and other sensitive third-party data. We are therefore subject to or affected by numerous data privacy and security obligations, such as federal, state, local and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations governing the processing of personal data. 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. 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 in the event of violations.

In addition, we may be unable to transfer personal data from the EEA and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. The EEA and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the 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, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 (such as Europe) 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 EEA regulators have prevented companies from transferring personal data out of the EEA 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 data privacy and security 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, as amended by the California Privacy Rights Act of 2020, or CPRA, collectively 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. 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. In addition, the CPRA establishes a 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 and security 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 became effective in 2023. If we become subject to new data privacy and security 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.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

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.

It is possible that, in the future, we may fail or be perceived to have failed to comply with applicable data privacy and security obligations. Moreover, despite our best compliance 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. If we or the third parties on which we rely 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; litigation; 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, clinical trials; 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.

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 April 1, 2014 and March 31, 2024, our stock has traded as high as $6.38 per share and as low as $0.89 per share. Between April 1, 2023 and March 31, 2024, the price has ranged between a high of $3.69 per share and a low of $1.74 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- announcements regarding the 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 and commercialization 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, as well as for our 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;
- our ability to obtain additional capital when needed to further advance the imetelstat program;
- changes in laws or regulations applicable to imetelstat, including but not limited to clinical trial requirements for approval or other regulatory developments related to imetelstat;
- 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;
- the size and growth of the market for our lead imetelstat indications of 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, enforce and defend 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;
- the demand in the market for our common stock;
- 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, government shutdowns, 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;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of commentary, articles or research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage, by securities analysts, bloggers, news media or other third parties;
- large stockholders increasing or exiting their position in our common stock or an increase in the short interest in our common stock;
- announcements of or developments concerning any 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.”

Provisions in our charter, bylaws and Delaware law may inhibit potential acquisition bids for us, which may adversely affect the market price of our common stock and/or 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.

In addition, 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.

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 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.

The exclusive forum provisions in our amended and restated bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or any of our directors, officers, or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

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 (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for:

- any derivative claim or cause of action or proceeding brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees, or our stockholders, to us or to our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, or our stockholders, arising pursuant to any provision of the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws;
- any claim or cause of action as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any claim or cause of action against us or any of our current or former directors, officers or other employees, or our stockholders, governed by the internal affairs doctrine or otherwise related to our internal affairs.

In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act of 1933, as amended, or the Securities Act, or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. The application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions, and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such an instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions, which costs could be borne by stockholders, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to the exclusive forum provisions in our amended and restated bylaws, including the Federal Forum Provision. These provisions could limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or our stockholders or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Furthermore, 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.

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.

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

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

The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops, including as we prepare to potentially launch and commercialize imetelstat. 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.

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. 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 Inflation Reduction Act of 2022 included provisions that impacted 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 is imposed on the corporation repurchasing such stock.

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 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. For example, under the Tax Cuts and Jobs Act of 2017, effective January 1, 2022, research and experimental expenses must be capitalized for tax purposes and amortized over five years for research activities conducted in the United States and over fifteen years for research activities conducted outside the United States, instead of being deducted in the year incurred. Unless this provision is modified or repealed by Congress, or the U.S. Department of the Treasury issues regulations narrowing its application, our future tax obligations could be increased, which could harm our operating results. The impact of this provision will depend on multiple factors, including the amount of research and experimental expenses we incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and experimental activities inside or outside the United States.

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. In addition, under current U.S. federal income tax law, 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 is limited to 80% of taxable income. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, 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, and 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. It is also uncertain if and to what extent various states will conform to current U.S. federal income tax law.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Trading Arrangements

During our last fiscal quarter, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of our securities set forth in the table below.

			Character of Trading Arrangement			
Name and Title	**Action**	**Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares to be Sold**	**Expiration Date**
V. Bryan Lawlis, Ph.D., Director	Adoption	February 14, 2024	X		35,000[1]	May 20, 2024
John A. Scarlett, M.D., Chairman of the Board, President and Chief Executive Officer	Adoption	February 20, 2024	X		600,000[2]	February 20, 2025
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.						
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.						

[1] Includes up to 35,000 shares subject to stock options previously granted by Geron to Dr. Lawlis.

[2] Includes up to 600,000 shares subject to stock options previously granted by Geron to Dr. Scarlett.

ITEM 6. EXHIBITS

		Incorporation by Reference			
Exhibit Number	**Description**	**Exhibit Number**	**Filing**	**Filing Date**	**File No.**
3.1	Certificate of Amendment of the Restated Certificate of Incorporation*	3.1	8-K	June 2, 2023	000-20859
3.2	Amended and Restated Bylaws of Registrant*	3.1	8-K	December 15, 2023	000-20859
4.1	Form of Pre-Funded Warrant to Purchase Common Stock	4.1	8-K	March 20, 2024	000-20859
10.1	At Market Issuance Sales Agreement, dated November 1, 2023, by and between Registrant and B. Riley Securities, Inc.*	10.1	8-K	November 2, 2023	000-20859
31.1+	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated May 2, 2024.				
31.2+	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated May 2, 2024.				
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 2, 2024.**				
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 2, 2024.**				
101	The following materials from the Registrant's March 31, 2024 Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Condensed Consolidated Balance Sheets as of March 31, 2024 and December 31, 2023, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2024 and 2023, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2024 and 2023, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2024 and 2023 and (v) Notes to Condensed Consolidated Financial Statements.				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

\+ Filed herewith.

* Included herein solely for purposes of correcting an incorrect hyperlink in the Exhibit Index to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

** 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: May 2, 2024

By: /s/ MICHELLE ROBERTSON

MICHELLE ROBERTSON

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

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: May 2, 2024

/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, Michelle Robertson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2024

/s/ MICHELLE ROBERTSON
MICHELLE ROBERTSON
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 March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: May 2, 2024

/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 March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: May 2, 2024

/s/ MICHELLE ROBERTSON

MICHELLE ROBERTSON

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.