UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 November 4, 2024:**
Common Stock, $0.001 par value	604,501,016 shares

GERON CORPORATION
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2024

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,344	$ 70,023
Restricted cash	1,854	1,115
Marketable securities	279,430	263,676
Accounts receivable, net	28,007	—
Interest and other receivables	2,082	1,655
Inventory	20,283	—
Prepaid expenses and other current assets	6,057	4,879
Total current assets	398,057	341,348
Noncurrent marketable securities	37,312	43,298
Property and equipment, net	1,595	1,177
Operating leases, right-of-use assets	3,055	3,556
Deposits and other assets	4,931	4,697
	$ 444,950	$ 394,076
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,734	$ 6,161
Accrued compensation and benefits	15,180	13,759
Operating lease liabilities	968	949
Debt	71,562	46,893
Accrued liabilities	36,489	40,308
Total current liabilities	137,933	108,070
Noncurrent operating lease liabilities	2,458	3,006
Noncurrent debt	12,275	35,051
Commitments and contingencies		
Stockholders' equity:		
Common stock	603	545
Additional paid-in capital	2,037,653	1,844,988
Accumulated deficit	(1,746,989)	(1,597,769)
Accumulated other comprehensive loss	1,017	185
Total stockholders' equity	292,284	247,949
	$ 444,950	$ 394,076

See accompanying notes.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	28,209	—	28,989	—
Royalties	62	164	468	214
Total revenues	$ 28,271	$ 164	$ 29,457	$ 214
Operating expenses:				
Cost of goods sold	456	—	473	—
Research and development	20,153	29,426	80,305	92,135
Selling, general and administrative	35,877	18,350	102,361	47,734
Total operating expenses	56,486	47,776	183,139	139,869
Loss from operations	(28,215)	(47,612)	(153,682)	(139,655)
Interest income	4,877	4,965	14,448	13,556
Interest expense	(3,046)	(2,066)	(9,798)	(5,991)
Other income and (expense), net	(63)	(92)	(188)	(64)
Net loss	$ (26,447)	$ (44,805)	$ (149,220)	$ (132,154)
Basic and diluted net loss per share	$ (0.04)	$ (0.08)	$ (0.23)	$ (0.23)
Shares used in computing basic and diluted net loss per share	662,158,182	579,508,305	639,933,612	562,445,577

See accompanying notes.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Net loss	$ (26,447)	$ (44,805)	$ (149,220)	$ (132,154)
Net unrealized gain/(loss) on marketable securities	1,507	(11)	816	(722)
Foreign currency translation adjustments	48	6	17	(9)
Comprehensive loss	$ (24,892)	$ (44,810)	$ (148,387)	$ (132,885)

See accompanying notes.

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

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Gain (Loss)	Equity
Balance at December 31, 2023	544,912,215	$ 545	$ 1,844,988	$ (1,597,769)	$ 185	$ 247,949
Net loss	—	—	—	(55,390)	—	(55,390)
Other comprehensive loss	—	—	—	—	(448)	(448)
Foreign currency translation adjustment	—	—	—	—	(10)	(10)
Issuances 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
Issuances of common stock in connection with exercise of warrants	37,640	—	49	—	—	49
Issuances of common stock under equity plans	4,211,493	4	6,745	—	—	6,749
Stock-based compensation related to issuances of common stock and options for services	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
Net loss	—	—	—	(67,383)	—	(67,383)
Other comprehensive loss	—	—	—	—	(243)	(243)
Foreign currency translation adjustment	—	—	—	—	(21)	(21)
Offering expenses	—	—	(271)	—	—	(271)
Issuances of common stock in connection with exercise of warrants	281,211	—	365	—	—	365
Stock-based compensation related to issuances of common stock and options in exchange for services	1,916	1	15	—	—	16
Issuances of common stock under equity plans	9,400,121	9	16,364	—	—	16,373
Stock-based compensation for equity-based awards to employees and directors	—	—	12,625	—	—	12,625
Employee stock purchases	201,052	—	366	—	—	366
Balance at June 30, 2024	601,048,108	$ 601	$ 2,027,173	$ (1,720,542)	$ (537)	$ 306,695
Net loss	—	—	—	(26,447)	—	(26,447)
Other comprehensive income	—	—	—	—	1,507	1,507
Foreign currency translation adjustment	—	—	—	—	47	47
Issuance of common stock in connection with exercise of warrants	3,080	—	4	—	—	4
Stock-based compensation related to issuance of common stock and options in exchange for services	1,767	—	14	—	—	14
Issuance of common stock under equity plans	2,049,118	2	3,572	—	—	3,574
Stock-based compensation for equity-based awards to employees and directors	—	—	6,890	—	—	6,890
Balance at September 30, 2024	603,102,073	$ 603	$ 2,037,653	$ (1,746,989)	$ 1,017	$ 292,284

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

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Gain (Loss)	Equity
Balance at December 31, 2022	390,262,524	$ 390	$ 1,493,469	$ (1,413,642)	$ (219)	$ 79,998
Net loss	—	—	—	(38,122)	—	(38,122)
Other comprehensive income	—	—	—	—	75	75
Foreign currency translation adjustment	—	—	—	—	(16)	(16)
Issuance of common stock and pre-funded warrant to purchase common stock in public offering, net of issuance costs of $14,507	68,007,741	68	213,269	—	—	213,337
Issuance of common stock in connection with exercise of warrants	44,983,193	45	59,790	—	—	59,835
Stock-based compensation related to issuance of common stock and options in exchange for services	9,360	1	111	—	—	112
Issuance of common stock under equity plans	5,469,028	5	7,870	—	—	7,875
Stock-based compensation for equity-based awards to employees and directors	—	—	2,961	—	—	2,961
Balance at March 31, 2023	508,731,846	$ 509	$ 1,777,470	$ (1,451,764)	$ (160)	$ 326,055
Net loss	—	—	—	(49,227)	—	(49,227)
Other comprehensive loss	—	—	—	—	(786)	(786)
Foreign currency translation adjustment	—	—	—	—	1	1
Issuance of common stock in connection with exercise of warrants	12,842,857	13	17,754	—	—	17,767
Stock-based compensation related to issuances of common stock and options in exchange for services	6,327	—	99	—	—	99
Issuance of common stock under equity plans	361,074	—	573	—	—	573
Stock-based compensation for equity-based awards to employees and directors	—	—	3,945	—	—	3,945
Balance at June 30, 2023	521,942,104	$ 522	$ 1,799,841	$ (1,500,991)	$ (945)	$ 298,427
Net loss	—	—	—	(44,805)	—	(44,805)
Other comprehensive loss	—	—	—	—	(11)	(11)
Foreign currency translation adjustment	—	—	—	—	6	6
Stock-based compensation related to issuance of common stock and options in exchange for services	19,523,808	19	28,290	—	—	28,309
Issuance of common stock in connection with exercise of warrants	9,581	—	440			440
Issuances of common stock under equity plans	1,004,173	1	1,043	—	—	1,044
Stock-based compensation for equity-based awards to employees and directors	—	—	7,204	—	—	7,204
Balance at September 30, 2023	542,479,666	$ 542	$ 1,836,818	$ (1,545,796)	$ (950)	$ 290,614

See accompanying notes.

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (149,220)	$ (132,154)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	404	328
Accretion and amortization on investments, net	(7,281)	(8,335)
Amortization of debt issuance costs/debt discounts	1,894	742
Stock-based compensation for services by non-employees	122	650
Stock-based compensation for employees and directors	24,392	14,110
Amortization of right-of-use assets	501	464
Changes in assets and liabilities:		
Inventory	(20,283)	—
Accounts receivable, net	(28,007)	—
Prepaid expenses, interest receivable and other assets	(1,842)	(13,694)
Current and noncurrent liabilities	4,647	11,084
Net cash used in operating activities	(174,673)	(126,805)
Cash flows from investing activities:		
Purchases of property and equipment	(821)	(766)
Purchases of marketable securities	(292,141)	(459,727)
Proceeds from maturities of marketable securities	290,469	232,602
Net cash used in investing activities	(2,493)	(227,891)
Cash flows from financing activities:		
Proceeds from issuances of common stock from equity plans	26,696	9,492
Proceeds from issuance of common stock from offering and pre-funded warrant, net of paid issuance costs	140,729	213,337
Proceeds from exercise of warrants	418	105,912
Proceeds from employee stock purchase plan	366	—
Net cash provided by financing activities	168,209	328,741
Effect of exchange rates on cash, cash equivalents and restricted cash	17	(9)
Net increase in cash, cash equivalents and restricted cash	(8,940)	(25,964)
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	$ 62,198	$ 31,245

See accompanying notes.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The terms “Geron”, the “Company”, “we” and “us” as used in this Report refer to Geron Corporation and its wholly-owned subsidiaries, Geron UK Limited, or Geron UK, a United Kingdom company, and Geron Netherlands B.V., or Geron Netherlands, a Netherlands company. Geron UK was incorporated in September 2021, and its operations commenced in January 2022. Geron Netherlands was incorporated in February 2023, and its operations commenced in June 2023.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by United States, or U.S., generally accepted accounting principles, or GAAP, for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024 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 2023 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 September 30, 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 and nine months ended September 30, 2024 and 2023, the diluted net loss per share calculation excludes potential dilutive securities of 76,588,779 and 77,651,673, 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.

Accounts Receivable

In general, accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts, product returns, and chargebacks. Accounts receivable are stated net of an allowance that reflects our current estimate of credit losses expected to occur over the life of the receivable. In developing our allowance for expected credit losses, we use assumptions to capture the risk of loss, even if remote, based on a number of factors including existing contractual payment terms, individual customer circumstances, historical payment patterns of our customers, a review of the local economic environment and its potential impact on expected future customer payment patterns. The payment terms on our trade receivables are relatively short. As a result, our collection risk is mitigated to a certain extent by the fact that sales are collected in a relatively short period of time, allowing for the ability to reduce exposure on defaults if collection issues are identified. We update our allowance as necessary to reflect expected credit losses over the remaining lives of the accounts receivable for outstanding trade receivables that are past due, have known disputes or have experienced any negative credit events that may result in future collectability issues. We do not currently expect our current or future exposures to credit losses to have a significant impact on us. The estimated allowance for expected credit losses was not material as of September 30, 2024, nor were the changes to the allowance during any of the periods presented.

Inventory

Inventory is recorded at the lower of cost or net realized value, with cost determined under the weighted average method. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, salaries, wages and stock-based compensation for personnel involved in the manufacturing process, and indirect overhead costs. We periodically review our inventories to identify obsolete, slow moving, excess or otherwise unsaleable items. If obsolete, slow moving, excess or unsaleable items are observed and there are no alternate uses for the inventory, we record a write-down to net realizable value. The determination of net realizable value requires judgment including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions and potential product obsolescence, among others. Prior to regulatory approval, we expensed costs associated with the manufacture of a product candidate to research and development expense unless we are reasonably certain such costs have future commercial use and net realizable value. Since we consider attaining regulatory approval of a product candidate to be highly uncertain and difficult to predict, we expect only in rare instances that pre-launch inventory will be capitalized, if at all.

We began capitalizing inventory related to RYTELO in the quarter ended June 30, 2024, as we received approval of RYTELO on June 6, 2024, and the related costs were expected to be recoverable through the commercialization of RYTELO.

Cost of Goods Sold

Cost of goods sold includes the cost of producing and distributing inventories that are related to product revenue during the respective period, including salary related and stock-based compensation expense for employees involved with production and distribution, freight, and indirect overhead costs. Cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. For the three and nine months ended September 30, 2024, other than packaging costs, substantially all of our RYTELO inventory sold had a zero-cost basis as it was recorded as research and development expenses prior to the FDA's approval.

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 4 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, based on whether they are capable of being distinct and distinct in the context of the agreement; (iii) determine 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. We recognize shipping and handling costs as an expense in cost of goods sold when we transfer control to a customer.

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.

We distribute RYTELO in the U.S. through third party distributors and specialty pharmacies who are our customers. The third party distributors subsequently resell our product through their related specialty pharmacy providers to patients and health care providers. Separately, we have or may enter into payment arrangements with various third-party payers including pharmacy benefit managers, private healthcare insurers and government healthcare programs who provide coverage and reimbursement for our product that have been prescribed to a patient.

The 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. To date, our only source of product revenue has been from the U.S. sales of RYTELO, which we began shipping to our customers in June 2024. See Note 2 Revenue Recognition.

Net Product Revenues

Our net product revenues are recognized, net of variable consideration related to certain allowances and accruals, at the time our customers obtain control of our product, which is generally upon delivery to our customers. We use the expected value method, which

is the sum of probability-weighted amounts in a range of possible consideration amounts to estimate variable consideration and consideration payable to parties other than our customers related to our product sales.

We record reserves, based on contractual terms, for components related to product sold during the reporting period, as well as our estimate of product that remains in the distribution channel inventory at the end of the reporting period that we expect will be sold to qualified healthcare providers. On a quarterly basis, we update our estimates and record any needed adjustments in the period we identify the adjustments.

We sell RYTELO to our customers at wholesale acquisition cost, and calculate product revenue from RYTELO sales, net of variable consideration and consideration payable to parties other than our customers. Variable consideration and consideration payable to parties other than our customers consists of estimates related to the following categories:

Other Allowances

We pay fees for distribution services, such as fees for certain data that customers provide to us. We estimate our customers will earn these fees and deduct these fees from gross product revenues and accounts receivable at the time we recognize the related revenues.

Discounts for Prompt Payment

We provide for prompt payment discounts to our customers, which are recorded as a reduction in gross product revenue in the same period that the related product revenue is recognized.

Product Returns

We offer customers the right to return products if they are damaged, defective, or expired, as defined in customer agreements. We estimate product returns considering experience from similar products in the market, historical return patterns, sales data, and inventory levels in the distribution channel. These estimates are recorded as a reduction in gross product revenue at the time of sale. Once products are returned, they are destroyed; we do not record a right of return asset.

Chargebacks

Chargebacks occur when our contracted customers, mainly federal agencies that can purchase off the Federal Supply Schedule and Public Health Service 340B covered entities, buy directly from our distributors and wholesalers at discounted prices. The distributors and wholesalers then charge us the difference between their purchase price and the discounted price. We estimate chargebacks considering the terms of the applicable arrangement and our visibility regarding utilization. These chargebacks are recorded in the same period as the related revenue, reducing our net product revenue and receivables. We typically issue credits for these amounts within a few weeks of notification.

Government Rebates

We are subject to discount obligations under government programs. Reserves for rebates payable under these government programs are recorded in the same period as gross product revenue, reducing our gross product revenue and creating a liability in accrued liabilities. Major rebates include those from the Medicare and Medicaid programs. Estimates for rebates are made considering statutory discount rates and expected utilization. These estimates are updated each period with actual claims and other current information, taking into account historical data, comparable products and other considerations.

Co-payment Assistance

We offer co-payment assistance to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. We estimate the average co-payment assistance amounts for our products based on expected customer demographics and record any such amounts within accrued expenses and a reduction to product revenue.

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 and nine months ended September 30, 2024 and 2023, which was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2024	2023	2024	2023
Research and development	$ 1,904	$ 2,951	$ 7,960	$ 5,847
Selling, general and administrative	4,986	4,253	16,432	8,263
Total stock-based compensation expense	$ 6,890	$ 7,204	$ 24,392	$ 14,110

Stock-based compensation of $0.3 million and $0.4 million was capitalized to inventory for the three and nine months ended September 30, 2024, respectively.

As stock-based compensation expense recognized in our condensed consolidated statements of operations for the three and nine months ended September 30, 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 recognized stock-based compensation expense for the achievement of a milestone achieved upon FDA approval of RYTELO on our condensed consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023.

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 nine months ended September 30, 2024 and 2023 has been estimated at the date of grant using the Black- Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2024	2023
Dividend yield	0%	0%
Expected volatility range	82.94% to 86.68%	81.53% to 82.12%
Risk-free interest rate range	3.53% to 4.62%	3.42% to 4.62%
Expected term	6 years	6 years

Employee Stock Purchase Plan

The fair value of employees' stock purchase rights during the nine months ended September 30, 2024 and 2023 has been estimated using the Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2024	2023
Dividend yield	0%	0%
Expected volatility range	72.08% to 119%	79.05% to 83.22%
Risk-free interest rate range	4.79% to 5.37%	4.73% to 5.40%
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 and commercialization 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 and 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. REVENUE RECOGNITON

Net Product Revenue

To date, our only source of product revenue has been from the U.S. sales of RYTELO, which we began shipping to our customers in June 2024. The reconciliation of gross product sales to net product sales by each significant category of gross-to-net adjustments was as follows for the three and nine months ended September 30, 2024 (in thousands):

	Three Months Ended September 30, (in thousands)	Nine Months Ended September 30, (in thousands)
Gross product revenue	$ 32,657	$ 33,547
Gross-to-net adjustments:		
Chargebacks and distributor service fees	(4,002)	(4,099)
Government rebates	(364)	(375)
Sales returns and allowances	(82)	(84)
Total gross-to-net adjustments (1)	$ (4,448)	$ (4,558)
Net product revenue	$ 28,209	$ 28,989

(1)As of September 30, 2024 approximately $1.4 million of estimated gross-to-net accruals have been recorded within accounts payable and accrued expenses on the condensed consolidated balance sheets.

3. INVENTORY

All of our inventories are related to the manufacturing of RYTELO. The following table presents our inventory as of September 30, 2024 (in thousands):

	As of September 30, 2024 (in thousands)
Raw materials	$ 5,871
Work-in-process	13,544
Finished goods	868
Total inventory	$ 20,283

4. FAIR VALUE MEASUREMENTS

Cash Equivalents and Marketable Securities

Cash equivalents, restricted cash and marketable securities by security type at September 30, 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	$ 31,854	$ —	$ —	$ 31,854
Commercial paper	4,970	2	—	$ 4,972
	$ 36,824	$ 2	$ —	$ 36,826
Restricted cash:				
Money market fund	$ 1,581	$ —	$ —	$ 1,581
Certificate of deposit	273	—	—	273
	$ 1,854	$ —	$ —	$ 1,854
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 35,481	$ 56	$ —	$ 35,537
Government-sponsored enterprise securities (due in less than one year)	19,680	27	—	19,707
Government-sponsored enterprise securities (due in one to two years)	5,000	—	—	5,000
Commercial paper (due in less than one year)	135,717	327	(1)	136,043
Corporate notes (due in less than one year)	87,816	327	(2)	88,141
Corporate notes (due in one to two years)	32,042	273	(1)	32,314
	$ 315,736	$ 1,010	$ (4)	$ 316,742

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 September 30, 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 September 30, 2024:						
Commercial paper (due in less than one year)	$ 10,929	$ —	$ —	$ —	$ 10,929	$ —
Corporate notes (due in less than one year)	—	—	1,986	(2)	1,986	(2)
Corporate notes (due in one to two years)	1,913	(2)	—	—	1,913	(2)
	$ 12,842	$ (2)	$ 1,986	$ (2)	$ 14,828	$ (4)
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 September 30, 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 and nine months ended September 30, 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 September 30, 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 September 30, 2024:				
Money market funds[1][2]	$ 33,435	$ —	$ —	$ 33,435
Certificate of deposit[2]	273	—	—	273
U.S. Treasury securities[3]	—	35,536	—	35,536
Government-sponsored enterprise securities[3][4]	—	24,707	—	24,707
Commercial paper[3]	—	141,015	—	141,015
Corporate notes[3][4]	—	120,454	—	120,454
Total	$ 33,708	$ 321,712	$ —	$ 355,420
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.

5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following as of September 30, 2024 and December 31, 2023:

(In thousands)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
CRO and clinical trial costs	$ 19,392	$ 23,541
Manufacturing activities	12,326	14,629
Professional legal and accounting fees	751	556
Interest payable	853	768
Other	3,167	814
	$ 36,489	$ 40,308

6. 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 Hercules 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 Hercules Loan Agreement. As of September 30, 2024, a total of $80.0 million had been drawn under the Hercules 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 Hercules Loan Agreement remained at $125.0 million at September 30, 2024, with such principal available in a series of tranches, subject to certain terms and conditions. The third amendment also provided that (i) the fourth tranche of the Hercules Loan Agreement was increased from $10.0 million to $30.0 million, (ii) the commitment period for the fifth tranche of the Hercules Loan Agreement of $20.0 million, which was made available due to achievement of a regulatory milestone and satisfaction of certain capitalization requirements and was extended through December 15, 2024, (iii) the variable annual interest rate on the outstanding loans was 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 Hercules Loan Agreement was extended from June 30, 2024 through December 31, 2024, due to regulatory approval of RYTELO and satisfaction of certain financial and capitalization requirements. In connection with the third amendment, on the third amendment effective date, we borrowed and received the entire fourth tranche of the Hercules Loan Agreement in the amount of $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Hercules Loan Agreement was $80.0 million at September 30, 2024. 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 Hercules Loan Agreement was 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 Hercules Loan Agreement expired and was no longer available for us, but was added to the fourth tranche as part of the third amendment to the Hercules Loan Agreement.

Under the Hercules Loan Agreement as amended, the Hercules Loan Agreement matures on October 1, 2025, or the Loan Maturity Date, which was extended from April 1, 2025 upon regulatory approval of RYTELO. The Hercules Loan Agreement 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% (12.5% as of September 30, 2024). The interest only period of the Hercules Loan Agreement was extended from June 30, 2024 through December 31, 2024. due to regulatory approval of RYTELO and satisfaction of certain financial and capitalization requirements. Following the expiration of the interest-only period, we are required to repay the Hercules Loan Agreement in equal monthly amortization payments of principal and interest until the Loan Maturity Date. Upon full repayment of the Hercules Loan Agreement, we are also obligated to pay an end of term charge in an amount equal to 6.55% of the amount of the Hercules Loan Agreement actually borrowed. Such end of term charge is being accrued to interest expense over the term of the Loan Agreement using the effective interest rate method. At our option, upon at least seven business days' prior written notice to Hercules, we are able to 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 was 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 were in compliance with the covenants under the Hercules Loan Agreement as of September 30, 2024.

As of September 30, 2024, the net carrying value of the debt under the Hercules Loan Agreement was $83.8 million, which includes the principal amount of $80.0 million less net unamortized debt discounts and issuance costs of $258,000 plus accrued end of term charge of $4.1 million. The carrying value of the debt approximates the fair value as of September 30, 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 September 30, 2024 (in thousands):

Remainder of 2024	$ 2,548
2025	89,955
Total	92,503
Less: amount representing interest	(7,263)
Less: unamortized debt discount and issuance costs	(258)
Less: unaccrued end of term charge	(1,145)
Less: current portion of debt	(71,562)
Noncurrent portion of debt	$ 12,275

Subsequent to September 30, 2024, all obligations outstanding under the Hercules Loan Agreement, amounting to $86.5 million, were repaid in full by us in connection with our entry into and funding under a new loan agreement, with BioPharma Credit PLC and the lenders party thereto. See Note 9 on Subsequent Events in Notes to Condensed Consolidated Financial Statements of this Report for additional information.

7. CONTINGENCIES AND UNCERTAINTIES

Legal Proceedings

We are not currently a party to any material pending legal proceedings. From time to time, we may and have previously been involved in legal proceedings arising in the ordinary course of business, including potential securities lawsuits. Such lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. We could be forced to expend significant resources in the defense of any additional lawsuits, and we may not prevail. 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 the 2023 Form 10-K. As of September 30, 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.

Purchase Commitments

We have engaged third-party contract manufacturers and have re-established our own manufacturing supply chain to manufacture and supply additional quantities of RYTELO that meet applicable regulatory standards for current and potential future clinical trials and commercial uses. Related to those contract manufacturing agreements, we have noncancelable commercial purchase commitments for approximately $62.4 million in the aggregate as of September 30, 2024. These purchase commitments can vary based on the commercial demand of RYTELO and are binding based on future manufacturing needs.

In the normal course of business, we enter into agreements with CROs for clinical trials 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.

8. 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 September 30, 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. In the second quarter of 2024, warrants to purchase 281,211 shares of our common stock were exercised for net cash proceeds of approximately $365,000. In the third quarter of 2024, warrants to purchase 3,080 shares of our common stock were exercised for net cash proceeds of approximately $4,000. 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 September 30, 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 2,152,570 shares of our common stock related to the public offering of our common stock in May 2020, which expire on December 31, 2025.

9. SUBSEQUENT EVENTS

Pharmakon Loan Agreement

On November 1, 2024, we entered into a loan agreement, or the Pharmakon Loan Agreement, with BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership, each, a Lender, which are investment funds managed by Pharmakon Advisors, LP, and BioPharma Credit PLC, as collateral agent, that provides for a 5-year senior secured term loan facility of up to $250.0 million, divided into three committed tranches: (i) a Tranche A Loan in an aggregate principal amount of $125.0 million, or the Tranche A Loan, which was funded on November 1, 2024, or the Tranche A Closing Date; (ii) a Tranche B Loan in an aggregate principal amount of $75.0 million, or the Tranche B Loan, which is available, subject to certain limited conditions, at our option; and (iii) a Tranche C Loan in an aggregate principal amount of $50.0 million, or the Tranche C Loan, and together with the Tranche A Loan and the Tranche B Loan, collectively, the Term Loans, which is available to us upon reaching a specified trailing twelve-month RYTELO revenue milestone. The Tranche B Loan and the Tranche C Loan, once available, may be requested on or prior to December 31, 2025. A portion of the proceeds from the Tranche A Loan were used to repay, in full, all amounts owed ($86.5 million) under the Hercules Loan Agreement, which was terminated effective November 1, 2024. The remaining proceeds will be used to fund our general corporate and working capital requirements.

The Term Loans mature on November 1, 2029. The Term Loans bear interest at a variable rate per annum equal to 5.75% plus the three-month Secured Overnight Financing Rate, or SOFR, with a SOFR floor of 3.00%. As of inception of the Tranche A Loan, the interest rate applicable to the Tranche A Loan was 10.32%. Interest is due and payable quarterly on the last day of each quarter with the first payment due on December 31, 2024. The Pharmakon Loan Agreement requires we pay an amount equal to 2.50% of the Lenders' total committed amount to fund the Term Loans, payable with respect to each Term Loan on the funding date of such Term Loan.

We may elect to prepay the Term Loans in part or in whole prior to the Maturity Date with such prepayments being subject to a prepayment premium equal to the principal amount so prepaid multiplied by 3% if made prior to the 3rd anniversary of the funding date of the applicable Term Loan, 2% if made on or after the 3rd anniversary of the funding date of the applicable Term Loan but prior to the 4th anniversary of the funding date of the applicable Term Loan, and 1% if made on or after the 4th anniversary of the funding date of the applicable Term Loan but prior to the Maturity Date. In addition to the prepayment premium, prepayments of any Term Loan prior to the 2nd anniversary of the funding date of such Term Loan are subject to a makewhole amount equal to the sum of all interest that would have accrued through such 2nd anniversary.

Our obligations under the Pharmakon Loan Agreement are secured by substantially all of our assets, including our intellectual property. Certain of our subsidiaries may, from time to time after the Tranche A Closing Date, be required to guarantee our obligations under the Pharmakon Loan Agreement and, in connection with such guarantee, pledge substantially all of their assets, including intellectual property, to secure such guarantee.

The Pharmakon Loan Agreement contains customary affirmative and restrictive covenants and representations and warranties. We and our subsidiaries are bound by certain affirmative covenants setting forth actions that are required during the term of the Pharmakon Loan Agreement, including, without limitation, certain information delivery requirements, obligations to maintain certain insurance, and certain notice requirements. There are no financial covenants. Additionally, we and our subsidiaries are bound by certain restrictive covenants setting forth actions that are not permitted to be taken during the term of the Pharmakon Loan Agreement, including, without limitation, (i) selling or disposing of assets, (ii) amending, modifying or waiving our rights under material agreements, (iii) consummating change in control transactions unless all amounts becoming due under the Loan Agreement are paid in full immediately upon (and concurrent with) the consummation of any such change in control transaction, (iv) incurring additional indebtedness, (v) incurring non-permitted liens or encumbrance on our or our subsidiaries' assets, (vi) paying dividends or making any distribution or payment on or redeeming, retiring or purchasing any equity interests, and (vii) making payments on subordinated indebtedness, in each case, subject to specified exceptions. The Pharmakon Loan Agreement also contains the following events of default: (i) failure to pay principal, interest and other amounts when due, (ii) the breach of the covenants under the Loan Agreement, (iii) the occurrence of a material adverse change or a withdrawal event in respect of RYTELO, (iv) certain attachments of the credit parties assets and restraints on their business, (v) certain insolvency, liquidation, bankruptcy or similar events, (vi) certain cross-default of third-party indebtedness and royalty revenue contracts, (vii) the failure to pay certain judgements, (viii) material misrepresentations, (ix) the loan documents ceasing to create a valid security interest in a material portion of the collateral, (x) the occurrence of certain ERISA events and (xi) the occurrence of a default under any subordination or intercreditor agreement, in each case subject to the grace periods, cure period and thresholds as specified in the Pharmakon Loan Agreement. Upon the occurrence of an event of default, the Lenders may, among other things, accelerate our obligations under the Pharmakon Loan Agreement (including all obligations for principal, interest and any applicable makewhole and prepayment premiums); provided that upon an event of default relating to certain insolvency, liquidation, bankruptcy or similar events, all outstanding obligations will be immediately accelerated.

Termination of the Hercules Loan Agreement

All obligations outstanding under the Hercules Loan Agreement were repaid in full on November 1, 2024, upon which the Hercules Loan Agreement was terminated and all liens on our assets in granted in connection with the Hercules Loan Agreement were released. See Note 6 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information about the Hercules Loan Agreement.

Royalty Pharma Revenue Participation Right Purchase Agreement

On November 1, 2024, we entered into a revenue participation right purchase and sale agreement, or the Royalty Pharma Agreement, with Royalty Pharma Development Funding, LLC, or Royalty Pharma.

Pursuant to the Royalty Pharma Agreement, we received an upfront payment of $125.0 million, or the Purchase Price, in exchange for which Royalty Pharma obtained the right to receive tiered revenue interest payments with respect to annual U.S. net sales, or Annual Net Sales, of RYTELO beginning on July 1, 2024, ranging from: (i) 7.75% of Annual Net Sales up to $500.0 million; (ii) 3.0% of Annual Net Sales in excess of $500.0 million but less than or equal to $1.0 billion; and (iii) 1.0% in respect of Annual Net Sales in excess of $1.0 billion, or the Revenue Interest Payments. The Revenue Interest Payments to Royalty Pharma are capped, such that they will cease upon reaching a multiple of 1.65 times the Purchase Price if Royalty Pharma receives Revenue Interest Payments in that amount in respect of net sales occurring on or before June 30, 2031, or upon reaching a multiple of 2.0 times the Purchase Price thereafter. Our revenue payment obligations under the Royalty Pharma Agreement may be discharged in connection with a change of control of the Company in an amount equal to 1.65 times the Purchase Price minus the aggregate Revenue Interest Payments received by Royalty Pharma as of the date of the closing of the change of control, if the closing of the change of control occurs on or prior to December 31, 2027, or in an amount equal to 2.0 times the Purchase Price minus the aggregate Revenue Interest Payments received by Royalty Pharma as of the date of the closing of the change of control, if the closing of the change of control occurs after December 31, 2027. There are no other royalties payable on RYTELO, which was developed internally and is exclusively owned by Geron.

The Royalty Pharma Agreement contains customary representations, warranties and indemnities of the Company and Royalty Pharma and customary covenants relating to the Revenue Interest Payments.

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 commercial-stage biopharmaceutical company aiming to change lives by changing the course of blood cancer. Our first-in-class telomerase inhibitor, RYTELO™ (imetelstat), harnesses Nobel Prize winning science in a treatment that aims to potentially reduce proliferation and induce death of malignant cells in the bone marrow, potentially altering the underlying course of these hematologic malignancies.

On June 6, 2024, the U.S. Food and Drug Administration (FDA) approved RYTELO for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes, or lower-risk MDS, with transfusion-dependent, or TD, anemia requiring four

or more red blood cell units over eight weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents, or ESAs. In September 2023, we submitted a marketing authorization application, or MAA, in the European Union, or EU, that was validated for review by the European Medicines Agency, or EMA, for RYTELO for the same proposed indication as in the U.S. We expect review of the MAA by the Committee for Medicinal Products for Human Use, or CHMP, could be completed in late 2024 or early 2025, with a potential approval decision by the European Commission in the first half of 2025. We are continuing to prepare for the potential launch of RYTELO in the EU and subject to regulatory approval, are planning to commercialize RYTELO in select EU markets commencing in 2026.

Our regulatory approval in the U.S. for lower-risk MDS and our EMA submission are each 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. The most common Grade 3/4 adverse reactions were neutropenia (72%) and thrombocytopenia (65%), which lasted a median duration of less than two weeks, and in more than 80% of patients were resolved to Grade <2 in under four weeks.

In addition to lower-risk MDS, we are developing imetelstat for the treatment of several myeloid hematologic malignancies. Our Phase 3 clinical trial IMpactMF is evaluating 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 August 2024, the trial reached approximately 70% 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 October 3, 2024, the U.S. Centers for Medicare & Medicaid Services assigned a permanent and product-specific J-code (J0870) for RYTELO, which will become effective on January 1, 2025. J-codes are permanent reimbursement codes used by government payers and commercial insurers to facilitate billing of Medicare Part B treatments, which must be administered by a healthcare professional.

On November 1, 2024, we entered into the Pharmakon Loan Agreement with BioPharma Credit Investments V (Master) LP and BPCR Limited Partnership, each, a Lender, which are investment funds managed by Pharmakon Advisors, LP, and BioPharma Credit PLC, as collateral agent, that provides for a 5-year senior secured term loan facility to us in an aggregate principal amount of up to $250.0 million, divided into three committed tranches: (i) a Tranche A Loan in an aggregate principal amount of $125.0 million, which was funded on November 1, 2024; (ii) a Tranche B Loan in an aggregate principal amount of $75.0 million, which is available, subject to certain limited conditions, at our option; and (iii) a Tranche C Loan in an aggregate principal amount of $50.0 million, which is available to us upon reaching a specified trailing twelve-month RYTELO revenue milestone. The Tranche B Loan and the Tranche C Loan, once available, may be requested on or prior to December 31, 2025. A portion of the proceeds from the Tranche A Loan were used to repay, in full, all amounts owed ($86.5 million) under the Hercules Loan Agreement, which was terminated effective November 1, 2024. The remaining proceeds will be used to fund the Company's general corporate and working capital requirements.

On November 1, 2024, we entered into the Royalty Pharma Agreement with Royalty Pharma. Pursuant to the Royalty Pharma Agreement, we received an upfront payment of $125.0 million, or the Purchase Price, in exchange for which Royalty Pharma obtained the right to receive tiered Revenue Interest Payments with respect to Annual Net Sales of RYTELO beginning on July 1, 2024, ranging from: (i) 7.75% of Annual Net Sales up to $500.0 million; (ii) 3.0% of Annual Net Sales in excess of $500.0 million but less than or equal to $1.0 billion; and (iii) 1.0% in respect of Annual Net Sales in excess of $1.0 billion. The Revenue Interest Payments to Royalty Pharma are capped, such that they will cease upon reaching a multiple of 1.65 times the Purchase Price if Royalty Pharma receives Revenue Interest Payments in that amount in respect of net sales occurring on or before June 30, 2031, or upon reaching a

multiple of 2.0 times the Purchase Price thereafter. Our revenue payment obligations under the Royalty Pharma Agreement may be discharged in connection with a change of control of the Company in an amount equal to 1.65 times the Purchase Price minus the aggregate Revenue Interest Payments received by Royalty Pharma as of the date of the closing of the change of control, if the closing of the change of control occurs on or prior to December 31, 2027, or in an amount equal to 2.0 times the Purchase Price minus the aggregate Revenue Interest Payments received by Royalty Pharma as of the date of the closing of the change of control, if the closing of the change of control occurs after December 31, 2027. There are no other royalties payable on RYTELO, which was developed internally and is exclusively owned by Geron.

The Royalty Pharma Agreement contains customary representations, warranties and indemnities of the Company and Royalty Pharma and customary covenants relating to the Revenue Interest Payments.

See Note 9 on Subsequent Events in Notes to Condensed Consolidated Financial Statements of this Report for additional information about the Pharmakon Loan Agreement, Royalty Pharma Agreement and the repayment and termination of the Hercules Loan Agreement.

Financial Overview

Since our inception, we have primarily financed our operations through the sale of equity securities, draw downs on our debt facilities, interest income on our marketable securities and payments we received under the Royalty Pharma Agreement and our prior collaborative and licensing arrangements. As of September 30, 2024, we had approximately $378.9 million in cash, cash equivalents, restricted cash and marketable securities. On a pro forma basis, including gross proceeds from the upfront payment under the Royalty Pharma Agreement and the Tranche A Loan, and after repayment of our existing debt under the Hercules Loan Agreement, we had approximately $542.4 million in cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2024.

We began commercializing RYTELO in June 2024, and the commercial potential of and our ability to successfully commercialize RYTELO is unproven. Our success in commercializing RYTELO will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, as well as compliance with applicable laws and regulations. In addition, although we recently began commercializing RYTELO, 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 reported a small profit for the year ended December 31, 2015, 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 September 30, 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 RYTELO, our sole product. In addition, we are developing RYTELO for the treatment of several myeloid hematologic malignancies that will continue to require additional time and significant investment in clinical trials to complete. We also expect to continue to seek regulatory approvals of RYTELO in jurisdictions outside of the United States. As a result, we expect research and development expenses and selling, general and administrative expenses to increase in future periods as we continue to support the commercialization of RYTELO in the U.S. and further development of RYTELO, including the conduct and completion of IMpactMF, IMproveMF and IMpress, as well as the potential commercialization of RYTELO in the EU, if approved, in lower-risk MDS. In addition, we expect our interest expense to increase due to the draw down of the Tranche A Loan and potential future draw downs of the other Term Loans under the Pharmakon Loan Agreement, and our royalty expense to increase due to our revenue interest payments associated with the Royalty Pharma Agreement.

On March 21, 2024, we completed an underwritten 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 September 30, 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.

As described above, we entered into the Pharmakon Loan Agreement and the Royalty Pharma Agreement on November 1, 2024, and in connection with these transactions all obligations outstanding under the Hercules Loan Agreement were repaid in full on November 1, 2024, upon which the Hercules Loan Agreement was terminated and all liens on our assets in granted in connection with the Hercules Loan Agreement were released.

Successful drug development and commercialization requires significant amounts of capital. As of September 30, 2024, we had approximately $378.9 million in cash, cash equivalents, restricted cash and marketable securities. On a pro forma basis, including gross proceeds from the upfront payment under the Royalty Pharma Agreement and the Tranche A Loan, and after repayment of our existing debt under the Hercules Loan Agreement, we had approximately $542.4 million in cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2024. Based on our current operating plans and assumptions, we believe that our existing cash, cash equivalents, and marketable securities (including the $250 million received under the Pharmakon Loan Agreement and the

Royalty Pharma Agreement), together with anticipated revenues from U.S. sales of RYTELO, will be sufficient to fund our projected operating requirements for at least the next 12 months from the date of this filing. We believe that our projected financial resources will be sufficient to (i) support commercial launch of RYTELO in the U.S. and potential launch in the EU, (ii) complete the Phase 3 IMpactMF trial in relapsed/refractory MF, (iii) invest in supply chain redundancy for RYTELO, and (iv) fund our general working capital requirements. If we do not generate sufficient funds from commercial sales of RYTELO, or if we experience regulatory delays or other unforeseen events or choose to make other investments in our business, we may require additional funding, which could include a combination of public or private equity offerings, debt financings (including additional tranches under the Pharmakon Loan Agreement, if available), collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, which may not be possible. If adequate funds are not available on a timely basis, if at all, our RYTELO commercialization efforts may be adversely affected and we may be unable to pursue further development of imetelstat, which would severely harm our business and we might cease operations.

If approved for marketing in the EU by the EMA, we are planning to commercialize RYTELO in select EU markets commencing in 2026. Until international regulatory authorities approve RYTELO for marketing, if at all, we cannot begin commercialization activities outside of the U.S.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our significant accounting policies are described in Note 1 of Item 1 of this Report and in Item 7, “Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K. There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 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 Report 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. In this regard, although we have begun to recognize revenue from RYTELO product sales in the U.S., we are early in the product launch. We expect that our sales revenue may vary significantly from period to period as the launch progresses.

RYTELO is our only product approved for marketing by the FDA and is approved solely for certain patients with lower-risk MDS. Revenue based on sales of RYTELO is dependent on our ability to execute a successful commercial launch of RYTELO in the U.S., and obtaining regulatory approval to commercialize RYTELO in other countries and other indications. 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 RYTELO; uncertainty of non-clinical and clinical trial results or regulatory approvals or clearances; the future development of imetelstat by us and its use by patients generally, including any future efficacy or safety results from clinical or commercial use 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.

The following table summarizes our results of operations for the three and nine months ended September 30:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Change $	Change %	2024	2023	Change $	Change %
	(in thousands, except for percentage data)							
Revenues:								
Product revenues, net	$ 28,209	$ —	$ 28,209	**	$ 28,989	$ —	$ 28,989	**
Royalties	62	164	(102)	-62%	468	214	254	119%
Total revenues	28,271	164	28,107	**	29,457	214	29,243	**
Operating expenses:								
Cost of goods sold	456	—	456	**	473	—	473	**
Research and development	20,153	29,426	(9,273)	-32%	80,305	92,135	(11,830)	-13%
Selling, general and administrative expenses	35,877	18,350	17,527	96%	102,361	47,734	54,627	**
Total operating expenses	56,486	47,776	8,710	18%	183,139	139,869	43,270	31%
Interest income	4,877	4,965	(88)	-2%	14,448	13,556	892	7%
Interest expense	(3,046)	(2,066)	(980)	47%	(9,798)	(5,991)	(3,807)	64%
Other income and (expense), net	(63)	(92)	29	-32%	(188)	(64)	(124)	194%
Net income (loss)	$ (26,447)	$ (44,805)	$ 18,358	-41%	$ (149,220)	$ (132,154)	$ (17,066)	13%

** Percentage not meaningful

Revenues:

Product Revenues, Net

On June 6, 2024, we announced that the FDA approved RYTELO for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes, or lower-risk MDS, with transfusion-dependent, or TD, anemia requiring four or more red blood cell units over eight weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents, or ESA. To date, our only source of product revenue has been from the U.S. sales of RYTELO, which we began shipping to our customers in June 2024. We did not generate any revenue from product sales prior to the three months ended June 30, 2024**.** Total product revenue, net for the three and nine months ended September 30, 2024 was approximately $28.2 million and $29.0 million, respectively. We expect product revenues, net to increase through the remainder of 2024.

Royalties

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 $62,000 and $468,000 in the three and nine months ended September 30, 2024, respectively compared to $164,000 and $214,000 respectively, 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.

Operating Expenses:

In connection with the FDA approval of RYTELO on June 6, 2024, we subsequently begin capitalizing inventory manufactured or purchased after this date. As a result, we expensed certain manufacturing costs of RYTELO as research and development expense prior to FDA approval and, therefore, these costs are not included in cost of goods sold. We expect our operating expenses to remain consistent through the remainder of 2024.

Our cost of goods sold consist of raw materials, third-party manufacturing costs to manufacture the raw materials into finished product, freight, and indirect overhead costs associated with the sale of RYTELO in the U.S.

The following table summarizes our expenses, including as a percentage of total expenses, for the three and nine months ended September 30:

(In thousands)	Three Months Ended September 30, 2024	2023	Change %	Nine Months Ended September 30, 2024	2023	Change %
Cost of goods sold	$ 456	$ —	**	$ 473	$ —	**
Research and development	20,153	29,426	-32%	80,305	92,135	-13%
Selling, general and administrative	35,877	18,350	96%	102,360	47,734	114%
Total operating cost and expenses	$ 56,486	$ 47,775	15%	$ 183,139	$ 139,869	24%

** Percentage not meaningful

Cost of Goods Sold

Cost of goods sold was approximately $456,000 and $473,000 for the three and nine months ended September 30, 2024, respectively, which consisted of costs to manufacture, and distribute our market product, RYTELO. We began capitalizing inventory upon FDA approval of RYTELO. All product costs incurred prior to FDA approval of RYTELO in June 2024 were expensed as research and development expenses.

Prior to receiving FDA approval for RYTELO in June 2024, we manufactured inventory to be sold upon commercialization and recorded the costs as research and development expense. As a result, the manufacturing costs related to the inventory manufactured prior to receiving FDA approval were expensed in a prior period and are therefore excluded from the cost of goods sold for the three and nine months ended September 30, 2024. We estimate our cost of sales related to product revenue as a percentage of net product revenue will continue to be positively affected for the next 18 to 24 months as we sell through certain inventory that was previously expensed prior to FDA approval.

Research and Development Expenses

During the three and nine months ended September 30, 2024 and 2023, our RYTELO (imetelstat) program and our research discovery program related to potential next generation telomerase inhibitors were the only research and development programs we supported. For these research and development programs, we incur direct external, personnel-related and other research and development costs. For the three and nine months ended September 30, 2024 and 2023, research and development expenses 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 supply, manufacturing costs for research and clinical trial materials, sponsored research at other labs, consulting, costs to maintain technology licenses and research-related overhead.

Research and development expenses for the three and nine months ended September 30, 2024 and 2023 were as follows:

(In thousands)	Three Months Ended September 30, 2024	2023	Nine Months Ended September 30, 2024	2023
Direct external expenses	$ 13,502	$ 18,756	$ 53,584	$ 62,298
Personnel-related expenses	6,207	8,812	25,206	24,266
All other expenses	444	1,858	1,515	5,571
Total research and development expenses	$ 20,153	$ 29,426	$ 80,305	$ 92,135

The decrease in research and development expenses for the three and nine months ended September 30, 2024, compared to the same period in 2023, was primarily due to manufacturing and quality costs that were capitalized in the current period due to FDA approval of RYTELO, versus being expensed in the prior period. The decrease is partially offset by an increase in labor costs due to higher headcount, incentive and stock-based compensation expense recognized due to the vesting of performance-based stock options upon FDA approval. A discussion of the risks and uncertainties associated with the development of imetelstat can be found in the sub-sections entitled “Risks Related to the Development of Imetelstat” and “Risks Related to the Commercialization of RYTELO” and “Risks Related to Regulatory Approval of RYTELO” in Part II, Item 1A entitled “Risk Factors” and elsewhere in this Report. As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of ongoing and potential future imetelstat research and development projects, anticipated completion dates, or when and to what extent we will receive cash inflows from the commercialization and sale of RYTELO in any other jurisdictions or indications we are pursuing or may in the future pursue, if at all.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $35.9 million and $102.4 million for the three and nine months ended September 30, 2024, respectively, compared to $18.4 million and $47.7 million for the same period in 2023. The increase in selling, general and administrative expenses for the three and nine months ended September 30, 2024, compared to the same period in 2023, primarily reflects higher personnel-related expenses and stock-based compensation recognized upon FDA approval of RYTELO due to the vesting of performance-based stock options.

Interest Income

Interest income was $4.9 million and $14.4 million for the three and nine months ended September 30, 2024, compared to $5.0 million and $13.6 million for the same period in 2023. The decrease in interest income for the three months ended September 30, 2024, compared to the same period in 2023 was due to a decrease in interest rates. The increase in interest income for the nine months ended September 30, 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 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 $3.0 million and $9.8 million for the three and nine months ended September 30, 2024, compared to $2.1 million and $6.0 million for the same period in 2023. The increase in interest expense for the three and nine months ended September 30, 2024, compared to the same period in 2023, primarily reflects higher interest rates. As of September 30, 2024, we had $80.0 million in principal debt outstanding. Interest expense reflects interest owed under the Hercules 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 6 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information about the Hercules Loan Agreement.

On November 1, 2024, we entered into the Pharmakon Loan Agreement and the Royalty Pharma Agreement, and in connection with these transactions, all obligations outstanding under the Hercules Loan Agreement were repaid in full on November 1, 2024, upon which the Hercules Loan Agreement was terminated. See Note 9 on Subsequent Events in Notes to Condensed Consolidated Financial Statements of this Report for additional information about the Pharmakon Loan Agreement, Royalty Pharma Agreement and the repayment and termination of the Hercules Loan Agreement. We expect our interest expense to increase in future periods due to the draw down of the Tranche A Loan and potential future draw downs of the other Term Loans under the Pharmakon Loan Agreement.

Other Income and (Expense), Net

Other income and expense, net was an expense of $63,000 and $188,000 for the three and nine months ended September 30, 2024, respectively, compared to an expense of $92,000 and $64,000 for the three and nine months ended September 30, 2023,

respectively. 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 September 30, 2024, we had cash, restricted cash, cash equivalents, and marketable securities of $378.9 million, compared to $378.1 million at December 31, 2023. The slight increase in cash, restricted cash, cash equivalents and marketable securities during the nine months ended September 30, 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, offset by cash used in operations.

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 September 30, 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 8 on Stockholders' Equity in Notes to Condensed Consolidated Financial Statements of this Report for additional information about the underwritten offering completed in March 2024.

From January 1, 2024 through September 30, 2024, we received $419,000 in cash proceeds from the exercise of warrants we issued in 2020, covering 321,931 shares of our common stock. As of September 30, 2024, we had warrants remaining from our 2020 issuance covering 2,152,570 shares of our common stock, which if exercised in full for cash, would provide $2.8 million in cash proceeds.

As of September 30, 2024, we had a long-term principal debt balance of $80.0 million under the Hercules Loan Agreement with Hercules and SVB. On November 1, 2024, we entered into the Pharmakon Loan Agreement. We drew the Tranche A Loan of $125.0 million on November 1, 2024, a portion of which was utilized to repay all outstanding indebtedness associated with the Hercules Loan Agreement. The Pharmakon Loan Agreement provides two additional committed term loan tranches, the Tranche B Loan and the Tranche C Loan, in principal amounts of $75.0 million and $50.0 million, respectively, subject to customary conditions to fund and, in the case of the Tranche C Loan, achieving certain minimum net sales milestone. The Tranche B Loan and the Tranche C Loan may be requested on or prior to December 31, 2025. The Term Loans mature on November 1, 2029. The Term Loans bear interest at a variable rate per annum equal to 5.75% plus three-month SOFR with a SOFR floor of 3.00%.

On November 1, 2024, we entered into a the Royalty Pharma Agreement with Royalty Pharma. Pursuant to the Royalty Pharma Agreement, we received the Purchase Price in exchange for which Royalty Pharma obtained the right to receive the Revenue Interest Payments. The Revenue Interest Payments to Royalty Pharma are capped, such that they will cease upon reaching a multiple of 1.65 times the Purchase Price if Royalty Pharma receives Revenue Interest Payments in that amount in respect of net sales occurring on or before June 30, 2031, or upon reaching a multiple of 2.0 times the Purchase Price thereafter. There are no other royalties payable on RYTELO, which was developed internally and is exclusively owned by Geron.

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 plans and assumptions, we believe that our existing cash, cash equivalents, and marketable securities (including the $250 million received under the Pharmakon Loan Agreement and the Royalty Pharma Agreement), together with anticipated revenues from U.S. sales of RYTELO, will be sufficient to fund our projected operating requirements for at least the next 12 months from the date of this filing. We believe that our projected financial resources will be sufficient to (i) support commercial launch of RYTELO in the U.S. and potential launch in the EU, (ii) complete the Phase 3 IMpactMF trial in relapsed/refractory MF, (iii) invest in supply chain redundancy for RYTELO, and (iv) fund our general working capital requirements. If we do not generate sufficient funds from commercial sales of RYTELO, or if we experience regulatory delays or other unforeseen events or choose to make other investments in our business, we may require additional funding, which could include a combination of public or private equity offerings, debt financings (including additional tranches under the Pharmakon Loan Agreement, if available), collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, which may not be possible. . If adequate funds are not available on a timely basis, if at all, our RYTELO commercialization efforts may be adversely affected and we may be unable to pursue further development of imetelstat, which would severely harm our business and we might cease operations.

Despite FDA approval of RYTELO in June 2024, the outcome of any clinical activities and/or regulatory approval process is highly uncertain, we cannot reasonably estimate whether our future development activities may succeed; whether we will obtain regulatory approval for RYTELO in the EU in lower-risk MDS, or in any other jurisdictions or indications we are pursuing or may in the future pursue, or whether we will be able to effectively commercialize RYTELO in the U.S. for lower-risk MDS or other potential indications, if at all. We may never recoup our investment in any RYTELO 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 level of sales and market acceptance of RYTELO;
- the scope, progress, timing, magnitude and costs of non-clinical and clinical development, manufacturing and commercialization of imetelstat, including potential commercialization in the EU for lower-risk MDS, if approved, or in any other jurisdictions or other indication we may pursue, 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 RYTELO;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to RYTELO, including with respect to our MAA submission for RYTELO in the EU for 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 RYTELO, including with respect to third-party vendors and service providers and our ability to achieve any meaningful reduction in manufacturing costs;
- the sales price for RYTELO;
- the availability of coverage and adequate third-party reimbursement for RYTELO;
- 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 RYTELO;
- the extent to which we are able to enter into and conduct successful arrangements with third parties, including for the commercialization and marketing of RYTELO in certain regions outside of the U.S., if approved for commercialization;
- the extent and scope of our selling, 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 sales of RYTELO 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 Tranche B Loan and the Tranche C Loan under the Pharmakon Loan Agreement, which is subject to certain funding conditions, 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 effectively commercialize RYTELO, or raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for RYTELO, the development and commercialization of RYTELO 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 the Pharmakon Loan Agreement or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as the Pharmakon 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 RYTELO or our technologies or grant licenses on terms that are not favorable to us.

Cash Flows from Operating Activities

Net cash used in operations for the nine months ended September 30, 2024 and 2023 was $174.7 million and $126.8 million, respectively. The increase in net cash used in operations for the nine months ended September 30, 2024, compared to the same period in 2023, primarily reflects an increase in net loss to $149.2 million, adjusted for non-cash items including stock based compensation expense related for employees and directors.

Cash Flows from Investing Activities

Net cash used in investing activities was $2.5 million for the nine months ended September 30, 2024 and $227.9 million for the nine months ended September 30, 2023. The decrease in net cash used in investing activities for the nine months ended September 30, 2024, compared to the same period in 2023, primarily reflects decreased purchases of marketable securities, as well as increased proceeds from maturities of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 and 2023 was $168.2 million and $328.7 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 as of September 30, 2024 primarily consisted of our current and noncurrent debt obligations under the Hercules Loan Agreement with Hercules and SVB, as described above and in Note 6 on Debt in Notes to Condensed Consolidated Financial Statements of this Report, 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 nine months ended September 30, 2024. Subsequent to September 30, 2024, we entered into the Pharmakon Loan Agreement, as described above in Note 9 on Subsequent Events to Condensed Consolidated Financial Statements of this Report.

We have engaged third-party contract manufacturers and have re-established our own manufacturing supply chain to manufacture and supply additional quantities of RYTELO that meet applicable regulatory standards for current and potential future clinical trials and commercial uses. Related to those contract manufacturing agreements, we have noncancelable commercial purchase commitments for approximately $62.4 million in the aggregate as of September 30, 2024. These purchase commitments can vary based on the commercial demand of RYTELO and are binding based on future manufacturing needs.

In the normal course of business, we enter into agreements with CROs for clinical trials 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 September 30, 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 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 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 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 7 on Contingencies and Uncertainties in Notes to Condensed Consolidated Financial Statements of this Report 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 Commercialization of RYTELO™ (Imetelstat)

- Our near-term prospects are wholly dependent on RYTELO. We have limited experience with the commercialization of RYTELO, and if we are unable to successfully commercialize RYTELO in the U.S. for lower-risk MDS, or to expand its indication of use, our ability to generate meaningful revenue or achieve profitability will be materially and adversely affected.
- We have limited experience as a commercial company and our sales, marketing, and distribution of RYTELO may be unsuccessful or less successful than anticipated.
- If we are unable to continue to execute on our sales, marketing and distribution plans to commercialize RYTELO, we may be unable to generate meaningful product revenue.
- If we do not obtain acceptable prices or adequate reimbursement for RYTELO, the use of RYTELO could be severely limited.
- To be commercially successful, RYTELO must be accepted by the healthcare community, which can be slow to adopt or unreceptive to new technologies and products.
- If the market opportunities for RYTELO are smaller than we believe, our revenue may be adversely affected and our business may suffer.
- We rely on a select network of third party distributors, specialty pharmacies and other vendors to distribute RYTELO, and any failure by such distributors, specialty pharmacies and vendors could adversely affect our revenues, financial condition, or results of operations.
- We are seeking regulatory approval to commercialize RYTELO in the EU, and any such approval, if received, will be subject to pricing, drug marketing and reimbursement regulations in the EU, which may materially affect our ability to commercialize and receive reimbursement coverage for RYTELO in the EU.

Risks Related to Regulatory Approval of RYTELO

- We may be unable to maintain regulatory approval from the FDA for RYTELO in the U.S. for lower-risk MDS, which would severely and adversely affect our business and business prospects, and might cause us to cease operations.
- Our regulatory approval for RYTELO in the U.S. for lower-risk MDS is subject to certain post-marketing requirements and commitments, and we may be subject to penalties or product withdrawal if we fail to comply with such regulatory requirements or commitments, or if we experience unanticipated problems with RYTELO.
- We may be unable to obtain regulatory approval to commercialize RYTELO in any other jurisdictions or for any new indications, or may experience significant delays in doing so, any of which could severely and adversely affect our business and business prospects, and might cause us to cease operations.
- Although orphan drug designation has been granted to RYTELO for the treatment of MDS and MF 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 market exclusivity, which could limit the period of exclusivity we are able to maintain for the commercialization of RYTELO, and would likely harm our business and business prospects.

Risks Related to Compliance with Healthcare Laws

•The FDA, the Department Of Justice, or DOJ, and other regulatory authorities actively enforce regulations related to the promotion and advertisement of pharmaceutical products, and if we were found to have violated the Food, Drug and Cosmetic Act, we could be subject to significant penalties, including civil, criminal and administrative penalties.

•If our business activities become subject to challenge under supranational, national, federal, state or 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.

•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.

Risks Related to the Further Development of RYTELO (Imetelstat)

•We cannot be certain that we will be able to continue to develop RYTELO (imetelstat) or advance it in clinical trials, or that we will be able to receive regulatory approval for RYTELO in any other indications in the U.S., the EU or any other region, on a timely basis or at all.

•RYTELO (imetelstat) may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could halt or limit its commercialization, delay or prevent its regulatory approval in any other jurisdiction or indication, or cause us to delay or terminate our clinical trials.

•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, including IMpactMF, will lead to similar results and data that could potentially enable us to obtain any further regulatory approvals.

•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 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, or our imetelstat development program as a whole.

Risks Related to Manufacturing RYTELO

•Failure by us to maintain a manufacturing supply chain to appropriately and adequately supply RYTELO for commercial and future clinical uses would adversely affect our ability to commercialize RYTELO and result in a further delay in or cessation of clinical trials, and our business and business prospects could be severely harmed.

•If third parties that manufacture RYTELO fail to perform as needed, the commercial and clinical supply of RYTELO will be limited, and we may be unable to successfully commercialize RYTELO or conduct or complete current or potential future clinical trials.

Risks Related to Our Operating Results, Financial Position and Need for Additional Capital

•We have a history of net losses. We expect to continue to incur net losses in the near term and may not achieve consistent future profitability for some time, if ever.

•Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our common stock could decline.

•Our failure to obtain additional capital when needed would force us to further delay, reduce or eliminate the further development of imetelstat, or to halt the commercialization of RYTELO, any of which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

Risks Related to Our Indebtedness and Liabilities

•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 RYTELO, our competitors could develop and commercialize products similar or identical to RYTELO, and our ability to successfully commercialize RYTELO may be adversely affected.

•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.

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

•The validity, scope and enforceability of any patents listed in the Orange Book that cover RYTELO or its methods of use can be challenged by third parties and may not protect us from generic or innovator competition.

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 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.

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 herein and 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 COMMERCIALIZATION OF RYTELO

Our near-term prospects are wholly dependent on RYTELO. We have limited experience with the commercialization of RYTELO, and if we are unable to successfully commercialize RYTELO in the U.S. for lower-risk MDS, or to expand its indication of use, our ability to generate meaningful revenue or achieve profitability will be materially and adversely affected.

In June 2024, we received FDA approval to commercialize RYTELO in the U.S. for certain patients with lower-risk MDS, and we initiated a commercial launch of RYTELO in the U.S. in that indication. RYTELO is our only product approved for marketing by the FDA, and our ability to generate revenue from product sales and achieve profitability is wholly dependent on our ability to successfully commercialize RYTELO in the U.S. for lower-risk MDS or to expand its indications of use. We may not be able to successfully commercialize RYTELO for a number of reasons, including:

•we may not be able to establish or demonstrate in the medical community the safety and efficacy of RYTELO and its potential advantages over and side effects compared to existing treatments;

•physicians may be reluctant to prescribe RYTELO until longer-term efficacy and safety data exists;

•our limited historical experience in marketing, selling and distributing RYTELO;

•reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators;

•the relative price of RYTELO as compared to alternative treatment options;

•the relatively low incidence and prevalence of patients in RYTELO's approved indication, including the reliability of our market and sales estimates;

•future competitive or other market factors may adversely affect the commercial potential of RYTELO;

•we may not be able to obtain and maintain regulatory approvals for RYTELO in any other jurisdictions or for any other indications, including in the EU for lower-risk MDS or in any other jurisdiction for relapsed/refractory MF;

•changed or increased regulatory restrictions;

•changes to the label for RYTELO that further restrict how we market and sell RYTELO, including adverse events observed in ongoing and future studies of imetelstat such as our Phase 3 IMpactMF clinical trial;

•the capabilities of third party manufacturers may adversely affect the success of our commercialization of RYTELO;

•we may need additional financial or other resources to successfully commercialize RYTELO; and

•we may not be able to maintain adequate commercial supplies of RYTELO to meet demand or at an acceptable cost or at all.

Moreover, successful commercialization of RYTELO may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all. In any event, if we are unable to successfully commercialize RYTELO in the U.S. for lower-risk MDS, or to expand its indications of use, our ability to generate meaningful revenue from product sales and achieve profitability will be materially and adversely affected, which in turn would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

We have limited experience as a commercial company and our sales, marketing, and distribution of RYTELO may be unsuccessful or less successful than anticipated.

As a company, we have limited prior experience in selling and marketing or commercializing an approved drug product in the U.S., and we have no experience marketing or commercializing an approved drug outside of the U.S. The success of our commercialization efforts is subject to, among other things, managing our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the management of such capabilities. For example, our commercial launch of RYTELO in the U.S. may not continue as planned or anticipated, which may require us to, among others, adjust or amend our commercialization plan and incur significant expenses. Further, given our limited historical experience commercializing drug products, we do not have a track record of successfully executing a commercial launch. If we are unsuccessful in accomplishing our objectives or if our commercialization efforts do not continue as planned, we may not be able to successfully commercialize RYTELO in lower-risk MDS, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry, any of which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

If we are unable to continue to execute on our sales, marketing and distribution plans to commercialize RYTELO, we may be unable to generate meaningful product revenue.

To successfully commercialize RYTELO in the U.S., we need to continue to execute on our sales, marketing and distribution plans. The ongoing execution of our sales, marketing and distribution plans is, and will continue to be, expensive and time-consuming and we cannot be certain that we will be able to continue to execute on these plans successfully. In addition, we compete with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. If we are unable to recruit as needed, and to retain and effectively train marketing and sales personnel and equip them with compliant and effective materials, our efforts to successfully commercialize RYTELO could be adversely affected.

We currently have no marketing or sales organization outside of the U.S. We do not yet have any products approved for sale outside of the U.S, and we, as a company, have no experience selling and marketing approved drugs outside of the U.S. To successfully commercialize any approved drugs outside of the U.S, we will need to develop these capabilities, either on our own or with others. Doing so will be expensive, difficult and time-consuming. If we receive regulatory approval to commercialize RYTELO in any other regions, such as the EU, we may seek strategic partnerships, collaborations, alliances or licensing arrangements, at an appropriate time, to assist us in the potential development and commercialization of RYTELO, or we may seek to self-commercialize and need to establish business operations in such regions. We may be unsuccessful in our efforts to recruit, hire, train and retain personnel to support such business operations; or we may be unable to enter into and conduct successful strategic partnerships, collaborations, alliances or licensing arrangements with third parties to commercialize RYTELO in such regions, should we seek to do so. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of RYTELO outside the U.S.. Further, given our lack of prior experience in marketing and selling our product, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product. As such, we may be required to hire substantially more sales representatives and medical support liaisons to adequately support the commercialization of RYTELO, if approved, or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into arrangements with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such arrangements on favorable terms, if at all. If our potential future partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. If we are unable to establish sales and marketing capabilities for RYTELO, whether on our own or through collaborations, our results of operations will be negatively impacted. Any of the foregoing would negatively impact our business and business prospects, severely and adversely affect our financial results, and might cause us to cease operations.

If we do not obtain acceptable prices or adequate reimbursement for RYTELO, the use of RYTELO could be severely limited.

Our ability to successfully commercialize RYTELO will depend significantly on obtaining acceptable prices and the availability of coverage and adequate reimbursement to patients 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. Although we have received a permanent and product-specific J-code (J0870) for RYTELO which will become effective on January 1, 2025, the resulting reimbursement payment rates may not be adequate or may require significant restrictions on use or increased co-payments from commercially insured patients that patients may find unacceptably high. Patients are unlikely to use RYTELO 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 market acceptance of RYTELO.

Further, the status of reimbursement codes for RYTELO could also affect reimbursement. J-Codes are reimbursement codes maintained by the Centers for Medicare and Medicaid Services, or CMS, that are a component of the Healthcare Common Procedure Coding System and are typically used to report drugs that ordinarily cannot be self-administered. On October 3, 2024, CMS assigned a permanent and product specific J-code (J0870) for RYTELO, which will become effective on January 1, 2025. For the remainder of 2024, and until CMS systems are updated, physicians will continue to use the non-specific miscellaneous J-Code to bill third-party payors for RYTELO. Because miscellaneous J-Codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. These claims increase the provider administrative burden and must often be submitted with additional information and manually processed, which can delay claims processing times as well as increase the likelihood for claim denials and claim errors.

In addition, government authorities and other third-party payors in the U.S. and other jurisdictions 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 RYTELO. 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 RYTELO 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 RYTELO, and, if reimbursement is available, what the level of reimbursement will be. Although we have received a permanent and product-specific J-code (J0870) for RYTELO which will become effective on January 1, 2025, 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 RYTELO. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize RYTELO, which would negatively impact our business and business prospects.

To be commercially successful, RYTELO must be accepted by the healthcare community, which can be slow to adopt or unreceptive to new technologies and products.

RYTELO may not achieve market acceptance in the U.S. for lower-risk MDS or any other indication that might be approved in the future, or achieve the potential U.S. or international revenue we believe may be possible if approved outside the U.S., since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize RYTELO. RYTELO competes with a number of conventional and widely accepted drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of RYTELO depends on a number of factors, including:

- the clinical indications for which RYTELO is or may in the future be approved;
- the establishment and demonstration to the medical community of the clinical efficacy and safety of RYTELO;
- the ability to demonstrate that RYTELO 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, RYTELO, or to continue to use RYTELO;
- the publication of unfavorable safety or efficacy data concerning RYTELO by third parties or us;
- restrictions on use of RYTELO alone or in combination with other products;

•the label and promotional claims allowed by the FDA for RYTELO, as well as any such claims allowed by similar international regulatory authorities for RYTELO, 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 RYTELO as well as competitive products, including sequencing of available products;

•the effectiveness of sales, marketing and distribution support for RYTELO;

•the ability of the third party distributors and specialty pharmacies we contract with to process prescriptions and dispense RYTELO and the processes required to place orders with such distributors and specialty pharmacies;

•the extent to which RYTELO is approved for inclusion on formularies in hospitals and managed care organizations;

•the pricing of RYTELO, 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 RYTELO 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 RYTELO may provide to clinical outcomes in myeloid hematologic malignancies is not adequate to justify the potential adverse effects or the costs of treatment with RYTELO. If the healthcare community does not accept RYTELO for any of the foregoing reasons, or for any other reasons, our ability to commercialize RYTELO in the U.S. for lower-risk MDS may be negatively impacted or precluded altogether, which would seriously and adversely affect our business and business prospects.

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

We are commercializing RYTELO in lower-risk MDS, and the addressable patient population in lower-risk MDS is 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 patients with lower-risk MDS in the U.S. Additionally, the potentially addressable patient population for RYTELO may not ultimately be amenable to treatment with RYTELO, or we may be unable to successfully identify patients and achieve a significant market share in RYTELO's approved indication, or initial sales of RYTELO may deplete the prevalence pool of patients in the RYTELO's approved indication more quickly than expected, which would have a negative impact on sales of RYTELO in the future. Our commercialization of RYTELO in the U.S. is limited to lower-risk MDS, and any future potential commercialization will 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 RYTELO for any other indications not expressly approved by those regulatory authorities. Future regulatory approvals for RYTELO, if any, could be conditioned upon label restrictions that materially limit the addressable patient population.

Our market opportunity may also be limited by the pricing, reimbursement and access we are able to achieve for RYTELO, the quality and expiration of our intellectual property rights and regulatory exclusivity, duration of RYTELO treatment in lower-risk MDS and future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunities for RYTELO 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, and would adversely affect our ability to achieve profitability.

We rely on a select network of third party distributors, specialty pharmacies and other vendors to distribute RYTELO in the U.S., and any failure by such distributors, specialty pharmacies and vendors could adversely affect our revenues, financial condition, or results of operations.

We rely on a select network of third party distributors, specialty pharmacies and other vendors to distribute RYTELO, and the financial failure of any of these parties could adversely affect our revenues, financial condition or results of operations. We rely on such distributors and specialty pharmacies to effectively distribute RYTELO in a timely manner, provide certain patient support services, manage prescription intake, collect accurate patient and inventory data and collect payments from payors. While we have entered into agreements with each of these parties, they may not perform as agreed, our strategic priorities may change or they may terminate their agreements with us. Further, an inability by our distributors or specialty pharmacies to meet our patients' needs may lead to reputational harm or patient loss. In the event that such network fails to properly meet our or our patients' needs, we may need to partner with other distributors, specialty pharmacies or vendors to replace or supplement our current network and there is no guarantee that we will be able to do so on commercially reasonable terms or at all.

We are seeking regulatory approval to commercialize RYTELO in the EU, and any such approval, if received, will be subject to pricing, drug marketing, post-market and reimbursement regulations in the EU, which may materially affect our ability to commercialize and receive reimbursement coverage for RYTELO in the EU.

We are seeking approval to market RYTELO in the EU for lower-risk MDS. Even if we obtain approval for RYTELO in the EU, the competent regulatory authorities may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies, post-market surveillance or patient or drug restrictions. We will also be subject to rules and regulations in the EU applicable to the manufacturing, marketing, promotion and sale of medicinal products. If we or a regulatory authority discovers previously unknown problems with RYTELO, such as adverse events of unanticipated severity or frequency, or problems with a facility where RYTELO is manufactured, a regulatory authority may impose restrictions relative to RYTELO or the manufacturing facility, including requiring recall or withdrawal of RYTELO from the market or suspension of manufacturing. Moreover, product labeling, advertising and promotion for RYTELO will be subject to regulatory requirements and continuing regulatory review.

Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

In addition, the pricing of RYTELO will be subject to governmental control and other market regulations which could put pressure on the pricing and usage of RYTELO. In the EU, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, if approved, market acceptance and sales of RYTELO will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for RYTELO and may be affected by existing and future healthcare reform measures.

The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. If RYTELO is approved for commercialization in the EU, in some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of RYTELO to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for RYTELO, if it is approved for marketing in the EU. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of RYTELO is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of RYTELO in those countries would be negatively affected.

Much like the federal Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.Infringement of related laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians may require prior notification or approval by the physician's or healthcare professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

If our competitors have existing products or develop new products, product candidates or technologies that are superior to or more cost-effective than RYTELO, this could significantly impact the commercial viability and further development of RYTELO, which would severely and adversely affect our financial results, business and business prospects.

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 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. RYTELO will compete 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 RYTELO 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 have or develop more commercially desirable or affordable products than RYTELO, or achieve earlier or longer patent and regulatory exclusivity protection or product commercialization than we may be able to achieve with RYTELO. 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 RYTELO. Competitors may have or develop products that are safer, more effective, or less costly than RYTELO, or more convenient to administer to patients. In addition, competitors may price their products below our price for RYTELO, may receive better third-party payor coverage and/or reimbursement, or may be more cost-effective than RYTELO. Such competitive products or activities by competitors may limit the commercial potential of RYTELO, which may cause us to cease commercialization and any further development of RYTELO, which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

RISKS RELATED TO REGULATORY APPROVAL OF RYTELO

We may be unable to maintain regulatory approval from the FDA for RYTELO in the U.S. for lower-risk MDS, which would severely and adversely affect our business and business prospects, and might cause us to cease operations.

In June 2024, we received regulatory approval from the FDA to commercialize RYTELO in the U.S. in lower-risk MDS. Federal, state and local governments in the U.S. have significant regulations in place that may limit or prevent us from successfully commercializing RYTELO in the U.S. for lower-risk MDS. We do not currently have regulatory approval for RYTELO in any other jurisdiction or for any other indication, and governments in other jurisdictions have significant regulations that may limit or prevent us from successfully commercializing RYTELO in other jurisdictions. _Failure to maintain regulatory approval for RYTELO from the FDA in the U.S. for lower-risk MDS, or delays in obtaining, failure to obtain, or limitations in the scope of such approvals in any other jurisdictions or for any other indications, could:

- result in a withdrawal of RYTELO from the market or could otherwise delay, limit or preclude any revenue we may receive from the commercialization of RYTELO in the U.S. for lower-risk MDS;
- significantly harm the commercial potential of RYTELO;
- impede, halt or increase the costs of our activities and plans for clinical development;
- 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 RYTELO in any other jurisdictions or for any other indications, if any.

In addition, 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. Commercialization and sales of RYTELO are subject to government regulations 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 revenue from the commercialization of RYTELO will be materially and adversely impacted.

Further, if RYTELO causes serious or unexpected side effects, or if other safety risks are observed as a result of our commercialization efforts for RYTELO in the U.S. in lower-risk MDS or in current or potential future clinical trials, a number of potential significant negative consequences could result, including:

- the FDA may withdraw its approval of RYTELO;
- we may be required to recall RYTELO, seek to change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the FDA may require revisions to the labeling of RYTELO, 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;
- we may experience manufacturing delays and supply disruptions if regulatory inspectors identify regulatory noncompliance by third-party manufacturers requiring remediation;
- RYTELO may be rendered less competitive and sales, if any, 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, such as our MAA in the EU, 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 RYTELO (imetelstat), which would negatively impact the development of RYTELO (imetelstat) for other potential indications.

Any of these events could prevent us from achieving or maintaining market acceptance for RYTELO, could substantially increase the costs and expenses of commercializing RYTELO, or could limit its commercial potential, which in turn could delay or prevent us from generating any meaningful revenues from the sale of the RYTELO. If RYTELO is approved outside the U.S., we will be subject to similar requirements, considerations and risks in other regions.

Our regulatory approval for RYTELO in the U.S. for lower-risk MDS is subject to post-marketing requirements and commitments, and we may be subject to penalties or product withdrawal if we fail to comply with these regulatory requirements and commitments or if we experience unanticipated problems with RYTELO.

Our regulatory approval for RYTELO in lower-risk MDS is subject to clinical, non-clinical and manufacturing post-marketing requirements and commitments, including the requirement of continuing to assess long-term safety of RYTELO (imetelstat) in the IMerge trial and a clinical trial to evaluate alternative dosing regimens in lower-risk MDS, with timelines for completion and reporting established by the FDA. In addition, RYTELO and the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities related to RYTELO 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, or 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 post-marketing requirements and commitments or any other regulatory requirements, or later discovery of previously unknown problems with RYTELO, or our manufacturers, or manufacturing processes for RYTELO, may result in actions such as:

- restrictions on RYTELO manufacturing, distribution or use;
- restrictions on labeling or marketing;
- additional post-marketing requirements or commitments; warning letters, withdrawal of RYTELO from the market;
- product recalls;
- suspension or termination of ongoing clinical trials of imetelstat in other indications;
- significant civil, criminal and administrative penalties, including fines, restitutions or disgorgement of profits or revenues;
- refusal to permit the import or export of RYTELO;
- 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 the post-marketing requirements and commitments established by the FDA for RYTELO in lower-risk MDS, or that may be applied to the approval and commercialization of RYTELO 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 RYTELO. Under such circumstances, we or our respective service providers may be subject to the actions listed above, including losing marketing approval for RYTELO, which would severely and adversely affect our business and business prospects, and might cause us to cease operations. If RYTELO is approved outside the U.S., we will be subject to similar requirements, considerations and risks in other regions.

We may be unable to obtain regulatory approval to commercialize RYTELO in any other jurisdictions or for any new indications, or may experience significant delays in doing so, any of which could severely and adversely affect our business and business prospects, and might cause us to cease operations.

We may never receive regulatory approval for RYTELO in any other jurisdictions or for any new indications. It can take many years to obtain approval, if approval is obtained at all. Of the large number of drugs in development, only a small percentage complete the development and regulatory approval process and are successfully commercialized. In addition, the lengthy review process and the unpredictability of future or ongoing clinical trials may result in a delay in obtaining, or our failure to obtain, regulatory approval for RYTELO in lower-risk MDS in any jurisdiction other than the U.S., and for relapsed/refractory MF or for any other indications, which could significantly harm our business and business prospects, 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 the EU. Although RYTELO is approved in the U.S. in lower-risk MDS and the EMA has validated our MAA for RYTELO for lower-risk MDS, there can be no assurance that we will receive regulatory approval from the European Commission for the commercialization of RYTELO for lower-risk MDS in the EU in a timely manner, or at all. Further, because non-clinical and clinical data are often susceptible to varying interpretations and analyses, the 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 RYTELO for lower-risk MDS in the EU, if at all, any of which could result in increased costs to us, or could delay or limit our ability to generate revenue from sales in the EU and adversely affect our commercial prospects.

Even though we reported positive top-line results from IMerge Phase 3 in January 2023 and received regulatory approval from the FDA in June 2024 to commercialize RYTELO in lower-risk MDS, the top-line results from IMerge Phase 3 are not necessarily predictive of RYTELO's 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 RYTELO in any indication other than lower-risk MDS in the U.S., which could severely and adversely affect our business and business prospects.

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 sodium 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 for relapsed/refractory MF, 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.

Regulatory authorities have substantial discretion in the approval process and can delay, limit or deny approval of RYTELO in other indications or outside of the U.S. for any indication, 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 that RYTELO'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 RYTELO or drugs similar to RYTELO;

•disagreement with our interpretation of data from non-clinical studies or clinical trials;

•rejection by the FDA of foreign data included in any future supplemental NDA, or sNDA, submissions for any future indications 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 the MAA and any future sNDA and lead to a rejection by the FDA, EMA, or similar international regulatory authorities;

•a determination by the EMA, or similar international regulatory authorities that regulatory approval for RYTELO should be narrowed or made more restrictive than our current approval in the U.S. for lower-risk MDS, or any future indication for which approval is sought, if any;

•failure to satisfy the requirement to develop a risk management plan for the EU, including any post-marketing studies, as a potential condition to approval in the EU for lower-risk MDS;

•disagreement regarding the formulation, labeling and/or the specifications for RYTELO in the EU;

•the failure of the quality or stability of RYTELO to meet acceptable regulatory standards;

•the EMA or 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 EMA, 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.

Any marketing approval that we may receive for RYTELO in the EU for lower-risk MDS, or in any other country for any other indication, may also be limited or subject to restrictions or post-approval commitments that increase our costs or render RYTELO not commercially viable, which would harm 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 RYTELO. For example, although we received regulatory approval from the FDA in June 2024 to commercialize RYTELO in lower-risk MDS, any future regulatory clearances that we might obtain for RYTELO 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 RYTELO, 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 RYTELO 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.

Any delay in obtaining or failure to obtain required approvals of RYTELO in any other jurisdictions or for any other indications, or limitations on any regulatory approval that we might receive in the future, if any, could reduce the potential commercial use of RYTELO, and potential market demand for RYTELO and therefore result in decreased revenue for us from any commercialization of RYTELO in any other jurisdictions or for any other indications, any of which could severely and adversely affect our financial results and ability to raise additional capital, the price of our common stock, our business and business prospects, and might cause us to cease operations.

If we obtain regulatory approval to commercialize RYTELO in the EU for lower-risk MDS or any other indication, we may experience additional risks related to marketing outside of the U.S. that could materially adversely affect our business.

We are seeking regulatory approval to market RYTELO in the EU, 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 in the EU or of 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.; 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.

Although orphan drug designation has been granted to RYTELO for the treatment of MDS and MF 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 market exclusivity, which could limit the period of exclusivity we are able to maintain for the commercialization of RYTELO, and would likely harm our business and business prospects.

The FDA granted orphan drug designation to RYTELO 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 RYTELO for the treatment of MF and in July 2020 for the treatment of MDS. Orphan drug exclusivity confers seven and 10 years of exclusivity in the U.S. and E.U., respectively, following approval, subject to satisfying regulatory requirements. The FDA has confirmed seven years of orphan drug exclusivity for RYTELO following its approval on June 6, 2024 for its approved indication in lower-risk MDS. Designation as an orphan drug does not guarantee that any regulatory authority will accelerate regulatory review of, or ultimately approve, RYTELO for any indication, or at all, in the U.S., EU or any other country, 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 RYTELO prior to RYTELO 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 RYTELO to meet the needs of patients with lower-risk MDS or MF. 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 RYTELO, the exclusivity may not effectively protect RYTELO 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, such as the approval of RYTELO in the U.S. for lower-risk MDS in June 2024, 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 limit the period of exclusivity we are able to maintain for RYTELO, and may harm our business and business prospects. In addition, for any other indication that we are currently or may in the future seek to develop or obtain regulatory approval for RYTELO, such as our pending MAA for RYTELO in lower-risk MDS in the EU, orphan drug designation will neither shorten the development time nor regulatory review time for RYTELO, and it does not give RYTELO any advantage in the regulatory review or approval process.

RISKS RELATED TO COMPLIANCE WITH HEALTHCARE LAWS

The FDA, DOJ and other regulatory authorities actively enforce regulations related to the promotion and advertisement of pharmaceutical products, and if we were found to have violated the Food, Drug and Cosmetic Act, we could be subject to significant civil, criminal and administrative penalties.

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, DOJ and other agencies actively enforce regulations related to the promotion and advertisement of pharmaceutical products. If we were found to have violated the Food, Drug, and Cosmetic Act, we could be subject to significant civil, criminal and administrative penalties, which could inhibit our ability to commercialize RYTELO 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 RYTELO;
- restrictions on, or prohibitions against, importation or exportation of RYTELO;
- 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 RYTELO;
- suspension or withdrawal of regulatory approval for RYTELO;
- 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, could severely and adversely affect our financial results, business and business prospects, including the commercialization of RYTELO, and might cause us to cease operations. Similar requirements and related consequences apply outside the U.S.

If our business activities become subject to challenge under supranational, national, federal, state or 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 market, sell and distribute RYTELO. 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 or comparable foreign 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.

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 authorities, 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 sales of RYTELO in the U.S. and outside the U.S. if approved.

RISKS RELATED TO THE FURTHER DEVELOPMENT OF RYTELO (IMETELSTAT)

We cannot be certain that we will be able to continue to develop RYTELO (imetelstat) or advance it in clinical trials, or that we will be able to receive regulatory approval for RYTELO in any other indications in the U.S., the EU or any other region, on a timely basis or at all.

We are wholly dependent on the success of RYTELO (imetelstat), which is our only product approved for marketing by the FDA and our ability to generate revenue from product sales and achieve profitability is wholly dependent on our ability to successfully commercialize RYTELO for lower-risk MDS or to expand its indications of use. In this regard, in addition to lower-risk MDS, which is the only indication for which RYTELO has received marketing approval in the U.S., we are developing imetelstat for the treatment

of several myeloid hematologic malignancies. Our ability to further develop imetelstat and to expand its indications of use to other myeloid hematologic malignancies is subject to significant risks and uncertainties, including, among other things, our ability to:

- receive regulatory approval to commercialize RYTELO in lower-risk MDS from the 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 in the EU;
- 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 imetelstat clinical trials in other myeloid hematologic malignancies;
- obtain and maintain required regulatory clearances and approvals to enable continued clinical development of imetelstat;
- enter into and maintain commercially reasonable arrangements with third parties to provide services needed to further research, develop and commercialize RYTELO, 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 commercialization of RYTELO in potential other approved indications and outside the U.S. if approved;
- enter into and maintain arrangements with third parties to provide services needed to support the commercialization of RYTELO for territories outside of the U.S. in compliance with applicable laws;
- achieve acceptance of RYTELO treatment 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 relapsed/refractory MF, and potentially other myeloid hematologic malignancies;
- obtain appropriate coverage and reimbursement levels for the cost of RYTELO from governmental authorities, private health insurers and other third-party payors; and
- obtain, maintain and enforce adequate intellectual property and regulatory exclusivity for RYTELO 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 commercialization of RYTELO in indications other than lower-risk MDS, we may be forced to abandon our development and/or commercialization of RYTELO in indications other than lower-risk MDS, which could severely harm our business, prospects and our ability to raise additional capital.

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.

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 trial 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 for 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, of imetelstat, any of which could severely and adversely affect our financial results, business and business prospects.

RYTELO (imetelstat) may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could halt or limit its commercialization, delay or prevent its regulatory approval in any other jurisdiction or indication, or cause us to delay or terminate our clinical trials.

RYTELO (imetelstat) has been administered only to a limited number of patients in clinical trials. While the FDA granted approval of RYTELO based on the data included in our NDA, including data from the Phase 3 IMerge trial, we do not know whether the results when a larger number of patients receive RYTELO from commercial use, including results related to safety, will be consistent with the results from earlier clinical trials that served as the basis for its approval.

In addition, because remaining patients in ongoing clinical trials continue to receive imetelstat, 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. New data relating to imetelstat, including from adverse event reports and our post-marketing requirements in the United States, and from ongoing clinical trials of imetelstat, may result in changes to the product label and may adversely affect sales, or result in withdrawal of imetelstat from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing our marketing applications for additional indications and/or in other jurisdictions, or impose post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

Further, as a result of commercialization of RYTELO (imetelstat), or in current or potential future clinical trials, RYTELO 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 its commercialization or current or potential future clinical trials. In this regard, adverse events and dose-limiting toxicities observed in previous and ongoing clinical trials 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 who receive RYTELO as a result of commercialization or in any clinical trials 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 from our commercialization efforts or in clinical trials do not support an adequate benefit-risk profile to justify continued treatment of patients, then the FDA or other similar international regulatory authorities may halt or restrict the commercialization of RYTELO or place one or more of our INDs on clinical hold, as occurred in March 2014. If this were to occur, there could be a significant delay in, or possible termination of, one or more of our clinical trials, and our commercialization efforts could be halted, which might cause us to cease operations. If such toxicities or other safety issues identified as a result of our commercialization of RYTELO or in any clinical trial are determined by us, the FDA or similar international regulatory authorities to result in an unacceptable benefit-risk profile, then:

•the FDA could withdraw or restrict regulatory approval for RYTELO in the U.S. for lower-risk MDS;

•additional information supporting the benefit-risk profile of RTYELO 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, regulatory approval could be withdrawn by the FDA in the U.S., and/or current clinical trials 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 RYTELO in a specific patient population;

•additional, unexpected clinical trials or non-clinical studies may be required to be conducted; or

•RYTELO may not receive or maintain regulatory clearances and approvals required to enable its continued development.

The occurrence of any of these events could interrupt, further delay, or halt, our commercialization or RYTELO or its further development, and as a result, could preclude the commercialization of RYTELO in any additional indications, as well as increase costs for continued development in additional indications, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business and business prospects, 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, including IMpactMF, will lead to similar results and data that could potentially enable us to obtain any further 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 and business prospects, 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 of imetelstat, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business and business prospects.

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 halt the commercialization of RYTELO, 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, including the commercialization of RYTELO, 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 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 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 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 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. 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. 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 and business prospects, including the commercialization of RYTELO, 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 and business prospects.

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 or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities 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 or comparable foreign regulatory authorities 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 future applications for regulatory approval of imetelstat, including in any additional indications by the FDA.

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, or our imetelstat development program as a whole.

We do not control the design or administration of investigator-led clinical 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 current or potential future investigator-led clinical trial could have a material adverse effect on our ability to maintain regulatory approval for RYTELO in lower-risk MDS, or to further develop or advance it in 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 RYTELO in any indication, including lower-risk MDS in the EU. To the extent that the results of any investigator-led clinical trials raise safety or other concerns, regulatory authorities may withdraw or restrict approval for RYTELO, 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 withdrawal of approval of RYTELO, partial or full clinical holds being placed on our INDs by the FDA or other similar international regulatory authorities, as occurred in March 2014, which would further delay or prevent us from commercializing RYTELO or advancing it into further clinical development. Any of the foregoing would delay or preclude any future marketing approvals for RYTELO and could cause us to discontinue our development of it, which would severely harm our business and prospects and could potentially cause us to cease operations.

RISKS RELATED TO MANUFACTURING RYTELO (IMETELSTAT)

Failure by us to maintain a manufacturing supply chain to appropriately and adequately supply RYTELO for commercial and future clinical uses would adversely affect our ability to commercialize RYTELO and result in a further delay in or cessation of clinical trials, and our business and business prospects could be severely harmed, and we could cease operations.

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

•the ability to consistently manufacture and attain sufficient production yields with acceptable quality control and quality assurance to meet market demand for our commercialization of RYTELO, as well as the needs for continuing clinical trials;

•our ability to maintain existing commercial supply agreements and to establish additional or alternative supply agreements if necessary, including our ability to successfully transfer manufacturing technology and attain regulatory approval at any such additional or alternative suppliers;

•reliance on third-party manufacturers and suppliers, whose efforts we do not control;

•supply chain issues, including the timely availability of product and management of shelf-life, including raw materials, drug substance, and drug product 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 at any of our third party suppliers; 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.

As a result of these and other risks, we may be unable to maintain a manufacturing infrastructure and supply chain capable of providing RYTELO for clinical and commercial use, which would delay or adversely affect our RYTELO commercialization efforts; result in lost sales; delay or result in a cessation of our current or potential future clinical trials; delay or preclude potential future regulatory approvals of RYTELO in other jurisdictions or indications; and could cause financial and reputational harm.

If third parties that manufacture RYTELO fail to perform as needed, the commercial and clinical supply of RYTLEO will be limited, and we may be unable to successfully commercialize RYTELO or conduct or complete current or potential future clinical trials.

Our RYTELO manufacturing supply chain relies, and will continue to rely, solely upon third-party manufacturers to perform certain manufacturing, quality control, and other technical and scientific work with respect to RYTELO, as well as to supply starting materials and manufacture drug substance and drug product for our commercialization of RYTELO, as well as current and potential future clinical trials. While we have established arrangements with third parties for the manufacture of RYTELO, 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 commercialize RYTELO and/or pursue further development of RYTELO on our own, increase our costs, result in lost sales, and otherwise negatively affect our financial results, business and business prospects. In this regard, recent FDA inspections of one of our third-party drug product manufacturers identified certain deficiencies in the manufacturer's processes and facilities which, while not directly related to the FDA approval or ongoing production of RYTELO, could impact the manufacturer's ability to produce and deliver products, including RYTELO, 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 RYTELO and other materials to support commercialization and clinical trials 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 or production orders with any additional third-party manufacturers and suppliers that we may identify 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, including to provide the quantities of RYTELO required to meet commercial and clinical needs;

•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 additional manufacturer, which could involve technology transfer, new testing, compliance inspections, and would likely require FDA or comparable foreign regulatory authority approval;

•the inability of third-party manufacturers to timely formulate and manufacture RYTELO or to produce or ship RYTELO in the quantities or of the quality required to meet commercial and clinical needs;

•the possible mislabeling by third-party manufacturers of finished drug product for both commercial and clinical use, potentially resulting in product recall and harm to our business;

•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 RYTELO 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 commercialization, and non-clinical and clinical activities, which could severely and adversely affect our financial results, business and business prospects.

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 commercialization of RYTELO. 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, regulatory risks, and because the number of potential manufacturers for oligonucleotide products 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 OPERATING RESULTS, FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have a history of net losses. We expect to continue to incur net losses for the foreseeable future and may not achieve consistent future profitability for some time, if ever.

We are incurring and have incurred net losses every year since our operations began in 1990, except for one. As of September 30 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. In addition, we 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 continue with the commercialization of RYTELO, including as a result of our obligation to pay Royalty Pharma revenue interest payments under the Royalty Pharma Agreement. Although we have recently begun to commercialize RYTELO, our revenue and profit potential is unproven and our very limited operating history as a commercial company makes our future operating results difficult to predict. We will need to generate significant revenues to achieve consistent future profitability. We may never achieve consistent future profitability. Even if we do become profitable in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve consistent future profitability could negatively impact the market price of our common stock and our ability to sustain operations.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our common stock could decline.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. Due to the approval by the FDA in June 2024 of RYTELO for lower-risk MDS and the limited historical sales data, RYTELO sales will be difficult to predict from period to period and as a result, you should not rely on RYTELO sales results in any period as being indicative of future performance. Sales of RYTELO may be below our own guidance or the expectations of securities analysts or investors in the future. To the extent that we do not meet our guidance or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

•the level of demand for RYTELO;

•the extent to which coverage and reimbursement for RYTELO is available from government and health administration authorities, private health insurers, managed care programs and other third-party payors;

•changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the government

discount percentage resulting from price increases we may take in the future, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;

•increases in the scope of eligibility for customers to purchase RYTELO at the discounted government price or to obtain government-mandated rebates on purchases of RYTELO;

•changes in our cost of sales;

•the timing and level of revenue interest payments under the Royalty Pharma Agreement;

•the timing, cost and level of investment in our sales and marketing efforts to support RYTELO sales;

•the timing, cost and level of investment in our research and development activities involving imetelstat and potential future product candidates; and

•expenditures we may incur to develop and/or commercialize any additional products, product candidates, or technologies that we may develop, in-license, or acquire.

Further, changes in our operations, such as increased development, manufacturing and clinical trial expenses in connection with RYTELO, or our undertaking of additional programs, business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price, the magnitude of the expense that we must recognize may vary significantly.

For these and other reasons, it is difficult for us to accurately forecast future sales of RYTELO, operating expenses or future profits or losses. As a result, our operating results in future periods could be below our guidance or the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps significantly.

Our failure to obtain additional capital when needed would force us to further delay, reduce or eliminate the further development of RYTELO, or to halt the commercialization of RYTELO, 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 September 30, 2024, we had approximately $378.9 million in cash, cash equivalents, restricted cash and marketable securities. On a pro forma basis, including gross proceeds from the upfront payment under the Royalty Pharma Agreement and the Tranche A Loan, and after repayment of our existing debt under the Hercules Loan Agreement, we had approximately $542.4 million in cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2024. Based on our current operating plans and assumptions, we believe that our existing cash, cash equivalents, and marketable securities (including the $250 million received under the Pharmakon Loan Agreement and the Royalty Pharma Agreement), together with anticipated revenues from U.S. sales of RYTELO, will be sufficient to fund our projected operating requirements for at least the next 12 months from the date of this filing. We believe that our projected financial resources will be sufficient to (i) support commercial launch of RYTELO in the U.S. and potential launch in the EU, (ii) complete the Phase 3 IMpactMF trial in relapsed/refractory MF, (iii) invest in supply chain redundancy for RYTELO, and (iv) fund our general working capital requirements. If we do not generate sufficient funds from commercial sales of RYTELO, or if we experience regulatory delays or other unforeseen events or choose to make other investments in our business, we may require additional funding, which could include a combination of public or private equity offerings, debt financings (including additional tranches under the Pharmakon Loan Agreement, if available), collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, which may not be possible. If adequate funds are not available on a timely basis, if at all, our RYTELO commercialization efforts may be adversely affected and we may be unable to pursue further development of imetelstat, which would severely harm our business and we might cease operations.

Despite FDA approval of RYTELO in June 2024, the outcome of any clinical activities and/or regulatory approval process is highly uncertain, and we cannot reasonably estimate whether our future development activities may succeed; whether we will obtain regulatory approval for RYTELO in the EU in lower-risk MDS, or in any other jurisdictions or indications we are pursuing or may in the future pursue, or whether we will be able to effectively commercialize RYTELO in the U.S. for lower-risk MDS or other potential indications, if at all. We may never recoup our investment in any RYTELO 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 level of sales and market acceptance of RYTELO;

•the scope, progress, timing, magnitude and costs of non-clinical and clinical development, manufacturing and commercialization of imetelstat, including potential commercialization in the EU for lower-risk MDS, or in any other jurisdictions or other indication we may pursue, 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 RYTELO;

•the costs, timing and outcomes of regulatory reviews or other regulatory actions related to RYTELO, including with respect to our MAA submission for RYTELO in the EU for 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 RYTELO, including with respect to third-party vendors and service providers and our ability to achieve any meaningful reduction in manufacturing costs;

•the sales price for RYTELO;

•the availability of coverage and adequate third-party reimbursement for RYTELO;

•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 RYTELO;

•the extent to which we are able to enter into and conduct successful arrangements with third parties, including for the commercialization and marketing of RYTELO in certain regions outside of the U.S., if approved for commercialization;

•the extent and scope of our selling, 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 sales of RYTELO 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 Tranche B Loan and the Tranche C Loan under the Pharmakon Loan Agreement, which are subject to certain funding conditions; 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 effectively commercialize RYTELO, or raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for

RYTELO when needed, the development and commercialization of RYTELO 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 Pharmakon Loan Agreement or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as the Pharmakon 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 RYTELO or our technologies or grant licenses on terms that are not favorable to us.

RISKS RELATED TO OUR INDEBTEDNESS AND LIABILITIES

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.

On November 1, 2024, we entered into the Pharmakon Loan Agreement. We drew the Tranche A Loan of $125.0 million on November 1, 2024 and as of November 1, 2024, the total outstanding principal amount under the Pharmakon Loan Agreement was $125.0 million. The tranches for the remaining $125.0 million available to us under the Pharmakon Loan Agreement are as follows: (a) a Tranche B Loan of $75.0 million, which is available until December 31, 2025 and is available at our option, subject to certain customary and limited conditions; and (b) the Tranche C Loan of $50.0 million, which is available through December 31, 2025, subject to certain conditions including achieving a certain revenue milestone on or prior to November 30, 2025. If we do not achieve such revenue milestone within the required timeline, we will not be eligible to draw funds under the Tranche C Loan under the Pharmakon Loan Agreement. In addition, before we would consider drawing down any of the remaining tranches under the Pharmakon 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 Pharmakon Loan Agreement are secured by substantially all of our assets, including our intellectual property. Further, the terms of the Pharmakon 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 Pharmakon 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 Pharmakon Loan Agreement could result in an event of default that, if not cured or waived, would permit the Lenders to accelerate our obligation to repay this indebtedness, and the Lenders 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 Pharmakon 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 Pharmakon Loan Agreement place restrictions on our operating and financial flexibility.

The Pharmakon 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.

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 interest 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 Pharmakon Loan Agreement or to comply with certain covenants in the Pharmakon Loan Agreement could result in an event of default, the occurrence and continuance of which provide the Lenders with the right to demand immediate repayment of all outstanding obligations under the Pharmakon Loan Agreement (and in the case of certain insolvency, liquidation, bankruptcy or similar events, automatically requires immediate repayment of all outstanding obligations under the Pharmakon Loan Agreement), and to exercise remedies against us and the collateral securing the Pharmakon Loan Agreement. These events of default include, among other things:

•insolvency, liquidation, bankruptcy or similar events;

•failure to observe covenants under the Pharmakon Loan Agreement and ancillary collateral documents, which failure, in certain limited cases, is not cured within 10 or 20 days;

•the occurrence of a material adverse change or a withdrawal event in respect to RYTELO;

•material misrepresentations;

•certain cross-default of third-party indebtedness or certain default or termination events of hedging assessments;

•certain money judgments being entered against us which are not timely paid, discharged or stayed; and

•our assets are attached or seized.

In the event of default, the Lenders could accelerate all of the amounts due under the Pharmakon 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 our RYTELO development or commercialization efforts or grant to others rights to develop and market RYTELO. The Lenders could also exercise their rights to take possession and dispose of the collateral securing the Pharmakon Loan Agreement, which collateral includes substantially all of our property including, without limitation, our intellectual property, subject to certain exceptions. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

The Royalty Pharma Agreement places restrictions on our operational flexibility.

The Royalty Pharma Agreement contains covenants that impose on us certain obligations with respect to revenue payments, diligence, reporting, indemnification and includes restriction on intellectual property transfers and out-licenses, and certain other actions. The Royalty Pharma Agreement also limits our ability to create or incur liens or dispose of certain assets related to imetelstat. We have no rights to repurchase the revenue interests in RYTELO sold to Royalty Pharma (other than in connection with a change of control event), thereby limiting our ability to eliminate future applicability of the covenants contained in the Royalty Pharma Agreement. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our stockholders.

RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain sufficient intellectual property protection for RYTELO, both in the U.S. and in other countries, our competitors could develop and commercialize products similar or identical to RYTELO, and our ability to successfully commercialize RYTELO may be adversely affected.

Protection of our proprietary technology is critically important to our business. Our success and the success of our commercialization and planned future development of RYTELO will depend on our ability to protect our technologies and RYTELO 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 RYTELO or our technology and/or limit the duration of the patent protection for RYTELO 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 RYTELO and/or our technologies will be adversely affected, and we may not be able to further develop or commercialize RYTELO.

While we have method-of-use patents that protect the use of RYTELO 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 RYTELO for an indication that is outside the scope of our approved use after our composition-of-matter patents or their patent term extensions, and any regulatory exclusivities 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.

In addition to our patents covering RYTELO, we also expect to rely on regulatory exclusivity, including orphan drug exclusivity of up to 7 years in the U.S. and 10 years in the E.U. following approval, to protect our rights to commercialize RYTELO for its approved uses, but such regulatory exclusivity may be limited or withdrawn. See "Risks Related to Regulatory Approval of RYTELO -- *Although orphan drug designation has been granted to RYTELO for the treatment of MDS and MF 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 market exclusivity, which could limit the period of exclusivity we are able to maintain for the commercialization of RYTELO, and would likely harm our business and business prospects.*"

Loss or impairment of our intellectual property rights related to RYTELO might further delay or halt ongoing or potential future clinical trials of RYTELO and any applications for regulatory approval, and might further delay or preclude any future development or commercialization of RYTELO by us. Furthermore, such loss of intellectual property rights could impair our ability to exclude others from commercializing products similar or identical to RYTELO 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 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 the same or similar products to RYTELO, and this circumstance could harm our financial condition, business and business prospects. 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 RYTELO 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. As a result, our intellectual property may not provide us with sufficient patent rights to exclude others from commercializing products similar or identical to RYTELO.

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 have applied to the Patent Office for patent term extension of some of our patents. 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. We expect to apply any patent term extension that is granted in the U.S. to our method of treatment patent for MDS and MF that expires on March 15, 2033. If such patent term extension is granted, we expect the term of the patent to extend through August 2037, although such timing is subject to approval by the Patent Office as part of its review of our application for patent term extension and could differ from our calculation. Currently, communication of patent term extension approval and the length of the granted extension period by the Patent Office may occur up to four 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. However, we might not be granted a patent term extension at all because of 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 and patent offices 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 and could be less than five years. 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. 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 indications. If we do not have sufficient patent life and regulatory exclusivity to protect RYTELO, our financial results, business and business prospects would be materially and adversely affected, which might cause us to cease operations.

In Europe and other countries, our composition of matter patent coverage expired 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 of up to five years 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. In Europe, we have separate method of treatment patents covering MDS and MF, and a SPC may only be applied to one patent. Accordingly, in countries of the European Economic Area, or EEA, we must rely on regulatory exclusivity and our method of treatment patents.

If regulatory approval of RYTELO 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 and regulatory exclusivity to protect RYTELO, our financial results, business and business prospects 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. Some of our patents have been listed in the Orange Book. Manufacturers of generic drugs may challenge the listing. If an appropriate patent covering RYTELO 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 RYTELO. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

The validity, scope and enforceability of any patents listed in the Orange Book that cover RYTELO or its methods of use can be challenged by third parties and may not protect us from generic or innovator competition.

If a third party files an application under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act or an abbreviated new drug application, or ANDA, under Section 505(j) to obtain permission to sell a generic version of RYTELO, and relies in whole or in part on studies conducted by or for us, the third-party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for RYTELO; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic product. A certification that the new product will not infringe the Orange Book-listed patents for RYTELO, or that such patents are invalid, is called a paragraph IV certification. If the third-party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third-party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay of FDA approval.

Our issued U.S. patents covering RYTELO or its methods of use may not provide adequate protection from competitive products if competitors receive approval of an ANDA application or are able to design around the patents. One or more competitors may circumvent these patents by filing a marketing application with the FDA for a competitive product containing the active moiety in RYTELO and successfully challenging the validity of the patents or successfully designing around the patents. Any successful challenge and/or designing around one or more of the patents could result in a generic version of RYTELO being commercialized before the expiration of the patents.

If the patents covering RYTELO or its methods of use are successfully challenged or designed around, or if we are unsuccessful in enforcing our patents against generics, we could face competition prior to the expiration of these patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful, and which could result in the invalidity or unenforceability of our patents covering RYTELO or its methods of use.

Competitors may infringe, misappropriate or otherwise violate our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file and prosecute legal claims against one or more third parties, which can be expensive and time-consuming, even if ultimately successful.

The initiation of a claim against a third party by us may also cause the third-party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or non-statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, IPR or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation.

In an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court and if any such lawsuits will ultimately be resolved successfully. Further, even if we prevail, the infringer may file an appeal and the court judgment may be overturned and/or that an adverse decision may be issued by an appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives. Even if we establish infringement, we may not seek, or the court may decide not to grant, an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection for RYTELO, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, any adverse outcome could allow third parties to commercialize RYTELO and compete directly with us, without payment to us.

Furthermore, if we are engaged in intellectual property litigation, there would be public announcements of filings, briefings, hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these events to be negative, it could have an adverse effect on the price of our common shares.

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.

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 RYTELO.

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 RYTELO, 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 RYTELO patent rights could severely and adversely affect our financial results, business and business prospects, 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 RYTELO. 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 RYTELO. 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 RYTELO 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 RYTELO 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 commercialization of RYTELO.

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 RYTELO patent rights could severely and adversely affect our financial results, business and business prospects, which might cause us to cease operations.

Certain jurisdictions, such as Europe, China, Japan, New Zealand and Australia, permit third parties to file oppositions or invalidation trials against granted patents or patents proposed to be granted. Because we seek to enable potential global commercialization of RYTELO, securing both proprietary protection and freedom to operate outside of the U.S. is important to our business.

Third party proceedings such as oppositions and invalidation trials require significant time and costs, and if we are unsuccessful or are unable to commit these types of resources to protect our RYTELO patent rights, we could lose our patent rights and we could be prevented or limited in the development and commercialization of RYTELO.

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, invalidation trials, 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 RYTELO, 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 RYTELO 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 RYTELO.

The commercial success of RYTELO will depend upon our ability to research, develop, manufacture, market and sell RYTELO 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 RYTELO and its uses, we do not know with certainty that RYTELO, or the 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 RYTELO, and while these patents have expired, or we believe that a reasonable court should find they are invalid and/or would not be infringed by the manufacture, use or sale of RYTELO, 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 RYTELO, 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 commercialization and continued development of RYTELO. If we are unable to resolve an infringement claim successfully, we could be subject to an injunction that would prevent us from commercializing RYTELO 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. 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 RYTELO. 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 RYTELO 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 RYTELO and could increase the development and/or production costs of RYTELO. 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 RYTELO, 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 RYTELO would further delay current and potential future clinical trials of RYTELO and any applications for regulatory approval, impair our ability to sell RYTELO, and therefore result in decreased sales of RYTELO for us. Occurrence of any of these events could materially and adversely affect our business and might cause us to cease operations.

We have a global trademark, RYTELO, for our product and failure to maintain such trademark could adversely affect our business.

We have a global trademark, RYTELO, which is the 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 trademark 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. We may be unable to maintain or enforce our current and future trademarks or trademark applications, and if we fail to satisfy the applicable regulatory requirements, we may not have enforceable trademark rights or registrations in such jurisdictions. Our product trademark, RYTELO, is approved by 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 could 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 commercialization and further development of RYTELO or to otherwise successfully manage our growth.

Our ability to successfully commercialize RYTELO in the U.S. for lower-risk MDS, and to continue to develop RYTELO in other myeloid hematologic malignancies 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 sales, marketing, market access, commercial operations, pricing, clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing, regulatory affairs, medical affairs, legal affairs, and compliance to enable us to further commercialize and further develop RYTELO.

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 commercialization and further development of RYTELO, 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 commercialize and further develop RYTELO 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 RYTELO depends, 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 RYTELO, we may be unable to establish such collaborative arrangements on acceptable terms, or at all, and may have to delay, alter or abandon commercialization or further development of RYTELO.

We intend to develop RYTELO broadly for hematologic malignancies, and to commercialize, market and sell RYTELO in the U.S. for lower-risk MDS and potentially in the EU for the same indication. We may seek to self-commercialize or seek a collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of RYTELO 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 RYTELO in lower-risk MDS in the 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 RYTELO. 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 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 RYTELO;
- delay or abandon the commercialization of RYTELO 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, 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 claims such as product liability or personal injury claims arising from our commercialization of RYTELO, 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 or personal injury claims related to the commercialization of RYTELO, or claims related to clinical trial conduct, including if the use of RYTELO is alleged to have injured patients, such as injuries alleged to arise from any hepatotoxicity or hemorrhagic event associated with the use of RYTELO. We currently have product liability and clinical trial liability insurance that we believe is adequate, but we may experience losses in excess of our coverage or that are not covered by our insurance, and we may not be able to maintain this type of insurance for the commercialization of RYTELO, or any of our current or potential future clinical trials of RYTELO. In addition, this type of insurance may become too expensive for us to afford because of the highly risky and uncertain nature of commercialization of RYTELO, 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 limit or cease our commercialization and further development of RYTELO.

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.

We are not currently a party to any material pending legal proceedings. However, securities 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, and final judgment with respect to the other two lawsuits was entered in October 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. All seven of the shareholder derivative actions have been 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. We could be forced to expend significant resources in the defense of any additional lawsuits, and we may not prevail. 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 any legal proceedings, 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. Our commercial launch of RYTELO may result in product or personal injury disputes, or other disputes with health care providers, patients or other third parties as a result of our commercialization efforts. We may experience employment-related disputes. We may become involved in performance or other disputes with the CROs we have retained to support our clinical development activities, or with other third parties such as service providers, vendors, manufacturers, suppliers or consultants. 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 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 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, targeted phishing campaigns, 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 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, particularly due to the reliance on software vendors to adequately patch and implement fixes to address critical or high-risk vulnerabilities in a timely manner. Further, we may be materially impacted by software updates applied by our software vendors if such updates cause significant downtime to our systems.

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 commercialization and development efforts, 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.

If we fail to successfully implement or upgrade our enterprise resource planning and other information systems, our business and results of operation could be adversely impacted.

We periodically implement or upgrade new or enhanced enterprise resource planning, or ERP, and other business systems in order to better manage our business operations. Implementation or upgrade of new business processes and information systems requires the commitment of significant personnel, training and financial resources, and entails risks to our business operations. If we do not successfully implement ERP and other information systems improvements, or if there are delays or difficulties in implementing these systems, we may not realize anticipated productivity improvements or cost efficiencies, and we may experience operational difficulties and challenges in effectively managing our business, all of which could result in quality issues, reputational harm, lost market and revenue opportunities, and otherwise adversely affect our business, financial condition and results of operations.

For example, we are currently in the process of implementing new ERP and other information systems to help us manage our operations and financial reporting. This project has required and may continue to require investment of capital and human resources, the re-engineering of processes of our business, and the attention of many employees who would otherwise be focused on other aspects of our business. Costs and risks inherent in this transition may include disruptions to business continuity, administrative and technical problems, interruptions or delays in sales, expenditure overruns, delays in paying our suppliers and employees, and data migration issues. If we do not properly address or mitigate these issues, this could result in increased costs and diversion of resources, negatively impacting our operating results and ability to effectively manage our business. Additionally, if we do not effectively implement the ERP system as planned, or the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively affected.

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 EU'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 EU 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: 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 continue to develop or commercialize RYTELO; 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 October 1, 2014 and September 30, 2024, our stock has traded as high as $6.38 per share and as low as $0.89 per share. Between October 1, 2023 and September 30, 2024, the price has ranged between a high of $5.34 per share and a low of $1.64 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:

- the level of RYTELO sales in the U.S.;
- announcements regarding regulatory approval or non-approval of RYTELO in any other jurisdictions or indications, or specific label indications for RYTELO; or restrictions, warnings or limitations in its use;
- announcements regarding the further research and development of RYTELO, 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 or potential future clinical trials, for any reason, or our inability, for any reason, to successfully continue the development of RYTELO;
- our ability to obtain additional capital when needed to further advance our development program;
- changes in laws or regulations applicable to RYTELO, including laws or regulations concerning the commercialization of RTYELO or clinical trial requirements for approval or other regulatory developments related to RYTELO;
- 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 RYTELO or inability to do so at acceptable prices;
- the size and growth of the market opportunity for RYTELO in its currently approved and any potential future approved indications;
- disputes or other developments relating to RYTELO 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 further development and commercialization of RYTELO 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;
- sales of stock by our officers and directors;
- 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 Pharmakon 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 in connection with our commercialization of RYTELO. 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. Moreover, we are currently in the process of implementing new ERP and other information systems to help us manage our operations and financial reporting. However, there is an increased risk that changing controls may be ineffective during the implementation and this ERP system may place additional burdens on employees to learn and adapt our processes to effectively operate under the ERP system. If the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively impacted. 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 the quarter ended September 30, 2024, 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**
Faye M. Feller, M.D., Executive Vice President and Chief Medical Officer	Adoption	July 12, 2024	X		974,167[1]	June 30, 2025
Andrew J. Grethlein, Ph.D., Executive Vice President and Chief Operating Officer	Adoption	July 12, 2024	X		1,279,985[2]	November 14, 2025
John A. Scarlett, M.D., Chairman of the Board, President and Chief Executive Officer	Adoption	July 12, 2024	X		1,374,298[3]	July 11, 2025
Anil Kapur Executive Vice President, Corporate Strategy, and Chief Commercial Officer (until August 31, 2024)	Adoption	July 9, 2024	X		1,587,500[4]	June 27, 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] Consists of 974,167 shares subject to stock options previously granted by Geron to Dr. Feller.

[2] Consists of 1,279,985 shares subject to stock options previously granted by Geron to Dr. Grethlein.

[3] Consists of 1,374,298 shares subject to stock options previously granted by Geron to Dr. Scarlett.

[4] Mr. Kapur's employment with Geron terminated on August 31, 2024. Consists of 1,587,500 shares subject to stock options previously granted by Geron to Mr. Kapur.

ITEM 6. EXHIBITS

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
10.1+*	Employment Agreement by and between the Registrant and James Ziegler, effective as of September 9, 2024.				
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 November 7, 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 November 7, 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 November 7, 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 November 7, 2024.**				
101	The following materials from the Registrant's September 30, 2024 Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three months ended September 30, 2024 and 2023, (iv) Condensed Consolidated Statements of Cash Flows for the three and nine months ended September 30, 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.

* Management contract or compensation plan or arrangement.

** The certifications attached as Exhibits 32.1 and 32.2 that accompany this Report 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: November 7, 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 10.1

Geron Corporation
919 E. Hillsdale Blvd., Suite 250
Foster City, CA 94404
+1 650 473 7700 main
+1 650 473 7750 fax
www.geron.com

EMPLOYMENT AGREEMENT

This Employment Agreement ("**Agreement**") is made effective as of September 9, 2024 (the "**Effective Date**"), by and between James Ziegler ("**Executive**") and Geron Corporation, a Delaware corporation (the "**Company**").

WHEREAS, the Company desires to employ Executive to provide personal services to the Company, and wishes to provide Executive with certain compensation and benefits in return for Executive's services;

WHEREAS, Executive wishes to be employed by the Company and provide personal services to the Company in return for certain compensation and benefits; and

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, it is hereby agreed by and between the parties hereto as follows:

ARTICLE I
DEFINITIONS

For purposes of the Agreement, the following terms are defined as follows:

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

1.2"**Cause**" means any of the following:

(a)any willful act or omission by Executive constituting dishonesty, fraud or other malfeasance against the Company;

(b) Executive's conviction of a felony under the laws of the United States or any state thereof or any other jurisdiction in which the Company conducts business;

(c) Executive's debarment by the U.S. Food and Drug Administration (FDA) from working in or providing services to any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992, or other ineligibility under any law or regulation to perform Executive's duties to the Company; or

(d) Executive's breach of any of the material policies of the Company.

1.3"**Change in Control**" shall have the meaning set forth in the Equity Incentive Plan.

1.4"**Code**" means the Internal Revenue Code of 1986, as amended.

1.5"**Company**" means Geron Corporation, any wholly-owned subsidiaries, and its successors in interest.

1.6"**Comparable Employment**" means employment on terms which provide (a) the same or greater rate of base pay or salary as in effect immediately prior to Executive's termination, (b) the same, equivalent or higher job title and level of responsibility as Executive had prior to Executive's termination, (c) equivalent or higher bonus opportunity as the bonus opportunity for the year preceding the year in which the termination occurs, and (d) a principal work location that is both (i) no more than forty-five (45) miles from Executive's principal work location immediately prior to Executive's termination and (ii) no more than thirty (30) miles farther from Executive's principal weekday residence than was Executive's principal work location immediately prior to the termination.

1.7"**Covered Termination**" means an Involuntary Termination Without Cause that occurs at any time, *provided* that such termination constitutes a "separation from service" within the meaning of Section 409A of the Code and the regulations promulgated thereunder, including Treasury Regulation Section 1.409A-1(h) (a "**Separation from Service**").

1.8"**Involuntary Termination Without Cause**" means Executive's dismissal or discharge other than (i) for Cause, or (ii) after an involuntary or voluntary filing of a petition under chapter 7 or 11 of 11 USC Section 101 et. seq., an assignment for the benefit of creditors, a liquidation of the company's assets in formal proceeding or otherwise or any other event of insolvency by the Company, in any case, without an offer of Comparable Employment by the Company or a successor, acquirer, or affiliate of the Company. For purposes of this Agreement, the termination of Executive's employment due to Executive's death or disability will not constitute a termination for Cause.

1.9"Inducement Plan" means the Company's 2018 Inducement Award Plan.

1.10"**Equity Incentive Plan**" means the Company's 2018 Equity Incentive Award Plan.

ARTICLE II
EMPLOYMENT BY THE COMPANY

2.1Position and Duties. Subject to the terms set forth herein, the Company agrees to employ Executive in the position of Executive Vice President, Chief Commercial Officer. During the Executive's employment in this position, Executive will report to the Chief Executive Officer. Executive shall serve in an employee capacity and shall perform such duties as are assigned to Executive by the Chief Executive Officer and, except as otherwise instructed by the Chief Executive Officer, such other duties as are customarily associated with the position of Executive Vice President, Chief Commercial Officer. During Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention (except for vacation periods as set forth herein and reasonable periods of illness or other incapacities permitted by the Company's general employment policies or as otherwise set forth in this Agreement) to the business of the Company.

2.2Employment at Will. Both the Company and Executive acknowledge and agree that Executive's employment with the Company is "at-will" and not for any specified period of time, and may be terminated at any time by Executive or the Company, with or without Cause, and with or without prior notice; provided, however, that if Executive's employment with the Company is terminated under circumstances that constitute a Covered Termination, Executive will be eligible to receive certain severance payments and benefits as set forth in Article IV below.

2.3Employment Policies. The employment relationship between the parties shall also be governed by the general employment policies and practices of the Company, including but not limited to those policies relating to protection of confidential information and assignment of inventions. In the event of a conflict between the terms of this Agreement and the Company's general employment policies or practices, this Agreement shall control.

2.4 Indemnification. The Company shall provide for indemnification of the Executive as set forth in the Indemnification Agreement attached hereto as Exhibit A.

ARTICLE III
COMPENSATION

3.1Base Salary. Executive shall receive for services to be rendered hereunder such annual base salary as is approved by the Board of Directors of the Company (the "**Board**") or the Compensation Committee of the Board, payable on the regular payroll dates of the Company, subject to increase in the sole discretion of the Board or Compensation Committee of the Board (the "**Base Salary**"). As of the Effective Date of this Agreement, Executive's Base Salary is $525,000.

3.2Bonus. As of the Effective Date of this Agreement, Executive shall be eligible to earn, for each fiscal year of the Company ending December 31, during Executive's employment with the Company, an annual discretionary cash bonus (an "**Annual Bonus**") targeted at forty-five percent (45%) of Executive's Base Salary. Executive's discretionary Annual Bonus will be paid during the standard timing for year-end performance bonuses, with the eligibility cutoff date for participation being October 1st in the performance year for which any bonus may be paid. It is tied to the achievement of certain performance goals established for the Company and each individual and prorated for the individual's performance period. The total bonus pool generated for distribution, if any, is determined at the discretion of the Board and then distributed based on individual performance. If the Company determines, in its reasonable discretion, that Executive has engaged in any misconduct intended to affect the payment of Executive's Annual Bonus or has otherwise engaged in any act or omission that would constitute Cause for termination of employment, as defined by Section 1.2 of the Agreement, Executive will automatically and immediately forfeit Executive's entire Annual Bonus. If the Annual Bonus has already been paid to Executive, such Annual Bonus will be deemed unearned, and the Company shall have the right to recover the entire amount of the Annual Bonus paid to Executive for the calendar year(s) in which such misconduct or other act or omission constituting Cause occurred. Without limiting the foregoing, any such misconduct or other act or omission constituting Cause will subject Executive to disciplinary action up to and including termination of employment. In addition, any Annual Bonus paid to Executive for the calendar year(s) in which such misconduct or other Cause occurred is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations, any other clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable laws, regulations, or statutes. Recovery by the Company of an Annual Bonus in accordance with this Section shall not constitute an event giving rise to a right by Executive to voluntarily terminate Executive's employment for Cause based on such recovery by the Company, nor shall it constitute "constructive termination", or any similar term or circumstance under the Agreement or any other plan or agreement with the Company.

3.3Inducement Stock Option. In accordance with the terms approved by Board or the Company's Compensation Committee of the Board, the Executive shall receive a time-based option (the "**Inducement Option**") to purchase one million, six hundred thousand (1,600,000) shares of Company

common stock having an exercise price equal to the fair market value of Company common stock, as reported by the Nasdaq Global Select Market, on the first date of Executive's employment, and vesting with respect to 12.5% of the shares on the six-month anniversary of the Executive's first date of employment and with respect to remaining shares on each monthly anniversary of the Executive's first date of employment in equal installments over 42 months thereafter. The Inducement Option serves as an inducement material to Executive entering into employment with the Company and will be granted under the Company's Inducement Plan as non-statutory stock options. The vesting of the Inducement Option shall be subject to Executive's continued service to the Company through the applicable vesting dates, provided, that upon the occurrence of a Change of Control, subject to Executive's continued service to the Company through the date of such Change of Control, the Inducement Option shall vest and become exercisable with respect to one hundred percent (100%) of the unvested shares subject thereto. The Inducement Option otherwise shall be subject to and governed in all respects by the terms of the Inducement Plan and the stock option agreement for the option grant to be entered into between the Company and Executive.

3.4Standard Company Benefits; Vacation. Executive shall be entitled to all rights and benefits for which Executive is eligible under the terms and conditions of the Company's benefit and compensation plans, practices, policies, and programs, as in effect from time to time, that are provided by the Company to its executive employees generally. Except as specifically provided herein, nothing in this Agreement is construed or interpreted to provide greater rights, participation, coverage, or benefits under such benefit plans or programs provided to executive employees pursuant to the terms and conditions of such benefit plans and programs. Executive will be eligible for vacation accruals in accordance with the Company's current time off policy, starting with twenty (20) days per year.

ARTICLE IV
SEVERANCE BENEFITS AND RELEASE

4.1Severance Benefits. If Executive's employment terminates due to a Covered Termination after the date of execution of this Agreement, Executive shall receive:

(i) Payment of Accrued Obligations Upon Termination of Employment. Upon a termination of Executive's employment for any reason at any time following the Effective Date, the Company shall pay to Executive in a single lump-sum cash payment as soon as administratively practicable following the date of termination, the aggregate amount of Executive's (A) earned but unpaid Base Salary, and (B) accrued but unpaid vacation pay. In addition, Executive shall be promptly paid for incurred but unreimbursed business expenses upon Executive's submission of such expenses in accordance with the Company's expense reimbursement policies. The amounts set forth in this Section 4.1(i) are collectively referred to as the "**Accrued Obligations**".

(ii) Severance Upon a Covered Termination. If Executive's employment terminates due to a Covered Termination at any time after the Effective Date, then, in addition to the Accrued Obligations:

(b) Executive shall be paid target Annual Bonus for the fiscal year in which the termination occurs, prorated for the length of service provided during the calendar year through the termination date, payable in a single lump-sum payment within thirty (30) days following the date of termination;

(c) Executive shall be paid an aggregate amount equal to twelve (12) months of Executive's Base Salary in effect on the date of termination, payable to Executive in a single lump-sum amount on the sixtieth (60th) day following the date of termination;

(d) Executive and Executive's covered dependents will be eligible to continue their health care benefit coverage as permitted by COBRA (Internal Revenue Code Section 4980B) at the Company's expense for the lesser of (i) twelve (12) months following the Covered Termination, or (ii) until the Executive and/or Executive's covered dependents are no longer eligible for COBRA (for clarification and as an example, in the event Executive is covered by another health plan, etc.). Thereafter, Executive and Executive's covered dependents shall be entitled to maintain coverage for Executive and Executive's eligible dependents at Executive's own expense for the balance of the period that Executive is entitled to coverage under COBRA; and

(e)the Inducement Option, along with any subsequent options or other exercisable equity interest in the Company held by Executive as of the date of termination shall remain outstanding and exercisable through the earlier of (i) the second (2nd) anniversary of the date of termination or (ii) the original expiration date of the option or other equity interest.

Notwithstanding the foregoing, if Executive's employment terminates due to a Covered Termination at any time after the Effective Date, Executive will receive the greater of (i) the severance benefits above, or (ii) the severance benefits provided for in the Amended and Restated Severance Plan attached hereto as Exhibit C, which may be amended from time-to-time by the Company at the Company's sole discretion, that is in effect at the time of termination. For the avoidance of doubt, all amounts payable under this Agreement shall be subject to applicable federal, state, local or foreign tax withholding requirements.

4.2Parachute Payments. If any payment or benefit Executive would receive in connection with a Change in Control from the Company or otherwise ("**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then such Payment shall be reduced to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the following order unless Executive elects in writing a different order (provided, however, that such election shall be subject to Company approval): reduction of cash payments; cancellation of accelerated vesting of stock awards; reduction of employee benefits. In the event that acceleration of vesting of stock award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's stock awards unless Executive elects in writing a different order for cancellation.

The Company for general audit purposes shall engage a nationally recognized public accounting firm (the "**Accounting Firm**") to perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Accounting Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date

on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. If the Accounting Firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with an opinion reasonably acceptable to Executive that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

4.3Release. Notwithstanding the foregoing, Executive's right to receive the amounts provided for in Sections 4.1(ii) and 4.2, and the Change of Control acceleration in any stock option agreement shall be subject to and conditioned upon Executive's execution and non-revocation of a release of claims in substantially the form attached hereto as Exhibit B (the "**Release**") (as such form may be modified to take into account changes in the law) within fifty (50) days following the termination date. Such Release shall specifically relate to all of Executive's rights and claims in existence at the time of such execution and shall confirm Executive's obligations under the Proprietary Information and Inventions Agreement (as defined below). It is understood that Executive has a certain period to consider whether to execute such Release, as set forth in the Release, and Executive may revoke such Release within seven (7) business days after execution. In the event Executive does not execute such Release within the applicable period, or if Executive revokes such Release within the subsequent seven (7) business day period, none of the aforesaid benefits set forth in Sections 4.1(ii), 4.2, and the Change of Control acceleration in any stock option agreement shall be payable to Executive under this Agreement and this Agreement shall be null and void.

4.4Section 409A. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of the Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (a) the expiration of the six-month period measured from the date of Executive's Separation from Service or (b) the date of Executive's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 4.4 shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due under the Agreement shall be paid as otherwise provided herein. For purposes of Section 409A of the Code, Executive's right to receive the payments of compensation pursuant to the Agreement shall be treated as a right to receive a series of separate payments and accordingly, each payment shall at all times be considered a separate and distinct payment.

4.5Mitigation. Executive shall not be required to mitigate damages or the amount of any payment provided under this Agreement by seeking other employment or otherwise, nor shall the amount of any payment provided for under this Agreement be reduced by any compensation earned by Executive as a result of employment by another employer or by any retirement benefits received by Executive after the date of the Covered Termination, or otherwise.

ARTICLE V
PROPRIETARY INFORMATION OBLIGATIONS

5.1Agreement. Executive agrees to abide by the Proprietary Information and Inventions Agreement (the "**Proprietary Information and Inventions Agreement**") attached hereto as Exhibit D.

5.2Remedies. Executive's duties under the Proprietary Information and Inventions Agreement shall survive termination of Executive's employment with the Company and the termination of this Agreement. Executive acknowledges that a remedy at law for any breach or threatened breach by Executive of the provisions of the Proprietary Information and Inventions Agreement would be inadequate, and Executive therefore agrees that the Company shall be entitled to injunctive relief in case of any such breach or threatened breach.

ARTICLE VI
OUTSIDE ACTIVITIES

6.1No Other Employment. Except with the prior written consent of the Board, Executive shall not during the term of Executive's employment with the Company, undertake or engage in any other employment, occupation, or business enterprise. Notwithstanding the foregoing, during the term of Executive's employment with the Company, Executive may (a) undertake or engage in any other employment, occupation or business enterprise in which Executive is a passive investor, and/or (b) engage in civic and not-for-profit activities, in each case, so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

6.2No Conflicting Business Interests. During the term of Executive's employment by the Company, except on behalf of the Company, Executive shall not directly or indirectly, whether as an officer, director, stockholder, partner, proprietor, associate, representative, consultant, or in any capacity whatsoever engage in, become financially interested in, be employed by, or have any business connection with any other person, corporation, firm, partnership, or other entity whatsoever which were known by Executive to compete directly with the Company, throughout the world, in any line of business engaged in (or planned to be engaged in) by the Company; *provided, however*, that anything above to the contrary notwithstanding, Executive may own, as a passive investor, securities of any competitor corporation, so long as Executive's direct holdings in any one such corporation shall not in the aggregate constitute more than 1% of the voting stock of such corporation.

ARTICLE VII
NONINTERFERENCE

While employed by the Company, and for one (1) year immediately following the date on which Executive terminates employment or otherwise ceases providing services to the Company, Executive agrees not to interfere with the business of the Company by soliciting or attempting to solicit any employee of the Company to terminate such employee's employment in order to become an employee, consultant, or independent contractor to or for any pharmaceutical or biotechnology competitor of the Company. Executive's duties under this Article VII shall survive termination of Executive's employment with the Company and the termination of this Agreement.

ARTICLE VIII
DEBARMENT

Executive certifies that Executive has never been: (a) debarred by any relevant authorities, pursuant to any applicable law, including, but not limited to, Section 306(a) and (b) of the US Federal Food, Drug, and Cosmetic Act; (b) convicted of any of the felonies identified among the Exclusion Authorities listed on the U.S. Department of Health and Human Services (HHS) Office of Inspector General website; or (c) listed as being suspended, debarred, or excluded, or otherwise ineligible to participate in Federal

procurement or non-procurement programs, including, but not limited to, being listed on the List of Excluded Individuals/Entities (LEIE) database on the HHS Office of Inspector General website. If Executive becomes suspended, debarred, or excluded pursuant to any of the foregoing, Executive must notify the Company immediately in writing.

ARTICLE IX
GENERAL PROVISIONS

9.1Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including personal delivery by telex) or the third day after mailing by first class mail, to the Company at its primary office location and to Executive at Executive's address as listed on the Company payroll.

9.2Section 409A. To the extend applicable, this Agreement shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretative guidance issued thereunder, including without limitation any such regulations or other such guidance that may be issued after the Effective Date ("**Section 409A**"). Notwithstanding any provision of this Agreement to the contrary, in the event that following the Effective Date, the Company determines in good faith that any compensation or benefits payable under this Agreement may not be either exempt from or compliant with Section 409A, the Company may adopt such amendments to this Agreement or adopt other policies or procedures (including amendments, policies and procedures with retroactive effect), or take any other commercially reasonable actions necessary or appropriate to preserve the intended tax treatment of the compensation and benefits payable hereunder, including without limitation actions intended to (i) exempt the compensation and benefits payable under this Agreement from Section 409A, and/or (ii) comply with the requirements of Section 409A, provided, that this Section 8.2 does not, and shall not be construed so as to, create any obligation on the part of the Company to adopt any such amendments, policies or procedures or to take any other such actions or to create any liability on the part of the Company for any failure to do so.

9.3Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal, or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality, or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed, and enforced in such jurisdiction as if such invalid, illegal, or unenforceable provisions had never been contained herein.

9.4Waiver. If either party should waive any breach of any provisions of this Agreement, they shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

9.5Complete Agreement. This Agreement and Exhibits A, B, C and D hereto constitute the entire agreement between Executive and the Company and are the complete, final, and exclusive embodiment of their agreement with regard to this subject matter (except for the Equity Incentive Plan and the Inducement Plan and award agreements thereunder, the Amended and Restated Severance Plan, and any successors thereto). As of the Effective Date, this Agreement supersedes any prior agreement between Executive and the Company or any predecessor employer in its entirety. Executive and the Company acknowledge and agree that this Agreement is entered into without reliance on any promise or

representation other than those expressly contained herein or therein and cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

9.6 Counterparts and Electronic Signatures. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement. The parties agree that execution of this Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

9.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

9.7Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors, and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder, without the written consent of the Company, which shall not be withheld unreasonably.

9.8Arbitration. In the event of any contractual, statutory or tort dispute or claim relating to or arising out of Executive's employment relationship with the Company (including but not limited to any claims of wrongful termination or age, sex, race, or other discrimination, but not including workers' compensation claims), Executive and the Company agree that all such disputes will be finally resolved by binding arbitration conducted by a single neutral arbitrator associated with the American Arbitration Association in Foster City, California. Executive and the Company hereby waive their respective rights to have any such disputes or claims tried to a judge or jury. However, the Company agrees that this arbitration provision will not apply to any claim, by either Executive or the Company, for injunctive relief. The administrative costs of any arbitration proceeding between Executive and the Company and the fees and costs of the arbitrator shall be borne by the Company.

9.9Attorneys' Fees. If either party hereto brings any action to enforce rights hereunder, each party in any such action shall be responsible for its own attorneys' fees and costs incurred in connection with such action.

9.10Acknowledgement. Executive acknowledges that Executive (a) has had the opportunity to discuss this matter with and obtain advice from independent counsel of Executive's own choice and has been advised to do so by the Company, (b) has carefully read and fully understands all the provisions of this Agreement, and (c) is knowingly and voluntarily entering into this Agreement. Executive represents that Executive (i) is familiar with the restrictive covenants set forth in the Proprietary Information and Inventions Agreement and (ii) is fully aware of Executive's obligations thereunder.

9.11Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the law of the State of California.

9.12Personal Information. Executive understands that the Company may hold certain personal information about him or her, including, but not limited to, your name, home address, telephone number, date of birth, social security number, salary, nationality, and job title (collectively, "**Personal**

Data"). Certain Personal Data may also constitute "Sensitive Personal Data" within the meaning of applicable local law. Such data include, but are not limited to, Personal Data and any changes thereto, and other appropriate personal and financial data about you. The Company's lawful basis for processing Personal Data and Sensitive Personal Data include fulfilling its role as an employer, compliance with law, and legitimate business interest. Executive hereby provides express consent to the Company to process such Personal Data and Sensitive Personal Data and to transfer any such Personal Data and Sensitive Personal Data to any third parties outside the country in which you are employed or retained, for purposes of administrating and managing your employment relationship with the Company. Executive may, at any time, review his or her Personal Data, request any necessary corrections to it, or withdraw his or her consent in writing by contacting the Company; however, withdrawal of your consent may affect your employment with the Company.

9.13Eligibility to Work. In accordance with federal law, all new employees are required to present evidence of their eligibility to be employed in the United States and this Agreement is subject to proof of Executive's ability to lawfully work in the United States. Accordingly, the Company requests that Executive provide the Company with appropriate documentation for this purpose within 72 hours of the first day of employment. Acceptable documents include, but are not limited to, a birth certificate, a passport, a visa, permanent residence card, or driver's license and social security card.

9.14Pre-Employment Screenings as a Condition of Employment. As a condition of employment, Executive will be required to submit to a background check which must yield results considered acceptable to the Company. Standard screenings include verification of prior employment and education, a drug test, and a criminal history check. Additional screenings, such as a credit check or Department of Motor Vehicles record check, may be applicable based on job function. Further, the Company will require the receipt of professional references that are predominately positive in content and character. If the results of any of these screenings are determined by the Company to be noncompliant with its policies, procedures, or general business requirements, the Company reserves the right to unilaterally revoke this Agreement, with no obligation or liability to you.

IN WITNESS WHEREOF, the parties have executed this Agreement on the respective dates set forth below:

GERON CORPORATION

By: /s/ John A. Scarlett
John A. Scarlett, MD
Chairman of the Board, President & CEO

Date: 08-Aug-2024

Accepted and agreed this 9 day of August, 2024.

/s/ James Ziegler
James Ziegler

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: November 7, 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: November 7, 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 September 30, 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: November 7, 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 September 30, 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: November 7, 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.