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, 2026

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 October 30, 2026:
Common Stock, $0.001 par value	644,238,859 shares

GERON CORPORATION
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2026

TABLE OF CONTENTS

		Page
	PART I. FINANCIAL INFORMATION	
Item 1:	Financial Statements (Unaudited)	3
	Condensed Consolidated Balance Sheets	4
	Condensed Consolidated Statements of Operations	5
	Condensed Consolidated Statements of Comprehensive Income (Loss)	6
	Condensed Consolidated Statements of Stockholders' Equity	7
	Condensed Consolidated Statements of Cash Flows	9
	Notes to Condensed Consolidated Financial Statements	10
Item 2:	Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Item 3:	Quantitative and Qualitative Disclosures About Market Risk	39
Item 4:	Controls and Procedures	39
	PART II. OTHER INFORMATION	
Item 1:	Legal Proceedings	40
Item 1A:	Risk Factors	40
Item 2:	Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities	90
Item 3:	Defaults Upon Senior Securities	90
Item 4:	Mine Safety Disclosures	90
Item 5:	Other Information	90
Item 6:	Exhibits	91
	SIGNATURES	92

RYTELO® and other trademarks or service marks of Geron Corporation appearing in this Quarterly Report on Form 10-Q (this "Report") are the property of Geron Corporation. This Report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(UNAUDITED)

	SEPTEMBER 30, 2026	DECEMBER 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,179	$ 77,560
Restricted cash	1,892	1,880
Marketable securities	217,300	280,359
Accounts receivable, net	45,979	36,987
Interest and other receivables	2,028	2,239
Inventory	126,603	116,636
Prepaid and other current assets	5,761	4,610
Total current assets	468,742	520,271
Noncurrent marketable securities	50,999	41,289
Property and equipment, net	1,106	884
Operating leases, right-of-use assets	563	2,151
Deposits and other assets	5,696	5,945
Total assets	$ 527,106	$ 570,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,464	$ 11,257
Accrued compensation and benefits	10,768	30,497
Operating lease liabilities	789	1,000
Liability related to sale of future royalties	23,318	17,448
Accrued liabilities	23,909	51,340
Total current liabilities	74,248	111,542
Noncurrent operating lease liabilities	—	1,445
Noncurrent liability related to sale of future royalties	105,724	112,134
Noncurrent debt	120,439	119,547
Total liabilities	300,411	344,668
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value	—	—
Common stock, $0.001 par value	644	640
Additional paid-in capital	2,101,451	2,080,804
Accumulated deficit	(1,874,813)	(1,855,841)
Accumulated other comprehensive income (loss)	(587)	269
Total stockholders' equity	226,695	225,872
Total liabilities and stockholders' equity	$ 527,106	$ 570,540

See accompanying notes to condensed consolidated financial statements.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2026	2025	2026	2025
Revenues:				
Product revenue, net	$ 60,114	$ 47,167	$ 169,358	$ 135,610
Royalties	76	60	149	256
Total revenues	60,190	47,227	169,507	135,866
Costs and operating expenses:				
Cost of goods sold	6,051	1,043	16,983	3,439
Research and development	12,709	21,070	49,695	57,884
Selling, general and administrative	35,702	39,001	109,990	117,588
Restructuring charges	(71)	—	(622)	—
Total costs and operating expenses	54,391	61,114	176,046	178,911
Income (loss) from operations	5,799	(13,887)	(6,539)	(43,045)
Interest income	3,025	4,264	9,417	14,072
Interest expense	(7,207)	(8,644)	(21,500)	(25,360)
Other income (expense), net	(267)	(161)	(350)	(305)
Net income (loss)	$ 1,350	$ (18,428)	$ (18,972)	$ (54,638)
Net income (loss) per share:				
Basic	$ 0.00	$ (0.03)	$ (0.03)	$ (0.08)
Diluted	$ 0.00	$ (0.03)	$ (0.03)	$ (0.08)
Weighted-average common shares:				
Basic	672,293	667,102	670,799	666,397
Diluted	674,052	667,102	670,799	666,397

See accompanying notes to condensed consolidated financial statements.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2026	2025	2026	2025
Net income (loss)	$ 1,350	$ (18,428)	$ (18,972)	$ (54,638)
Net unrealized gain (loss) on marketable securities	(265)	218	(732)	82
Foreign currency translation adjustment	17	73	(124)	65
Comprehensive income (loss)	$ 1,102	$ (18,137)	$ (19,828)	$ (54,491)

See accompanying notes to condensed consolidated financial statements.

GERON CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS)
(UNAUDITED)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2025	639,856	$ 640	$ 2,080,804	$ (1,855,841)	$ 269	$ 225,872
Net loss	—	—	—	(3,642)	—	(3,642)
Other comprehensive loss	—	—	—	—	(412)	(412)
Foreign currency translation adjustment	—	—	—	—	(48)	(48)
Issuance of common stock in connection with exercise of warrants	—	—	1,511	—	—	1,511
Issuances of common stock under equity plans	1,172	1	913	—	—	914
Stock-based compensation related to issuances of common stock and options for services	5	—	13	—	—	13
Stock-based compensation for equity-based awards to employees and directors	—	—	4,900	—	—	4,900
Balance at March 31, 2026	641,033	$ 641	$ 2,088,141	$ (1,859,483)	$ (191)	$ 229,108
Net loss	—	—	—	(16,680)	—	(16,680)
Other comprehensive loss	—	—	—	—	(55)	(55)
Foreign currency translation adjustment	—	—	—	—	(93)	(93)
Issuances of common stock under equity plans	1,131	1	1,070	—	—	1,071
Stock-based compensation related to issuances of common stock and options for services	6	—	16	—	—	16
Stock-based compensation for equity-based awards to employees and directors	—	—	4,933	—	—	4,933
Employee stock purchases	300	—	314	—	—	314
Balance at June 30, 2026	642,470	$ 642	$ 2,094,474	$ (1,876,163)	$ (339)	$ 218,614
Net income	—	—	—	1,350	—	1,350
Other comprehensive loss	—	—	—	—	(265)	(265)
Foreign currency translation adjustment	—	—	—	—	17	17
Issuances of common stock under equity plans	1,761	2	2,164	—	—	2,166
Stock-based compensation related to issuances of common stock and options for services	7	—	14	—	—	14
Stock-based compensation for equity-based awards to employees and directors	—	—	4,799	—	—	4,799
Balance at September 30, 2026	644,238	$ 644	$ 2,101,451	$ (1,874,813)	$ (587)	$ 226,695

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	606,388	$ 606	$ 2,051,794	$ (1,772,341)	$ 261	$ 280,320
Net loss	—	—	—	(19,835)	—	(19,835)
Other comprehensive gain	—	—	—	—	55	55
Foreign currency translation adjustment	—	—	—	—	(12)	(12)
Exercise of Pre-Funded Warrant	30,370	31	—	—	—	31
Issuances of common stock under equity plans	155	—	256	—	—	256
Stock-based compensation related to issuances of common stock and options for services	5	—	15	—	—	15
Stock-based compensation for equity-based awards to employees and directors	—	—	7,408	—	—	7,408
Balance at March 31, 2025	636,918	$ 637	$ 2,059,473	$ (1,792,176)	$ 304	$ 268,238
Net loss	—	—		(16,375)	—	(16,375)
Other comprehensive loss	—	—	—	—	(191)	(191)
Foreign currency translation adjustment	—	—	—	—	4	4
Issuances of common stock under equity plans	509	1	590	—	—	591
Stock-based compensation related to issuances of common stock and options for services	6	—	26	—	—	26
Stock-based compensation for equity-based awards to employees and directors	—	—	6,738	—	—	6,738
Employee stock purchases	417	—	500	—	—	500
Balance at June 30, 2025	637,850	$ 638	$ 2,067,327	$ (1,808,551)	$ 117	$ 259,531
Net loss	—	—	—	(18,428)	—	(18,428)
Other comprehensive income	—	—	—	—	218	218
Foreign currency translation adjustment	—	—	—	—	73	73
Stock-based compensation related to issuances of common stock and options for services	6	—	29	—	—	29
Issuance of common stock under equity plans	500	—	542	—	—	542
Stock-based compensation for equity-based awards to employees and directors	—	—	6,742	—	—	6,742
Balance at September 30, 2025	638,356	$ 638	$ 2,074,640	$ (1,826,979)	$ 408	$ 248,707

See accompanying notes to condensed consolidated financial statements.

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (18,972)	$ (54,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	407	387
Accretion and amortization on investments, net	(2,257)	(5,477)
Amortization of debt issuance costs/debt discounts	892	788
Non-cash interest expense on liabilities for sales of future royalties	11,647	15,043
Inventory write-off	11,197	—
Stock-based compensation expense	14,675	20,958
Amortization of right-of-use assets	587	542
Decrease in allowance for doubtful accounts	(821)	(4)
Changes in assets and liabilities:		
Inventory	(21,164)	(56,708)
Accounts receivable, net	(8,171)	589
Prepaid expenses and other assets	(691)	167
Accounts payable	4,207	2,516
Accrued compensation and benefits	(19,729)	(6,420)
Accrued liabilities	(27,431)	4,379
Payments on royalty agreement	(12,187)	(10,503)
Operating lease liabilities	(655)	(589)
Net cash used in operating activities	(68,466)	(88,970)
Cash flows from investing activities:		
Purchases of property and equipment	(629)	(49)
Purchases of marketable securities	(220,867)	(200,202)
Proceeds from maturities and sales of marketable securities	275,737	286,353
Net cash provided by investing activities	54,241	86,102
Cash flows from financing activities:		
Proceeds from issuances of common stock from equity plans	4,151	1,389
Proceeds from the exercise of warrants	1,511	—
Proceeds from employee stock purchase plan	314	500
Net cash provided by financing activities	5,976	1,889
Net effect of exchange rates on cash, cash equivalents and restricted cash	(120)	96
Net decrease in cash, cash equivalents and restricted cash	(8,369)	(883)
Cash, cash equivalents and restricted cash at the beginning of the period	79,440	80,876
Cash, cash equivalents and restricted cash at the end of the period	$ 71,071	$ 79,993
Supplemental disclosure of noncash activities		
Reduction of operating lease right-of-use assets and lease liabilities due to lease modification	$ 1,001	$ —

See accompanying notes to condensed consolidated financial statements.

1. BASIS OF PRESENTATION, PRINCIPLES OF CONSOLIDATION, USE OF ESTIMATES AND RECENT ACCOUNTING PRONOUNCEMENTS

Business Overview

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.

Basis of Presentation

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 considered necessary for a fair presentation have been included. These unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2025, or the 2025 Form 10-K. The accompanying unaudited condensed consolidated balance sheet as of December 31, 2025 has been derived from audited financial statements at that date. Operating results for the three and nine months ended September 30, 2026 are not necessarily indicative of the results that may be expected for the year ending December 31, 2026 or any other period. We operate as one operating segment.

Principles of Consolidation

The unaudited 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.

Use of Estimates

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, inventory valuation, operating leases (right-of-use assets), lease liabilities, income taxes, and stock-based compensation and interest expense related to sale of future royalties. 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.

Summary of Significant Accounting Policies

The significant accounting policies used in preparation of these unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2026 are consistent with those discussed in Note 1 to the consolidated financial statements in the 2025 Form 10-K, except for the policy related to product return reserves. Effective November 1, 2026, the Company revised its returned goods policy to significantly limit the circumstances under which customers may return product. As a result, the Company expects future product returns to be limited. Estimated returns, when applicable, continue to be recognized as a reduction of product revenue.

Recent Accounting Pronouncements

New Accounting Pronouncements – Issued But Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The amendments

in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. We are evaluating the impact of this ASU on our consolidated financial statements.

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

2. REVENUE RECOGNITION

Net Product Revenue

To date, our only source of product revenue has been from the sales of RYTELO, which we began shipping to our customers in the U.S. in June 2024. To date, product revenue pursuant to Named Patient Programs outside of the U.S. has been not material.

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, 2026 and 2025:

	Three Months Ended September 30,		Nine months ended September 30,	
(in thousands)	2026	2025	2026	2025
Gross product revenue	$ 74,496	$ 60,188	$ 212,285	$ 163,374
Gross-to-net adjustments:				
Chargebacks	(9,670)	(7,042)	(27,023)	(17,154)
Distributor service fees	(2,481)	(2,041)	(7,021)	(5,516)
Government rebates	(2,264)	(2,143)	(5,892)	(2,668)
Sales returns and allowances	33	(1,795)	(2,991)	(2,426)
Total gross-to-net adjustments	(14,382)	(13,021)	(42,927)	(27,764)
Net product revenue	$ 60,114	$ 47,167	$ 169,358	$ 135,610

Effective November 1, 2026, the Company revised its returned goods policy to significantly limit the circumstances under which customers may return product.

As of September 30, 2026, three customers individually accounted for approximately 45%, 38% and 16% of our gross accounts receivable associated with our product revenue, as compared to 43%, 38% and 17% as of December 31, 2025, respectively.

3. INVENTORY

All of our inventories are related to the manufacturing of RYTELO. The following table presents our inventory as of September 30, 2026 and December 31, 2025:

	September 30,	December 31,
(in thousands)	2026	2025
Raw materials	$ 7,942	$ 8,927
Work-in-process	102,579	91,969
Finished goods	16,082	15,740
Total inventory	$ 126,603	$ 116,636

4. Financial Instruments

Cash equivalents, restricted cash and marketable securities by security type at September 30, 2026 were as follows:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 40,345	$ —	$ —	$ 40,345
	$ 40,345	$ —	$ —	$ 40,345
Restricted cash:				
Money market fund	$ 1,617	$ —	$ —	$ 1,617
Certificate of deposit	275	—	—	275
	$ 1,892	$ —	$ —	$ 1,892
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 30,963	$ —	$ (26)	$ 30,937
Municipal securities (due in less than one year)	9,963	—	(38)	9,925
Municipal securities (due in one to two years)	1,918	5	—	1,923
Commercial paper (due in less than one year)	92,144	—	(143)	92,001
Corporate notes (due in less than one year)	84,560	5	(127)	84,438
Corporate notes (due in one to two years)	49,346	—	(271)	49,075
	$ 268,894	$ 10	$ (605)	$ 268,299

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2025 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 48,950	$ 1	$ —	$ 48,951
Commercial paper	4,979	—	—	4,979
	$ 53,929	$ 1	$ —	$ 53,930
Restricted cash:				
Money market fund	$ 1,606	$ —	$ —	$ 1,606
Certificate of deposit	274	—	—	274
	$ 1,880	$ —	$ —	$ 1,880
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 22,910	$ 41	$ —	$ 22,951
Municipal securities (due in less than one year)	10,032	9	—	10,041
Commercial paper (due in less than one year)	79,354	49	—	79,403
Corporate notes (due in less than one year)	167,805	175	(16)	167,964
Corporate notes (due in one to two years)	41,316	11	(38)	41,289
	$ 321,417	$ 285	$ (54)	$ 321,648

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, 2026 and December 31, 2025 were as follows:

	Less Than 12 Months		12 Months or Longer		Total	
(In thousands)	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
As of September 30, 2026:						
U.S. Treasury securities (due in less than one year)	30,937	(26)	—	—	30,937	(26)
Municipal securities (due in less than one year)	9,925	(38)	—	—	9,925	(38)
Commercial paper (due in less than one year)	92,001	(143)	—	—	92,001	(143)
Corporate notes (due in less than one year)	69,403	(127)	—	—	69,403	(127)
Corporate notes (due in one to two years)	49,075	(271)	—	—	49,075	(271)
	$ 251,341	$ (605)	$ —	$ —	$ 251,341	$ (605)
As of December 31, 2025:						
Corporate notes (due in less than one year)	17,987	(16)	—	—	17,987	(16)
Corporate notes (due in one to two years)	31,265	(38)	—	—	31,265	(38)
	$ 49,252	$ (54)	$ —	$ —	$ 49,252	$ (54)

The gross unrealized losses related to U.S. Treasury securities, municipal securities, commercial paper and corporate notes as of September 30, 2026 and December 31, 2025 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, 2026 as we have not identified any unrealized losses for these securities attributable to credit factors. We do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity.

5. FAIR VALUE MEASUREMENTS

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. Below is a description of the valuation methodologies used for financial instruments measured at fair value on our consolidated balance sheets, including the category for such financial instruments.

Money market funds and certificates of deposit are categorized as Level 1 within the fair value hierarchy as their fair values are based on quoted prices available in active markets. Commercial paper, U.S. Treasury securities, municipal securities, government-sponsored enterprise securities 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 embedded derivatives are classified within Level 3 of the fair value hierarchy. See Note 7 on Debt.

We determined the fair value of the liability related to the sale of future royalties based on our current estimates of future royalties expected to be paid to Royalty Pharma over the life of the arrangement, which are considered Level 3. See Note 7 on Debt.

There were no transfers between Level 1, Level 2, and Level 3 during the periods presented. In addition, there have been no changes to our valuation techniques as of September 30, 2026 and December 31, 2025.

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of September 30, 2026 and December 31, 2025 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, 2026:				
Assets:				
Money market funds[1][2]	$ 41,962	$ —	$ —	$ 41,962
Certificate of deposit[2]	275	—	—	275
Municipal securities[3][4]	—	11,848	—	11,848
U.S. Treasury securities[3]	—	30,937	—	30,937
Government-sponsored enterprises[3]	—	—	—	—
Commercial paper[1][3]	—	92,001	—	92,001
Corporate notes[3][4]	—	133,513	—	133,513
Total	$ 42,237	$ 268,299	$ —	$ 310,536
Liabilities:				
Sale of future royalties[5]	—	—	129,042	129,042
Total	$ —	$ —	$ 129,042	$ 129,042
As of December 31, 2025:				
Assets:				
Money market funds[1][2]	$ 50,557	$ —	$ —	$ 50,557
Certificate of deposit[2]	274	—	—	274
Municipal securities[3]	—	10,041	—	10,041
U.S. Treasury securities[3][4]	—	22,951	—	22,951
Commercial paper[3]	—	84,382	—	84,382
Corporate notes[3][4]	—	209,253	—	209,253
Total	$ 50,831	$ 326,627	$ —	$ 377,458
Liabilities:				
Sale of future royalties[5]	—	—	129,582	129,582
Total	$ —	$ —	$ 129,582	$ 129,582

(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) Included in current and noncurrent portion of liabilities related to sale of future royalties on our consolidated balance sheets.

6. OTHER CONDENSED CONSOLIDATED FINANCIAL STATEMENT DETAILS

Accrued liabilities consisted of the following as of September 30, 2026 and December 31, 2025:

(In thousands)	SEPTEMBER 30, 2026	DECEMBER 31, 2025
Contract research organization and clinical trial costs	$ 4,247	$ 3,677
Manufacturing activities	8,557	38,657
Professional, legal and accounting fees	2,904	881
Interest payable	—	3,110
Accrued revenue adjustments	5,938	3,486
Other	2,263	1,529
	$ 23,909	$ 51,340

Accrued compensation and benefits consisted of the following as of September 30, 2026 and December 31, 2025:

(In thousands)	SEPTEMBER 30, 2026	DECEMBER 31, 2025
Accrued bonuses	$ 8,383	$ 10,335
Accrued vacation	1,964	2,581
Accrued restructuring charges	56	17,032
Accrued other	365	549
	$ 10,768	$ 30,497

Cash, cash equivalents, and restricted cash included in the Company's condensed consolidated statement of cash flows were as follows:

(In thousands)	SEPTEMBER 30, 2026	SEPTEMBER 30, 2025
Cash and cash equivalents	$ 69,179	$ 78,117
Restricted cash	1,892	1,876
Total cash, cash equivalents, and restricted cash	$ 71,071	$ 79,993

7. DEBT

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. We drew a Tranche A Loan in an aggregate principal amount of $125.0 million, or the Tranche A Loan, on November 1, 2024. The Pharmakon Loan Agreement had also provided for two additional committed term loan tranches of up to $125.0 million in the aggregate: a Tranche B Loan, of $75.0 million and a Tranche C Loan of $50.0 million. On January 5, 2026, we entered into an amendment to the Pharmakon Loan Agreement, or the Pharmakon Amendment, which extended the date for requesting the Tranche B Loan and Tranche C Loan, once available, from December 31, 2025 to July 30, 2026. Nether the Tranche B Loan, nor the Tranche C Loan was drawn, and both are no longer available. A portion of the proceeds from the Tranche A Loan were used to repay, in full, all amounts owed 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 Pharmakon Amendment also extended the date before which any prepayment of the Tranche A Loan is subject to a make-whole premium, or the Makewhole Date, from November 1, 2026 to May 1, 2027. The Pharmakon Amendment was evaluated under ASC 470-50 and determined to be a modification. The unamortized debt issuance costs will continue to be amortized over the remaining term using a revised effective interest rate. Fees incurred in connection with the Pharmakon Amendment were not material and were expensed as incurred.

The Tranche A Loan matures on November 1, 2029. The Tranche A Loan bears 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 applicable interest rate was 10.32%. As of September 30, 2026, the applicable interest rate was 10.86%. Interest is due and payable quarterly on the last day of each quarter.

We may elect to prepay the Tranche A Loan in part or in whole prior to maturity, with such prepayments being subject to a prepayment premium equal to the principal amount so prepaid multiplied by 3% if made prior to November 1, 2027, 2% if made on or after November 1, 2027 but prior to November 1, 2028, and 1% if made on or after November 1, 2028 but prior to November 1, 2029. In addition to the prepayment premium, any prepayment of the Tranche A Loan prior to May 1, 2027 is subject to a make-whole amount equal to the sum of all interest that would have accrued through such date.

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, 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 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 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 encumbrances 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 the occurrence of 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 judgments, (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 and during the continuance 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 make-whole 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. We concluded that the likelihood of such acceleration is remote, and therefore all debt is classified as long-term. As of September 30, 2026, we were in compliance with our Pharmakon Loan Agreement covenants.

Future Minimum Payments

The following table presents future minimum payments, including interest and the end of term charge, under the Loan Agreement as of September 30, 2026 (in thousands):

2026	$	6,054
2027		12,009
2028		12,042
2029		135,034
Thereafter		—
Total	$	165,139
Less: amount representing interest		(40,139)
Less: unamortized debt discount and issuance costs		(4,561)
Noncurrent portion of debt	$	120,439

Embedded Derivatives

The conditional exercisable call option related to the event of default is considered to be an embedded derivative which is required to be bifurcated and accounted for as a separate financial instrument. In the periods presented, the value of the embedded derivative is not material and therefore, no amount has been recognized. If an event of default becomes more probable than is currently estimated, then the embedded derivative could become material in future periods and would be recognized as a separate financial instrument at that time. The embedded derivatives are classified within Level 3 of the fair value hierarchy due to the use of significant unobservable inputs.

Liabilities Related to Sale of Future Royalties

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, or the Revenue Participation Right, to receive certain amounts calculated as a percentage of future U.S. net sales of RYTELO for each calendar quarter, or Royalty Payments, during the term contemplated by the Royalty Pharma Agreement. Specifically, the revenue participation rate commences at 7.75% for annual U.S. net sales of up to and equal to $500.0 million declining to 1.0% for annual U.S. net sales exceeding $1.0 billion until the date when the aggregate Royalty Payments equal or exceed 1.65 times the Purchase Price, if this occurs by June 30, 2031, or the date when the aggregate Royalty Payments equal or exceed 2.0 times the Purchase Price.

In addition, we have the option to repurchase all of the Revenue Participation Right from Royalty Pharma for a purchase price of equal to the Buy-Out-Payment, as defined below, if we entered into a definitive agreement to consummate a change of control, or Buy-Back Option.

“Buy-Out Payment” means an amount equal to (a) 1.65 times the Purchase Price minus the aggregate Royalty Payments as of the change of control, if the change of control occurs on or prior to December 31, 2027, or (b) 2.0 times the Purchase Price minus the aggregate Royalty Payments as of the change of control, if the change of control occurs after December 31, 2027.

We accounted for the Royalty Pharma Agreement as a financing liability, primarily because it has significant continuing involvement in generating the future revenue on which the Royalty Payments are based. The liability related to Revenue Participation Right and the related interest expense are measured based on our current estimate of the timing and amount of expected future Royalty Payments expected to be paid over the estimated term of the Royalty Pharma Agreement using a discounted cash flow model. The liability is amortized using the effective interest rate method, resulting in recognition of interest expense over the estimated term of the agreement.

We have determined the fair value of the liability related to the sale of future royalties is based on our current estimates of future royalties expected to be paid to Royalty Pharma over the life of the arrangement, which are considered Level 3.

The following table shows the activity within the liability related to sale of future royalties during the nine months ended September 30, 2026:

(in thousands)	Liability Related to Sale of Future Royalties
Carrying value of liability related to sale of future royalties at December 31, 2025	$ 129,582
Interest expense recognized	3,912
Royalty payments	(3,721)
Carrying value of liability related to sale of future royalties at March 31, 2026	$ 129,773
Interest expense recognized	3,864
Royalty payments	(4,012)
Carrying value of liability related to sale of future royalties at June 30, 2026	$ 129,625
Interest expense recognized	3,871
Royalty payments	(4,454)
Carrying value of liability related to sale of future royalties at September 30, 2026	$ 129,042

8. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

On March 13 and March 14, 2025, we and certain of our current and former officers were named as defendants in two putative securities class action lawsuits filed in the United States District Court for the Northern District of California captioned *Dabestani v. Geron Corporation, et al.*, No. 3:25-cv-02507 and *Potvin v. Geron Corporation, et al.*, No. 3:25-cv-02563, respectively. Both lawsuits allege violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with allegedly false and misleading statements concerning the commercial potential of RYTELO. The plaintiffs allege, among other things, that we overstated RYTELO's commercial potential by making materially false and misleading statements and/or concealing material adverse facts concerning RYTELO's commercial potential, including the lack of awareness among healthcare providers for RYTELO, the burden of monitoring requirements in administering the drug, and the impacts of seasonality and existing competition on RYTELO's sales, and that our stock price dropped when we disclosed in our earnings call on February 26, 2025 that we had observed flat revenue trends over the prior few months. The plaintiffs seek damages and interest, and an award of reasonable costs, including attorneys' and experts' fees. On May 29, 2025, the Court consolidated the Dabestani and Potvin cases into one consolidated action captioned *In re Geron Corporation Securities Litigation*, or the Securities Class Action, and appointed lead plaintiffs and counsel for lead plaintiffs. On August 8, 2025, lead plaintiffs filed a consolidated amended complaint. On October 7, 2025, we filed our motion to dismiss the consolidated amended complaint. A hearing on the motion to dismiss was held on March 19, 2026, and on March 30, 2026, the Court entered an order granting our motion to dismiss without prejudice. On April 13, 2026, lead plaintiffs filed a second amended complaint. On May 18, 2026, we filed our motion to dismiss the second amended complaint. A hearing on the motion to dismiss was held on August 6, 2026, and on August 13, 2026, the Court entered an order denying our motion to dismiss. The case currently is in discovery, and we are vigorously defending against all claims.

In addition, on April 15, 2025 and April 16, 2025, three purported stockholders filed derivative complaints, each filed in the United States District Court for the Northern District of California, captioned *Bishop v. Scarlett, et al.*, No.

3:25-cv-03356, *Lerner v. Scarlett, et al.*, No. 3:25-cv-03401, and *Willis v. Scarlett, et al.*, No: 3:25-cv-03396, respectively. The three lawsuits name certain of our current and former directors and officers and allege that they breached their fiduciary duties and violated federal securities laws by issuing allegedly false and misleading statements concerning the commercial potential of RYTELO. The allegations in each of the three derivative complaints are substantially similar to the Securities Class Action. The plaintiff seeks damages and interest, and an award of reasonable costs, including attorneys' and experts' fees. The plaintiffs in *Bishop v. Scarlett, et al.* and *Willis v. Scarlett, et al.* also seek punitive damages. On May 16, 2025, the Court consolidated the three derivative complaints into one consolidated action captioned *In re Geron Corporation Derivative Litigation*, or the Consolidated Derivative Action. On June 17, 2025, the Court stayed the Consolidated Derivative Action pending a final ruling on the motion to dismiss in the Securities Class Action. On September 8, 2026, the Court extended the stay in the Consolidated Derivative Action pending the resolution of class certification in the Securities Class Action.

On August 29, 2025, a purported stockholder made a demand on our board of directors to commence a civil action against certain of our current and former directors for breaching their fiduciary duties and violating the securities laws by issuing allegedly false and misleading statements concerning the commercial potential of RYTELO. On September 19, 2025, the board of directors responded that it would defer a final decision on the demand given the other pending derivative lawsuits and the Securities Class Action. On October 7, 2025, the purported stockholder filed a suit in the United States District Court for the Northern District of California, captioned *Hyung v. Bir, et al.*, No. 3:25-cv-08575 (the "*Hyung* Derivative Action"). The derivative lawsuit names certain of our current and former directors and officers. The allegations in the derivative lawsuit are substantially similar to the Securities Class Action and the Consolidated Derivative Action. The plaintiff seeks damages and an award of reasonable costs, including attorneys' and experts' fees. On November 4, 2025, the Court stayed the *Hyung* Derivative Action pending a final ruling on the motion to dismiss in the Securities Class Action. On September 8, 2026, the Court extended the stay in the *Hyung* Derivative Action pending the resolution of class certification in the Securities Class Action. Additionally, on January 23 and February 19, 2026, respectively, two additional purported stockholders each made a similar demand on our board of directors. On March 25, 2026, the board of directors similarly responded that it would defer a final decision on the demands given the other pending derivative lawsuits and the Securities Class Action. On September 8, 2026, one of the purported stockholders filed a suit in the United States District Court for the Northern District of California, captioned *Russo v. Scarlett, et al.*, No. 3:26-cv-09979 (the "*Russo* Derivative Action"). The derivative lawsuit names certain of our current and former directors and officers. The allegations in the *Russo* Derivative Action are substantially similar to the Securities Class Action, the Consolidated Derivative Action, and the *Hyung* Derivative Action. On September 24, 2026, the plaintiffs in the *Hyung* Derivative Action and *Russo* Derivative Action filed a joint stipulation to consolidate the two derivative actions and stay the consolidated action pending the resolution of class certification in the Securities Class Action.

On September 29, 2026, a purported stockholder filed a derivative complaint in the United States District Court for the District of New Jersey, captioned *Weinstein v. Scarlett, et al.*, No. 2:26-cv-12796 (the "*Weinstein* Derivative Action"). The lawsuit names certain of our current and former directors and officers and alleges that they breached their fiduciary duties and violated federal securities laws by issuing allegedly false and misleading statements concerning the commercial potential of RYTELO. The allegations are substantially similar to the Securities Class Action, the Consolidated Derivative Action, the *Hyung* Derivative Action, and the *Russo* Derivative Action. The plaintiff seeks damages and an award of reasonable costs, including attorneys' and experts' fees. On October 19, 2026, the Court entered an order staying the *Weinstein* Derivative Action pending the resolution of class certification in the Securities Class Action.

It is possible that additional lawsuits will be filed or allegations made by stockholders with respect to these same or other matters and also naming us and/or our officers and directors as defendants. We intend to vigorously defend against the claims brought by the plaintiffs in these matters.

Such lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources and may incur substantial legal fees and costs in defending against the pending lawsuits and any other related 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. Additionally, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage. Given the early stage of these lawsuits and the inherent uncertainly of litigation, we cannot predict how long it may take to resolve the pending lawsuits or the potential outcome or

possible amount of any damages. As such, we currently are unable to reasonably estimate the possible losses or a range of possible losses that may result from these matters, if any. Expenses associated with the pending lawsuits and any potential related 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.

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 maintain a company-wide severance plan that provides severance benefits upon qualifying terminations, including enhanced benefits in connection with a change of control. As of September 30, 2026, all executive officers have employment agreements with severance provisions and will receive the greater of the severance benefits provided under their agreements or the severance plan (without duplication).

In December 2025, we implemented a workforce reduction, representing approximately one-third of our workforce prior to the reduction in headcount. See Note 11 on Restructuring for additional information.

Purchase Commitments

We have engaged third-party contract manufacturers 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 binding commercial purchase commitments of approximately $31.6 million that can be cancelled, but would incur cancellation penalties, and approximately $9.9 million in agreed upon manufacturing commitments that can be adjusted based on commercial demand of RYTELO as of September 30, 2026. Based on current plans and information available, the related commercial purchase commitments are intended to be utilized.

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.

In September 2026, the Company entered into agreements with a third-party service provider to support the commercial launch of RYTELO in Germany and France. The arrangements include medical and commercial field personnel and related operational support, and have initial terms through December 31, 2028. The underlying agreements may be terminated for convenience by either party upon nine months' prior written notice. During the notice period, monthly fees may not be less than the average monthly fees earned during the preceding 12 months. Upon termination, the Company may also be responsible for services performed through the termination date, approved noncancelable or nonrefundable commitments, certain vehicle lease termination charges, and applicable severance and employee-transition costs. After the initial term, agreements may be renewed for successive 12-month periods.

Operating Leases

New Jersey Office Space Leases

In September 2026, the Company entered into a new lease agreement for an office space in Parsippany, New Jersey. The new lease has an initial term of approximately eight and one-half years following commencement, with an option to extend the lease for an additional five years. Lease commencement is expected to occur upon substantial completion of certain landlord-funded improvements, which is currently expected in the first quarter of 2027. Concurrent with entering into the new lease, the Company entered into an agreement to terminate its existing lease for an office space in Parsippany, New Jersey. The existing lease will terminate, without a termination fee, upon substantial completion of the landlord's work under the new lease.

The Company accounted for the new lease and the termination of the existing lease as a combined contract under ASC 842, Leases. As a result, the Company reallocated the remaining consideration between the existing and new lease components based on their relative standalone prices and remeasured the lease liability associated with the existing lease over its shortened term, with a corresponding adjustment of $1.0 million to the related right-of-use asset. No gain or loss was recognized as a result of the modification. The Company expects to recognize a right-of-use asset and corresponding lease liability for the new lease when the lease commences.

The new lease provides for initial annual base rent of approximately $0.4 million, subject to annual increases over the lease term.

California Office Space Lease

In October 2019, we entered into an operating lease agreement for office space located in Foster City, California, or the Foster City Lease. The Foster City Lease commenced on March 10, 2020, and its initial term extends through June 2027, with an option to extend the lease for an additional five years. In October 2026, we notified the landlord that we do not intend to exercise the five-year renewal option. Accordingly, the Foster City Lease is expected to expire in June 2027 in accordance with its existing terms.

9. NET INCOME (LOSS) PER COMMON 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.

Diluted net income per share is 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.

The following table sets forth the computation of basic and diluted net income (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2026**	**2025**	**2026**	**2025**
Net income (loss)	$ 1,350	$ (18,428)	$ (18,972)	$ (54,638)
Weighted-average common shares - basic	672,293	667,102	670,799	666,397
Effect of dilutive securities:				
Options	1,575	—	—	—
Restricted stock units and restricted stock awards	184	—	—	—
Weighted-average common shares - diluted	674,052	667,102	670,799	666,397
Net income (loss) per share - basic	$ 0.00	$ (0.03)	$ (0.03)	$ (0.08)
Net income (loss) per share - diluted	$ 0.00	$ (0.03)	$ (0.03)	$ (0.08)

The following table sets forth the potential weighted-average common shares excluded from the calculation of diluted net income (loss) per share because their inclusion would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Options	75,538	72,981	78,140	67,772
Employee stock purchase plan	772	939	399	421
Restricted stock units and restricted stock awards	675	3,371	1,142	2,728
Total	76,985	77,291	79,681	70,921

10. SEGMENT REPORTING

We are currently developing therapies for the treatment of hematologic malignancies. To date, our main source of product revenue has been from U.S. sales of RYTELO, which began shipping to customers in June 2024. Additionally, we have generated insignificant royalty and license fee revenue under agreements that out-license technology to various companies.

We have one operating and reportable segment. We define our operating segment based on internally reported financial information that is regularly reviewed by the Chief Operating Decision Maker, or CODM, to analyze financial performance, make decisions, and allocate resources. Our President and Chief Executive Officer is the CODM.

The CODM reviews the segment's profit or loss based on net income (loss) reported on the consolidated statement of operations and comprehensive income (loss) and considers forecast-to-actuals variances on a quarterly basis for expenses that are deemed significant. Further, the CODM reviews the segment's assets based on total assets reported on the condensed consolidated balance sheet. All long-lived assets are held in the U.S.

Our CODM views specific categories within research and development expenses and selling, general and administrative expenses as significant given the correlation between cash burn and profitability. During the three months ended September 30, 2026, the Company revised the presentation of certain financial information regularly provided to the CODM, Accordingly, prior period segment expense disclosures have been recast to conform to the current period presentation. The following table reconciles reported revenues to net income (loss) under the significant expense principle for the three and nine months ended September 30, 2026 and 2025:

(in millions)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Revenues:				
Product revenue, net	$ 60.1	$ 47.2	$ 169.4	$ 135.6
Royalties	0.1	0.1	0.1	0.3
Total revenues	$ 60.2	$ 47.3	$ 169.5	$ 135.9
Costs and operating expenses:				
Cost of goods sold	6.1	1.0	17.0	3.4
Research and development				
Research and clinical expenses	11.7	18.0	38.5	51.5
Chemistry, manufacturing, and control expenses	0.9	3.0	10.9	6.4
Selling, general and administrative				
Commercial expenses	15.6	18.6	49.9	55.0
Medical Affairs	3.7	4.3	11.1	10.3
Other general and administrative expenses*	16.4	16.2	48.6	52.3
Total cost and operating expenses	$ 54.4	$ 61.1	$ 176.0	$ 178.9
Income (loss) from operations	5.8	(13.9)	(6.5)	(43.0)
Total interest and other income (expense)	(4.4)	(4.5)	(12.5)	(11.6)
Net income (loss)	$ 1.4	$ (18.4)	$ (19.0)	$ (54.6)

*Other general and administrative expenses includes stock-based compensation expense and other general and administrative expenses largely resulting from personnel costs for individuals in administrative functions and legal and professional fees.

11. RESTRUCTURING

In December 2025, the board of directors approved a workforce reduction representing approximately one-third of our workforce prior to the reduction in headcount. In 2025, we incurred approximately $17.0 million in restructuring and restructuring-related charges, primarily consisting of one-time employee severance payments, healthcare and related benefits, and other employee-related costs. The charges were recorded within restructuring charges in the consolidated statements of operations.

The workforce reduction was substantially completed in the first quarter of 2026. There were no restructuring charges during the three and nine months ended September 30, 2025.

(in thousands)		Restructuring
Accrued balance as of December 31, 2025	$	17,032
Expenses and adjustments		(394)
Payments		(13,532)
Accrued balance as of March 31, 2026	$	3,106
Expenses and adjustments		(157)
Payments		(2,771)
Accrued balance as of June 30, 2026	$	178
Expenses and adjustments	$	(51)
Payments		(71)
Accrued balance as of September 30, 2026	$	56

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

FORWARD-LOOKING STATEMENTS

This Report 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 this Report 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 Report. 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, titled "Risk Factors," and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part I, Item 2 of this Report.

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 Report; and the sections titled "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, 2025 as filed with the SEC on March 2, 2026, or the 2025 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 scientific evidence suggests reduces proliferation of malignant cells, allowing production of new healthy cells, which we believe drives differentiated clinical benefits, potentially altering the underlying course and modifying the disease of these hematologic malignancies.

We commercially launched RYTELO in the U.S. in June 2024 following its approval by the U.S. Food and Drug Administration, or FDA, on June 6, 2024 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. Lower-risk MDS is a progressive blood cancer with high unmet need, where many patients with anemia become dependent on red blood cell transfusions, which can be associated with clinical consequences and decreased quality of life. We believe that the high unmet need in lower-risk MDS and significant product differentiation, including observed benefit, of RYTELO in difficult-to-treat sub-populations such as patients with high transfusion burden and ring sideroblast negative, or RS- patients, as well as the favorable FDA label and the National Comprehensive Cancer Network, or NCCN®, Clinical Practice Guidelines in Oncology, or NCCN Guidelines®, position RYTELO to potentially compete for significant market segments in lower-risk MDS, including second-line ESA ineligible patients regardless of prior treatment or RS status and first-line ESA ineligible patients.

In March 2025, we were granted marketing authorization by the European Commission, or EC, for RYTELO as a monotherapy for the treatment of adult patients with TD anemia due to very low, low or intermediate risk myelodysplastic syndromes without an isolated deletion 5q cytogenetic, or non-del 5q, abnormality and who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy. To support the commercialization and marketing of RYTELO in the EU, we have engaged experienced third parties, including a commercialization partner, to assist with critical activities, including reimbursement, Health Technology Assessment, or HTA, submissions, market access and distribution, a contracted sales force and recording of sales. We have initiated a gated commercial launch in targeted European markets, with a commercialization partner and a related contracted sales force, with availability expected in Germany by the end of 2026 and in France in 2027. In addition, to enable paid access for patients outside the U.S. through approved Named Patient Programs, or NPPs, in 2025, we partnered with Tanner Pharma, a distributor with broad global reach. To date, product revenue generated through NPPs has been minimal.

We believe that telomerase inhibition with imetelstat represents a novel mechanism of action with unique benefits in hematologic malignancies and potentially in other tumor types. In addition to lower-risk MDS, we are developing imetelstat for the treatment of other myeloid hematologic malignancies, but there can be no assurance that we will obtain and maintain the necessary regulatory approvals to market RYTELO for any additional indications. In this regard, in October 2026, we announced our decision to discontinue our Phase 3 IMpactMF clinical trial evaluating imetelstat in patients with intermediate-2 or high-risk myelofibrosis, or MF, who have relapsed after or are refractory to treatment with a janus associate kinase inhibitor, or JAK inhibitor, or relapsed/refractory MF. The decision to discontinue the Phase 3 IMpactMF trial was based on a recommendation from an independent Data Monitoring Committee, or DMC, following the DMC's conclusion that the trial was unlikely to meet the primary endpoint of overall survival. No new safety signals that change the known safety profile of imetelstat or require additional safety monitoring were observed in the imetelstat arm of the Phase 3 IMpactMF. Given the discontinuation of the Phase 3 IMpactMF trial, we will be unable to pursue any regulatory approvals for the relapsed/refractory MF indication and we will otherwise not receive any return on, or recoup our investment in the relapsed/refractory MF indication. Moreover, the development of imetelstat for the treatment of other myeloid hematologic malignancies is in the early stages and we do not expect to receive any regulatory approvals to market RYTELO for any additional indications for a number of years, if ever. Accordingly, we will remain wholly dependent on the commercialization of RYTELO in lower-risk MDS for the foreseeable future.

Financial Overview

Since our inception, we have primarily financed our operations through the sale of equity securities, draw downs on our debt facilities, cash generated from sales of RYTELO, interest income on our marketable securities, payments we received under the Royalty Pharma Agreement and our prior collaborative and licensing arrangements. As of September 30, 2026, we had approximately $339.4 million in cash, cash equivalents, restricted cash and marketable securities.

We began commercializing RYTELO in June 2024, and the commercial potential of and our ability to successfully commercialize RYTELO in lower-risk MDS remains 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. Prior to our commercialization of RYTELO, substantially all of our revenues were generated from 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, with the exception of net income reported in the three months ended September 30, 2026. Our ability to maintain profitability is uncertain. 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, 2026, we had an accumulated deficit of approximately $1.9 billion.

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, which are investment funds managed by Pharmakon Advisors, LP, and BioPharma Credit PLC, as collateral agent. 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 Tranche A Loan matures on November 1, 2029 and bears interest at a variable rate per annum equal to 5.75% plus three-month SOFR with a SOFR floor of 3.00%. See Note 7 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information on the Pharmakon Loan 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 royalty 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 Royalty Payments. The Royalty 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 Royalty 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 Royalty Payment obligations under the Royalty Pharma Agreement may be discharged in connection with a change of control of Geron in an amount equal to 1.65 times the Purchase Price minus the aggregate Royalty 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 Royalty 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.

In December 2025, we implemented a workforce reduction, representing approximately one-third of our workforce prior to the reduction in headcount. We recorded approximately $17.0 million in restructuring and restructuring-related charges in the fourth quarter of 2025, primarily consisting of one-time employee severance payments, healthcare and related benefits, and other employee-related costs. The workforce reduction was substantially completed in the first quarter of 2026. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition could be adversely affected.

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 this regard, our ability to generate meaningful 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. We have seen and may continue to see variability in RYTELO sales trends and resulting revenue.

Our commercial strategy is designed such that RYTELO reaches eligible patients in its approved indication when they are most likely to benefit. Our commercial execution is focused on targeted engagement with high-volume accounts that treat earlier-line patients, investment in non-personal promotion and third-party education to further consistent, high-quality messaging across multiple touchpoints, and cross-functional execution of effective account management. However, our strategy to drive sales growth and our ongoing commercialization efforts have not to date achieved and may not in the future achieve meaningful sales growth, which may require us to, among others, further adjust or amend our commercialization strategy and plans and incur significant expenses, and there can be no assurance that we will be able to grow RYTELO net product revenue in future periods. In particular, our strategy may not drive new patient starts across the breadth of the eligible patient population in RYTELO's approved indication, particularly across appropriate second-line patients in RYTELO's approved indication, in a timely manner or at all, or the duration of therapy could be shorter than we expect, each of which would limit RYTELO’s growth potential and could preclude or delay our ability to generate meaningful revenue from product sales and to achieve sustained profitability.

In addition, in an effort to expand its indications of use, we are also 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. Moreover, we may continue to experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, which often occur in later-stage clinical trials. For example, notwithstanding the improvement in overall survival and potential disease-modifying activity observed in our Phase 2 IMbark clinical trial, we recently announced our decision to discontinue our Phase 3 IMpactMF clinical trial following the DMC’s conclusion that the trial was unlikely to meet the primary endpoint of overall survival. As a result, we will be unable to expand RYTELO’s indication to use to the relapsed/refractory MF indication and we will otherwise not receive any return on or recoup our investment in the relapsed/refractory MF indication. We also expect to continue to seek regulatory approvals of RYTELO in lower-risk MDS in jurisdictions outside of the U.S., such as our recent marketing authorization in the EU, and to establish arrangements with third parties to assist us in the commercialization of RYTELO in such jurisdictions. In this regard, we have initiated a gated commercial launch in targeted European markets with a commercialization partner, with availability expected in Germany by the end of 2026 and in France in 2027. As a result of these current and planned activities, we expect research and development expenses and selling, general and administrative expenses to continue to be substantial as we continue to support the commercialization of RYTELO in the U.S. and the EU and the further development of RYTELO, including the conduct and completion of our Phase 1 IMproveMF combination clinical trial in frontline MF, our Phase 2 investigator-led IMpress clinical trial in higher-risk MDS and acute myeloid leukemia, and our Phase 1/2 investigator-led IMAGINE clinical trial in relapsed/refractory acute myeloid leukemia, and as we continue our efforts to make RYTELO available to eligible lower-risk MDS patients outside of the U.S., such as our recently-initiated gated commercial launch in targeted European markets.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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.

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 U.S., and present a meaningful presentation of our financial condition and results of operations.

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Our critical accounting policies are described in Item 7, "Critical Accounting Policies and Estimates" in our 2025 Form 10-K. There have been no significant changes in our critical accounting policies and estimates during the three and nine months ended September 30, 2026, as compared to the critical accounting policies and estimates disclosed in our 2025 Form 10-K.

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 our commercialization efforts and our related strategy to drive sales growth in the U.S. We expect that our sales revenue may continue to vary from period to period as a result of the evolving effects of our commercialization strategy and as our commercialization efforts otherwise progress.

RYTELO is our only product approved for marketing in the U.S. and in the EU for certain patients with lower-risk MDS. Revenue based on sales of RYTELO is dependent on our ability to successfully commercialize RYTELO in the U.S. and the EU and to obtain regulatory approvals to commercialize RYTELO in other jurisdictions and in 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 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 development process; our ability to obtain and maintain contractual arrangements, strategic partnerships, collaborations, alliances or licensing arrangements with third parties to assist us with the commercialization of RYTELO in jurisdictions outside of the U.S.; overcoming disruptions and/or delays due to macroeconomic or other global conditions, such as further changes in tariffs and other trade restrictions, renegotiation of existing international trade agreements or further escalation of trade tensions, inflation, fluctuations in 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; our ability to obtain additional capital if and when needed; 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:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2026	2025	Change $	Change %	2026	2025	Change $	Change %
	(in thousands, except for percentage data)							
Revenues:								
Product revenue, net	$ 60,114	$ 47,167	$ 12,947	27 %	$ 169,358	$ 135,610	$ 33,748	25 %
Royalties	76	60	16	27 %	149	256	(107)	(42)%
Total revenues	60,190	47,227	12,963	27 %	169,507	135,866	33,641	25 %
Costs and operating expenses:								
Cost of goods sold	6,051	1,043	5,008	480 %	16,983	3,439	13,544	394 %
Research and development	12,709	21,070	(8,361)	(40)%	49,695	57,884	(8,189)	(14)%
Selling, general and administrative expenses	35,702	39,001	(3,299)	(8)%	109,990	117,588	(7,598)	(6)%
Restructuring charges	(71)	—	(71)	(100)%	(622)	—	(622)	(100)%
Total costs and operating expenses	54,391	61,114	(6,723)	(11)%	176,046	178,911	(2,865)	(2)%
Income (loss) from operations	5,799	(13,887)	19,686	(142)%	(6,539)	(43,045)	36,506	(85)%
Interest income	3,025	4,264	(1,239)	(29)%	9,417	14,072	(4,655)	(33)%
Interest expense	(7,207)	(8,644)	1,437	(17)%	(21,500)	(25,360)	3,860	(15)%
Other income (expense), net	(267)	(161)	(106)	66 %	(350)	(305)	(45)	15 %
Net income (loss)	$ 1,350	$ (18,428)	$ 19,778	(107)%	$ (18,972)	$ (54,638)	$ 35,666	(65)%

Revenues:

Product Revenue, Net

On June 6, 2024, we announced that the FDA approved RYTELO for the treatment of adult patients with lower-risk MDS, with 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 ESA. To date, our only source of product revenue has been from the sales of RYTELO, which we began shipping to our customers in the U.S. in June 2024.

Product revenue, net for the three and nine months ended September 30, 2026 was approximately $60.1 million and $169.4 million, respectively, compared to $47.2 million and $135.6 million for the three and nine months ended September 30, 2025, respectively. Product revenue, net increased by $12.9 million and $33.7 million during the three and nine months ended September 30, 2026, respectively, compared to the same periods in 2025, primarily due to increased sales volumes and, to a lesser extent, a higher selling price, partially offset by higher gross-to-net adjustments. The increase in sales volume in both periods was primarily driven by a higher number of accounts and patients on therapy.

Total gross-to-net adjustments for the three and nine months ended September 30, 2026 were 19.3% and 20.2% of gross product revenue, compared to 21.6% and 17.0% for the three and nine months ended September 30, 2025, respectively. The changes in gross-to-net adjustments as a percentage of revenue were driven by a greater proportion of sales made under governmental managed-care pricing programs and group purchasing organizations, partially offset by lower return provision due to the revised returned goods policy effective November 1, 2026. We expect total gross-to-net adjustments to be in the percentage range of low to mid-twenties of gross product revenue in the fourth quarter of 2026.

The reconciliation of gross product revenue to product revenue, net by each significant category of gross-to-net adjustments is set forth below:

(in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Gross product revenue	$ 74,496	$ 60,188	$ 212,285	$ 163,374
Gross-to-net adjustments:				
Chargebacks	(9,670)	(7,042)	(27,023)	(17,154)
Distributor service fees	(2,481)	(2,041)	(7,021)	(5,516)
Government rebates	(2,264)	(2,143)	(5,892)	(2,668)
Sales returns and allowances	33	(1,795)	(2,991)	(2,426)
Total gross-to-net adjustments	(14,382)	(13,021)	(42,927)	(27,764)
Product revenue, net	$ 60,114	$ 47,167	$ 169,358	$ 135,610

Effective November 1, 2026, we revised our returned goods policy to significantly limit the circumstances under which customers may return RYTELO. As a result, we reduced our estimated product returns reserve during the three months ended September 30, 2026, resulting in a reduction of gross-to-net deductions.

Royalties

In connection with the divestiture of our human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc., which acquired Asterias Biotherapeutics, Inc.), or Lineage, 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 $0.1 million in both the three and nine months ended September 30, 2026, compared to $0.1 million and $0.3 million for the same periods in 2025, respectively. Royalty revenues in the three and nine months ended September 30, 2026 and 2025 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.

Costs and Operating Expenses:

The following table summarizes our costs and operating expenses:

(In thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Change %	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	Change %
Cost of goods sold	$ 6,051	$ 1,043	480 %	$ 16,983	$ 3,439	394 %
Research and development	12,709	21,070	(40)%	49,695	57,884	(14)%
Selling, general and administrative	35,702	39,001	(8)%	109,990	117,588	(6)%
Restructuring charges	(71)	—	(100)%	(622)	—	(100)%
Total costs and operating expenses	$ 54,391	$ 61,114	(11)%	$ 176,046	$ 178,911	(2)%

Cost of Goods Sold

Cost of goods sold was approximately $6.1 million and $17.0 million for the three and nine months ended September 30, 2026, respectively, compared to $1.0 million and $3.4 million for the three and nine months ended September 30, 2025, respectively, which consists 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 as well as inventory provisions and non-cash inventory write-offs for the applicable period. Cost of goods sold increased in the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily due to higher sales and non-cash inventory write-offs of $4.8 million and $11.2 million, respectively.

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, a significant portion of the manufacturing costs related to the inventory manufactured prior to receiving FDA approval was partially expensed in a prior period and is therefore excluded from the cost of goods sold for the three and nine months ended September 30, 2026 and 2025. We estimate our cost of sales as a percentage of product revenue, net will continue to be positively impacted for at least the next 12 months as we sell through certain inventory that was partially expensed prior to FDA approval.

Research and Development Expenses

During the three and nine months ended September 30, 2026 and 2025, 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, 2026 and 2025, 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 expenses, costs to maintain technology licenses and research-related overhead.

Our research and development expenses were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2026**	**2025**	**2026**	**2025**
Direct external research and development expenses:				
Clinical program: imetelstat	$ 8,511	$ 12,605	$ 34,626	$ 32,361
Personnel-related expenses	3,525	7,943	12,980	23,584
All other expenses	673	522	2,089	1,939
Total research and development expenses	$ 12,709	$ 21,070	$ 49,695	$ 57,884

The decrease in research and development expenses for the three and nine months ended September 30, 2026, compared to the same periods in 2025, was primarily a result of lower personnel-related expenses driven by a decrease in headcount as a result of the workforce reduction in December 2025. In addition, the decrease in the three months ended September 30, 2026, compared to the same period in 2025, was driven by lower clinical and chemistry, manufacturing, and controls costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $35.7 million and $110.0 million for the three and nine months ended September 30, 2026, respectively, compared to $39.0 million and $117.6 million for the same periods in 2025. The decrease in selling, general and administrative expenses for the three and nine months ended September 30, 2026, compared to the same periods in 2025, was primarily due to lower general and administrative personnel-related expenses from decreased headcount as a result of the workforce reduction in December 2025, partially offset by higher marketing costs due to continued investment in our RYTELO commercialization strategy and higher legal costs.

Restructuring Charges

In December 2025, we implemented a workforce reduction, representing approximately one-third of our workforce prior to the reduction in headcount and recorded restructuring charges of $17.0 million. Restructuring charges consisted of termination benefits such as one-time employee severance payments, healthcare and related benefits, and other employee-related costs.

For the three and nine months ended September 30, 2026, a credit of $0.1 million and $0.6 million, respectively, in restructuring charges was recognized, primarily due to lower-than-expected utilization of previously

accrued amounts related to healthcare and related benefits. The credit was recorded in the condensed consolidated statement of operations as restructuring charges. The workforce reduction was substantially completed in the first quarter of 2026. There were no restructuring charges during the three and nine months ended September 30, 2025.

Interest Income

Interest income was $3.0 million and $9.4 million, respectively, for the three and nine months ended September 30, 2026, compared to $4.3 million and $14.1 million for the same periods in 2025. The decrease in interest income for the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily reflects a decrease in interest rates between the periods and a smaller marketable securities portfolio. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Interest Expense

Interest expense was $7.2 million and $21.5 million, respectively, for the three and nine months ended September 30, 2026, compared to $8.6 million and $25.4 million for the same periods in 2025. The decrease in interest expense for the three and nine months ended September 30, 2026, compared to the same periods in 2025, was primarily due to lower average interest rates related to the Royalty Pharma Agreement and the Pharmakon Loan Agreement, which were entered into in November 2024. See Note 7 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information.

Other Income (Expense), Net

Other income (expense), net was an expense of $0.3 million and $0.4 million, respectively, for the three and nine months ended September 30, 2026, compared to an expense of $0.2 million and $0.3 million for the same periods in 2025. Other income (expense), net primarily reflects realized losses on marketable securities and foreign currency transaction adjustments.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2026, we had cash, restricted cash, cash equivalents, and marketable securities of $339.4 million, compared to $401.1 million at December 31, 2025. The decrease in cash, restricted cash, cash equivalents and marketable securities during the nine months ended September 30, 2026 was primarily the net result of cash used in operations partially offset by the receipt of net cash proceeds from accounts receivable.

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 Tranche A Loan matures on November 1, 2029 and bears interest at a variable rate per annum equal to 5.75% plus three-month SOFR with a SOFR floor of 3.00%. See Note 7 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information on the Pharmakon Loan Agreement.

On November 1, 2024, we entered into the Royalty Pharma Agreement with Royalty Pharma. Pursuant to the Royalty Pharma Agreement, we received $125.0 million, or the Purchase Price, in exchange for which Royalty Pharma obtained the right to receive the Royalty Payments. The Royalty 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 Royalty 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. See Note 7 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information on the Royalty Pharma Agreement.

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 could have elected 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. No sales of common stock occurred under the 2023 Sales Agreement, which was terminated in January 2026.

On February 27, 2026, we entered into a sales agreement, or the 2026 Sales Agreement, with TD Securities (USA) LLC, or TD Cowen, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $150 million from time to time through TD Cowen as the sales agent. We will pay TD Cowen an aggregate commission rate equal to up to 2.5% of the gross proceeds of the sales price per share for common stock sold through TD Cowen under the 2026 Sales Agreement. We are not obligated to make any sales of common stock under the 2026 Sales Agreement. To date, no sales of common stock have occurred under the 2026 Sales Agreement.

We have an investment policy to invest our cash in liquid, investment grade securities, such as interest-bearing money market funds, certificates of deposit, U.S. Treasury securities, municipal securities, government and agency securities, commercial paper and corporate notes. Our investment portfolio does not contain securities with exposure to sub-prime mortgages, collateralized debt obligations, asset-backed securities or auction rate securities and, to date, we have not recognized any other-than-temporary impairment charges on our marketable securities or any significant changes in aggregate fair value that would impact our cash resources or liquidity. To date, we have not experienced lack of access to our invested cash and cash equivalents; however, access to our invested cash and cash equivalents may be impacted by adverse conditions in the financial and credit markets.

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

Successful drug development and commercialization requires significant amounts of capital. As of September 30, 2026, we had approximately $339.4 million in cash, cash equivalents, restricted cash and marketable securities. Based on our current operating plans and assumptions, we believe that our existing cash, cash equivalents, and marketable securities, together with anticipated net revenues from sales of RYTELO, will be sufficient to fund our projected operating requirements for the foreseeable future. However, if we do not generate net revenues from commercial sales of RYTELO at the levels we anticipate, if we experience unforeseen events or choose to make other investments in our business, or our assumptions regarding our projected operating expenses are otherwise incorrect, we may require additional funding, which could include a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, which may not be possible. For example, changes in our operations, such as increased development, manufacturing and clinical trial expenses, or our undertaking of additional programs, business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses, may cause our operating expenses to increase, perhaps significantly, which could require us to raise additional funding. If adequate funds are not available to us when we need them, 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 receiving FDA approval of RYTELO in the U.S. in June 2024 and marketing authorization in the EU in March 2025, 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 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. or in the EU for lower-risk MDS or other potential jurisdictions or 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 this regard, given our decision to discontinue our Phase 3 IMpactMF clinical trial, we will be unable to expand RYTELO's indication to use to the relapsed/refractory MF indication and we will otherwise not receive any return on or recoup our investment in the relapsed/refractory MF indication. As a result, we will remain wholly dependent on the commercialization of RYTELO in lower-risk MDS for the foreseeable future. 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 further changes in tariffs and other trade restrictions, renegotiation of existing international trade agreements or further escalation of trade tensions, inflation, fluctuations in interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts

such as the ongoing Russia and Ukraine military conflict and the ongoing military conflict involving the U.S., Israel and Iran, 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 overall 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 RYTELO, including commercialization in the U.S. and 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,
- 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 commercial arrangements with third parties, including for the commercialization and marketing of RYTELO in the EU and in any other regions outside of the U.S., if approved for commercialization in such other regions;
- expenses associated with the pending putative securities class action and shareholder derivative lawsuits and potential additional related lawsuits, as well as any other litigation;
- the extent and scope of our selling, general and administrative expenses, including expenses associated with pending and 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.

In the event we need to raise additional capital to fund our business, including pursuant to the 2026 Sales Agreement with TD Cowen, capital lease transactions or other financing sources, such additional capital 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, fluctuations in interest rates, prospects of a recession, government shutdowns, further changes in tariffs and other trade restrictions, 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 equity and credit markets and are expected to have further global economic consequences. For example, the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the U.S., Israel and Iran have created extreme volatility and disruption in the equity and credit markets and have had and may continue to have further global economic consequences, including continued disruptions of the global supply chain and energy markets, which could continue to drive inflationary pressures and increase global recession risk. If the equity and credit markets deteriorate, 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, if needed, 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 2026 Sales Agreement, our stockholders may be diluted, and the terms may include liquidation or other preferences that could materially and adversely affect the rights of our existing stockholders. In addition, we have borrowed, and in the future may borrow, additional capital from institutional and commercial banking sources to fund development and our future growth, including existing borrowings pursuant to our Pharmakon Loan Agreement or subsequent borrowing pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as our 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 Used in Operating Activities

Net cash used in operations for the nine months ended September 30, 2026 and 2025 was $68.5 million and $89.0 million, respectively. The decrease in net cash used in operations for the nine months ended September 30, 2026, compared to the same period in 2025, reflects a decrease in net loss, primarily due increased product revenue and lower personnel-related expenses as a result of the workforce reduction in December 2025, partially offset by net changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026 and 2025 was $54.2 million and $86.1 million, respectively. The decrease in net cash provided by investing activities for the nine months ended September 30, 2026, compared to the same period in 2025, primarily reflects higher purchases of marketable securities and decreased proceeds from the sale and maturities of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 and 2025 was $6.0 million and $1.9 million, respectively. The increase in net cash provided by financing activities primarily reflects higher proceeds from issuances of common stock under our equity plans and proceeds from the exercise of warrants.

Contractual Obligations

Our operating expenditures primarily consist of our obligations under commercial purchase commitments related to our manufacturing and supply agreements for RYTELO and operating leases.

RYTELO requires long lead times to manufacture. Therefore, we make substantial and often long-term investments in our supply chain in order to ensure we have enough drug product to meet potential future commercialization requirements, as well as clinical trial needs.

We have engaged third-party contract manufacturers 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 binding commercial purchase commitments of approximately $31.6 million that can be cancelled, but would incur cancellation penalties, and approximately $9.9 million in agreed upon manufacturing commitments that can be adjusted based on commercial demand of RYTELO. We expect to utilize all related commercial purchase commitments.

In the normal course of business, we enter into agreements with CROs for clinical trials and with other vendors for preclinical research studies, investigator-led trials and other services and products for operating purposes. We have not considered these commitments 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.

In September 2026, the Company entered into agreements with a third-party service provider to support the commercial launch of RYTELO in Germany and France. The arrangements include medical and commercial field personnel and related operational support, and have initial terms through December 31, 2028. The underlying agreements may be terminated for convenience by either party upon nine months' prior written notice. During the notice period, monthly fees may not be less than the average monthly fees earned during the preceding 12 months. Upon termination, the Company may also be responsible for services performed through the termination date, approved noncancelable or nonrefundable commitments, certain vehicle lease termination charges, and applicable severance and employee-transition costs. After the initial term, agreements automatically renew for successive 12-month periods.

In September 2026, the Company entered into a new lease agreement for an office space in Parsippany, New Jersey. The new lease has an initial term of approximately eight and one-half years following commencement, with an option to extend the lease for an additional five years. Lease commencement is expected to occur upon substantial completion of certain landlord-funded improvements, which is currently expected in the first quarter of 2027. Concurrent with entering into the new lease, the Company entered into an agreement to terminate its existing lease for an office space in Parsippany, New Jersey. The existing lease will terminate, without a termination fee, upon substantial completion of the landlord's work under the new lease. The new lease provides for initial annual base rent of approximately $0.4 million, subject to annual increases over the lease term.

In October 2019, we entered into an operating lease agreement for office space located in Foster City, California, or the Foster City Lease. The Foster City Lease commenced on March 10, 2020, and its initial term extends through June 2027, with an option to extend the lease for an additional five years. In October 2026, we notified the landlord that we do not intend to exercise the five-year renewal option. Accordingly, the Foster City Lease is expected to expire in June 2027 in accordance with its existing terms.

On November 1, 2024, we entered into the Pharmakon Loan Agreement, and in connection with this transaction, all obligations outstanding under the Hercules Loan Agreement were repaid in full on November 1, 2024, upon which the Hercules Loan Agreement was terminated. We expect our interest expense in future periods to reflect the continued amortization of debt discount and issuance costs associated with the Tranche A Loan under the Pharmakon Loan Agreement. As of September 30, 2026, we had a long-term principal debt balance of $120.4 million related to the Pharmakon Loan Agreement. See Note 7 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information on the Pharmakon Loan Agreement.

On November 1, 2024, we entered into the Royalty Pharma Agreement, pursuant to which we received an upfront payment of $125.0 million and Royalty Pharma obtained the right to receive Royalty Payments on future U.S. net sales of RYTELO for each calendar quarter during the term of the agreement. We are obligated to make Royalty Payments each quarter based on U.S. net sales of RYTELO at the royalty rates set forth in the agreement, which Royalty Payments are not determinable at this time, until the date when the aggregate Royalty Payments equal or exceed 1.65 times the Purchase Price, if this occurs by June 30, 2031, or the date when the aggregate Royalty Payments equal or exceed 2.0 times

the Purchase Price. See Note 7 on Debt in Notes to Condensed Consolidated Financial Statements of this Report for additional information on the Royalty Pharma Agreement.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2026, 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 2025 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 8 on Commitments and Contingencies 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, can be found under "Risk Factors" in Part II, Item 1A of this Report. The summary below is qualified in its entirety by that more complete discussion of such risks and uncertainties. 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 "Risk Factors" in Part II, Item 1A of this Report as part of your evaluation of an investment in our common stock.

Risks Related to the Commercialization of RYTELO® (Imetelstat)

- Our near-term prospects are wholly dependent on the successful commercialization of RYTELO for lower-risk MDS. We have limited experience with the commercialization of RYTELO, and if we are unable to successfully commercialize RYTELO in the U.S. and in the EU 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.
- Although we have established commercial operations and sales, marketing and distribution infrastructure for RYTELO in the U.S., our U.S. commercialization strategy may ultimately be unsuccessful or less successful than anticipated.
- We have no experience selling, marketing or commercializing an approved drug outside of the U.S. and currently rely on and plan to continue to rely on third parties for the commercialization of RYTELO outside of the U.S., and we and they may not be able to effectively market, sell and distribute RYTELO outside of the U.S. In addition, if such third parties fail to provide us with accurate information, perform as expected or comply with legal and regulatory requirements, our efforts to commercialize RYTELO outside of the U.S. may be significantly impacted and/or we may be subject to regulatory sanctions.
- 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.
- We face competition from existing products, product candidates and technologies, and competitors may develop new products and technologies. If these products, product candidates or technologies are deemed by the healthcare community to be superior to or more cost-effective than RYTELO, it would significantly impact the development and commercial viability of RYTELO, which would severely and adversely affect our financial results, business and business prospects, and the future of RYTELO, and might cause us to cease operations.
- We are subject to pricing and reimbursement regulations in the European Union, or 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 approvals for RYTELO in the U.S. and the EU 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. and in the EU for certain patients with 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.

Risks Related to Compliance with Healthcare Laws

- Our relationships with healthcare providers, including physicians and third-party payors, the methods by which we promote RYTELO, and the content of our promotional materials and programs, are subject to applicable promotional, anti-kickback, fraud and abuse, and other healthcare laws and regulations, and our failure to comply with these laws could expose us to criminal sanctions, civil penalties, exclusion from federal health care programs, contractual damages, reputational harm and may adversely affect our business and financial results.

Risks Related to the Further Development of Imetelstat

- We cannot be certain that we will be able to continue to develop imetelstat or advance it in clinical trials, or that we will be able to receive regulatory approval for imetelstat in any other indications in the U.S., the EU or any other region, on a timely basis or at all.
- RYTELO may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could halt or limit its further 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, as well as any data disclosed as a result of an interim analysis, may not predict success in later clinical trials or the final analysis, and we cannot assure you that any ongoing or future clinical trials of imetelstat will lead to similar results and data that could potentially enable us to obtain any further regulatory approvals.

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.

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

- We have a history of net losses and may not achieve consistent future profitability for some time, if ever.
- Our failure to obtain additional capital, if and 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.

Risks Related to Our Indebtedness and Royalty Payment Obligations

- 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, including by limiting our operating and financial flexibility.

Risks Related to Protecting Our Intellectual Property

- If we are unable to obtain and maintain sufficient intellectual property protection and relevant regulatory exclusivities 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.

Risks Related to Managing Our Growth and Other Business Operations

- Our strategic restructuring plan and the associated workforce reduction implemented in December 2025 may not result in anticipated savings and long-term value creation, could result in total costs and operating expenses that are greater than expected and could disrupt our business.
- We and certain of our current and former officers and directors have been named as defendants in securities class action lawsuits and derivative lawsuits. These lawsuits, and potential similar or related lawsuits, are costly to defend, 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.

We operate in a dynamic and rapidly changing environment involving numerous risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below, together with all of the other information included in this Report. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

RISKS RELATED TO THE COMMERCIALIZATION OF RYTELO

Our near-term prospects are wholly dependent on the successful commercialization of RYTELO for lower-risk MDS. We have limited experience with the commercialization of RYTELO, and if we are unable to successfully commercialize RYTELO in the U.S. and in the EU for lower-risk MDS, or to expand its indication of use, our ability to generate meaningful revenue or achieve sustained 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. While we have generated revenue from U.S. sales of RYTELO since mid-2024, the commercialization of RYTELO marks our first effort to commercially launch a product candidate, and our ability to grow revenue on a sustained basis has not yet been proven. RYTELO is our only product approved for marketing by the FDA, and our ability to generate meaningful revenue from product sales and achieve sustained profitability is wholly dependent on our ability to successfully commercialize RYTELO in the U.S. and in the EU 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;
- we may not be able to increase physician adoption of RYTELO through our commercialization strategy and plans, including any potential amendments or adjustments to those plans;
- our inability to achieve and maintain revenue growth in the near future under our current commercialization strategy and plans or any potential further amendments or adjustments thereto;
- potential future changes in the reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators;
- the relative position of RYTELO as compared to alternative treatment options in healthcare guidelines and recommendations, such as those developed by the National Comprehensive Cancer Network, or NCCN, and similar guidelines and recommendations outside the U.S.;
- 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;
- the market penetration rate of RYTELO across the breadth of eligible patient segments in its approved indication may continue to be lower than our expectations;
- our projections regarding the market opportunities for RYTELO may not be accurate, and the actual market for RYTELO may be smaller than we estimate;
- our current and potential future reliance currently on other third parties, which we do not control, for the commercialization of RYTELO outside of the U.S.;
- 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 for lower-risk MDS or for any other indications;
- 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;
- the capabilities of third party manufacturers may adversely affect the success of our commercialization of RYTELO;
- we may need additional financial or other resources that might not be available to us 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, we recently announced our decision to discontinue our Phase 3 IMpactMF clinical trial evaluating imetelstat in patients with relapsed/refractory MF. The decision to discontinue the Phase 3 IMpactMF trial was based on a recommendation from an independent DMC following the DMC's conclusion that the trial was unlikely to meet the primary endpoint of overall survival. Given the discontinuation of the Phase 3 IMpactMF trial, we will be unable to pursue any regulatory approvals for the relapsed/refractory MF indication and we will otherwise not receive any return on our recoup our investment in the relapsed/refractory MF indication, which has harmed our business and business prospects, including our prospects for sustained profitability in the near term. In addition, the development of imetelstat for the treatment of other myeloid hematologic malignancies is in the early stages and we do not expect to receive any regulatory approvals to market RYTELO for any additional indications for a number of years, if ever. Accordingly, will remain wholly dependent on the commercialization of RYTELO in lower-risk MDS for the foreseeable future. In this regard, RYTELO may not generate sufficient revenue from product sales in lower-risk MDS, and we may not achieve sustained profitability 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 in the future, our ability to generate meaningful revenue from product sales and achieve sustained 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.

Although we have established commercial operations and sales, marketing and distribution infrastructure for RYTELO in the U.S., our U.S. commercialization strategy may ultimately 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. 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. Our commercialization efforts in the U.S. have not to date achieved meaningful sales growth and our RYTELO sales trends and resulting revenue have been and may continue to be variable. Net product revenue was approximately $169.4 million and $135.6 million during the nine months ended September 30, 2026 and 2025, respectively. In an effort to better execute on our plans to commercialize RYTELO and generate more meaningful product revenue, we decided to focus our commercial execution on targeted engagement with high-volume accounts that treat earlier-line patients, and invest in non-personal promotion and third-party education to reach the full breadth of the eligible patient population, while cross-functionally collaborating for effective account management. However, our revised strategy to drive RYTELO commercial growth and our ongoing commercialization efforts may still not achieve meaningful sales growth, which may require us to, among other things, further adjust or amend our commercialization strategy and plans and incur significant expenses, and there can be no assurance that we will be able to meet or grow RYTELO net product revenue in future periods. In particular, our strategy may not drive new patient starts in lower-risk MDS U.S. patients, particularly in second-line lower-risk MDS, in a timely manner or at all, or the duration of therapy could be shorter than we expect, each of which would limit RYTELO's growth potential and could preclude or delay our ability to generate meaningful revenue from product sales and to achieve sustained profitability. If we are unsuccessful in accomplishing our objectives from our commercialization efforts and strategy, we may not be able to generate meaningful revenue from the commercialization of RYTELO in lower-risk MDS, or may require significant additional capital and financial resources to make further investment in our commercial operations. Any of these outcomes would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

In December 2025, we announced a strategic restructuring plan designed to position us for long-term value creation and improve our financial discipline. However, there can be no assurance that our recent restructuring will result in long-term value creation or that our commercialization strategy will result in meaningful improvement in our sales performance. Additionally, we may determine that we need further changes in the future that require additional hiring or other organizational changes to adequately support our strategy, which could further increase our costs. As such, we continue to 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, retain and effectively train marketing, sales and medical personnel as needed and equip them with compliant and effective materials, our efforts to successfully commercialize RYTELO could be adversely affected.

We have no experience selling, marketing or commercializing an approved drug outside of the U.S. and currently rely on and plan to continue to rely on third parties for the commercialization of RYTELO outside of the U.S., and we and they may not be able to effectively market, sell and distribute RYTELO outside of the U.S. In addition, if such third parties fail to provide us with accurate information, perform as expected or comply with legal and regulatory

requirements, our efforts to commercialize RYTELO outside of the U.S. may be significantly impacted and/or we may be subject to regulatory sanctions.

We expect to continue to seek regulatory approvals of RYTELO in lower-risk MDS in jurisdictions outside of the U.S., such as our recent marketing authorization in the EU, and to continue to establish arrangements with third parties, which we do not control, to assist us in the commercialization of RYTELO in such jurisdictions. Specifically, we currently intend to continue to seek contractual arrangements, strategic partnerships, collaborations, alliances or licensing arrangements with third parties to assist us in the commercialization of RYTELO in the EU and in any other regions outside of the U.S. Doing so will continue to require additional investment of capital and time. For example, to support the commercialization and marketing of RYTELO in the EU, we have engaged third parties, including a commercialization partner, to assist with critical activities, including reimbursement, Health Technology Assessment (HTA) submissions, market access and distribution, a contracted sales force and recording of sales. In this regard, there can be no assurance that the capabilities of our commercialization partner in the EU will be effective in marketing and selling RYTELO or that our commercialization partner's personnel will be more effective than an internally developed sales organization. Moreover, if these third parties fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, our ability to deliver RYTELO to meet commercial demand outside of the U.S. would be significantly impaired. In addition, if these third parties do not provide us with timely and accurate information, it could impact our ability to comply with our financial reporting, government price reporting and securities laws obligations, which could expose us to the risk of regulatory sanctions or shareholder lawsuits and adversely affect our business. In any event, any failure or delay in entering into and satisfactorily conducting such contractual arrangements, strategic partnerships, collaborations, alliances or licensing arrangements with third parties would adversely impact the commercialization of RYTELO in the EU or in any other regions outside the U.S. where RYTELO may be approved for marketing in the future.

If we do not maintain 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 maintaining 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. 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 are critical to market acceptance of RYTELO.

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 certain 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 the 2025 Form 10-K.

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 includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government, including the Medicare Drug Price Negotiation Program, which may ultimately have a negative effect on the pricing for RYTELO. However, the Medicare Drug Pricing Negotiation Program provisions of the law currently contain an orphan drug exception. Further, the final CY 2026 Medicare Physician Fee Schedule rule, issued by the Centers for Medicare & Medicaid Services, among other things, increases bona fide service fee documentation requirements, defines "bundled arrangement," to require "unbundling" of both contingent and non-contingent discounts and includes sales of Part B units at the Maximum Fair Price in average sales price calculations. These changes could lower reimbursement for Medicare Part B utilization and require manufacturers to comply with new, uncertain or complex reporting obligations and drug pricing documentation practices. Additionally, the administration is implementing or considering various CMS (Center for Medicare and Medicaid Innovation) most favored nation pricing

models, under which manufacturers may owe rebates for certain prescription drugs under Medicaid or Medicare if the price of a drug included in an applicable model exceeds an international benchmark calculated based on prices available in certain reference countries. These include the finalized Global Benchmark for Efficient Drug Pricing Model (GLOBE) Model for certain Medicare Part B drugs; and the proposed Guarding United States Medicare Against Rising Drug Costs (GUARD) Model for certain Medicare Part D drugs, among others.

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 time-consuming and costly, and it 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.

Although we have received a permanent and product-specific J-Code (J0870) for RYTELO which became effective on January 1, 2025, coverage may significantly change or may be more limited than the indications 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, and reimbursement policies in the U.S., the EU, and other jurisdictions may evolve which may adversely impact our ability to successfully commercialize RYTELO. Even if favorable coverage and reimbursement status is attained for RYTELO in additional indications or jurisdictions for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Moreover, we have in the past increased and may in the future increase the price of RYTELO, and there is no guarantee that price adjustments that we have taken or may take in the future will not negatively affect our ability to secure and maintain coverage and reimbursement for RYTELO, which could limit the price that we charge for RYTELO, limit the commercial opportunities for RYTELO and/or negatively impact our sales volumes and net revenues from sales of RYTELO. In any event, if coverage and reimbursement are not available or the reimbursement amount is inadequate, we may not be able to successfully commercialize RYTELO, which would negatively impact our business and business prospects.

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., the EU, and in any other jurisdictions where we may seek approval in the future.

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.

Our strategy to drive sales growth and our ongoing commercialization efforts have not to date achieved and may not in the future achieve the rate of market acceptance by the healthcare community or breadth of eligible patient segments that we expect, which may require us to, among others, further adjust or amend our commercialization strategy and plans and incur significant expenses, and there can be no assurance that we will be able to grow RYTELO net product revenue in future periods. While our current priority is to drive new patient starts across the breadth of the eligible patient population in RYTELO's sole approved indication, we may be unable to do so in a timely manner or at all, which would limit RYTELO's growth potential and which could delay or preclude our ability to generate meaningful revenue from product sales and to achieve sustained profitability. Furthermore, 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 favorable 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, 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 for new indications;
- the effectiveness of sales, marketing and distribution infrastructure 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. National health insurance and/or 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. or the EU for lower-risk MDS or for any other indications for which RYTELO may be approved, 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. or the EU. Additionally, the potentially addressable patient population for RYTELO may not ultimately be amenable to treatment with RYTELO, we may be unable to successfully identify patients and achieve a significant market share in all eligible patient segments in RYTELO's approved indication, or the duration of therapy for patients receiving RYTELO could be shorter than we expect, each of which would have a negative impact on sales of RYTELO in the future and may limit its growth potential. Our commercialization of RYTELO in the U.S. and our commercialization in the EU is limited to certain patients with lower-risk MDS, and any future potential commercialization will be limited to the therapeutic indications examined in our clinical trials and approved by the FDA and similar international regulatory authorities, which would preclude us from marketing 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 sustained profitability.

We face competition from existing products, product candidates and technologies, and competitors may develop new products and technologies. If these products, product candidates or technologies are deemed by the healthcare community to be superior to or more cost-effective than RYTELO, it would significantly impact the development and commercial viability of RYTELO, which would severely and adversely affect our financial results, business and business prospects, and the future of RYTELO, and might cause us to cease operations.

The pharmaceutical and biotechnology industries are characterized by intense and dynamic competition with rapidly advancing technologies and a strong emphasis on proprietary products. While we believe our proprietary oligonucleotide chemistry; experience with the biological mechanisms related to RYTELO, telomeres and telomerase; clinical data to date indicating potential disease-modifying activity with RYTELO treatment; and knowledge and expertise

around the development of potential treatments for myeloid hematologic malignancies may provide us with certain 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 competes 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. A discussion of current and potential future competitors of RYTELO can be found in the sub-section titled "Competition" in Part I, Item 1, titled "Business" in the 2025 Form 10-K.

Many of our competitors, either alone or with their strategic partners, 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. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We anticipate increased competition in the future as new companies explore treatments for myeloid hematologic malignancies, which may significantly impact the commercial viability of RYTELO. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to RYTELO. These companies and institutions compete with us in recruiting and retaining qualified development and management personnel as well as in acquiring technologies complementary to the RYTELO program.

As a result of the foregoing, competitors may develop more commercially desirable or affordable products than RYTELO. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, competitive to 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 develop products that are safer, more effective, more convenient to administer to patients, or less costly than RYTELO, and, therefore, present a serious competitive threat to RYTELO. In addition, competitors may price their products below what we may determine to be an acceptable 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 render RYTELO obsolete, which may cause us to cease any further development or future commercialization of RYTELO, which would severely and adversely affect our financial results, business and business prospects, and the future of RYTELO, and might cause us to cease operations.

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 in the U.S., 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 subject to pricing and reimbursement regulations in the EU, which may materially affect our ability to commercialize and receive reimbursement coverage for RYTELO in the EU.

In March 2025, we received marketing authorization for RYTELO in the EU for the treatment of adult patients with TD anemia due to lower-risk MDS without an isolated deletion 5q cytogenic abnormality and who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy. We have initiated a gated commercial launch in targeted European markets, with availability expected in Germany by the end of 2026 and in France in 2027. The pricing of RYTELO is 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 and 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, within the EU member states may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and may 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. In some countries in the EU, 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. This Health Technology Assessment (HTA) process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. At the EU level, on January 12, 2025, Regulation No 2021/2282 on Health Technology Assessment (HTA Regulation), entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The HTA Regulation is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. The Regulation establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. It permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. 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. 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.

RISKS RELATED TO REGULATORY APPROVAL OF RYTELO

We may be unable to maintain regulatory approvals for RYTELO in the U.S. and the EU 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 certain patients with lower-risk MDS, and in March 2025, we received marketing authorization from the EC to commercialize RYTELO in the EU for certain adult patients with TD anemia due to lower-risk MDS. Federal, state and local governments in the U.S., and regulatory authorities in the EU, have significant regulations in place that may limit or prevent us from successfully commercializing RYTELO for lower-risk MDS. We do not currently have regulatory approval for RYTELO in any other jurisdictions 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.

The regulatory frameworks and practices of the FDA, EMA/EC and comparable authorities in other countries may change over time, and we cannot predict the nature, timing, or impact of any such developments. We cannot project with certainty if or when we might submit or gain regulatory approval for RYTELO for other indications or in other jurisdictions. The FDA, EMA/EC and other regulatory authorities exercise broad discretion throughout the product review and approval process, including in determining the specific conditions for submission, including the requirement for a pre-approval inspection of RYTELO's listed manufacturing facility. As a result, the FDA, EMA/EC and other authorities may delay or extend application review, may decline to accept an application for substantive review, or may conclude, after review, that the information provided is inadequate to obtain or maintain approval of RYTELO. Any such decision could materially and adversely affect the timing of potential approval and our business prospects. If the FDA, for instance, determines that an NDA is not sufficiently complete for filing or issues a complete response letter, or CRL, requiring additional data or clarification, we may be required to resubmit the application and any such resubmission or CRL-driven delays could significantly postpone review and potential approval RYTELO for other indications. Even if we resubmit an NDA, it remains uncertain whether the FDA will ultimately accept the completed application or additional data, and any such outcome could delay or prevent approval of RYTELO for other indications.

Failure to maintain regulatory approval for RYTELO from the FDA in the U.S. and from the EC in the EU for lower-risk MDS, or delays in obtaining, failing 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 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, together with other vendors involved in the commercialization process, are subject to continual review, and discovery of previously unknown problems with a product or its manufacturer, including if regulatory inspectors identify regulatory noncompliance by third-party manufacturers requiring remediation, may result in restrictions on the product or manufacturer, including import restrictions, seizure, and withdrawal of the product from the market, or may otherwise cause manufacturing delays and supply disruptions.

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. or the EU in lower-risk MDS or in current or potential future clinical trials, a number of potential significant negative consequences could result, including:

- regulatory authorities may withdraw approval of RYTELO;
- we may be required to recall RYTELO, seek to change the way it is administered, conduct additional costly, time-consuming and burdensome clinical trials or change the labeling of the product;
- regulatory authorities 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 additional requirements in a risk evaluation and management plan or risk management plan;
- RYTELO may be rendered less competitive and sales, if any, may decrease;

- our reputation may suffer generally among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- regulatory authorities may refuse to approve 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, which would negatively impact the development of RYTELO 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 RYTELO. If RYTELO is approved outside the U.S. and EU, we will be subject to similar requirements, considerations and risks in other regions.

Our regulatory approval for RYTELO in the U.S. and in the EU for certain patients with 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 in the U.S. and EU are subject to non-clinical, clinical and manufacturing post-marketing requirements and/or commitments, including the requirement to assess the long-term safety of RYTELO (imetelstat) in the Phase 3 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 the EU, our regulatory approval for RYTELO in certain patients with TD anemia due to lower-risk MDS is subject to our commitment to submit the results from certain ongoing non-clinical and clinical studies required by the FDA, including the assessment of the long-term safety of RYTELO in the extension to the Phase 3 IMerge trial. 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, compliance with good pharmacovigilance practices, 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 on the timeline required or at all, or any other regulatory requirements, including the FDA's regulation of promotional claims, or later discovery of previously unknown problems with RYTELO, or our manufacturers, or manufacturing processes for RYTELO, may result in actions such as:

- adverse regulatory inspection findings;
- restrictions on RYTELO manufacturing, distribution or use;
- restrictions on, or prohibitions against, marketing, importing or exporting RYTELO;
- additional post-marketing requirements or commitments;
- fines, untitled letters, warning letters or the withdrawal of RYTELO from the market;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- suspension or termination of ongoing clinical trials of imetelstat in other indications;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs and/or eligibility for the award of government contracts for RYTELO; suspension or withdrawal of regulatory approval for RYTELO;
- significant civil, criminal and administrative penalties, including fines, restitutions or disgorgement of profits or revenues;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

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.

Any government investigation of alleged violations of law could require us to spend significant time and resources in response and could generate negative publicity. In addition, the regulations, policies or guidance of the FDA, EC or any other regulatory authority 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 U.S. or abroad.

If we are unable to fulfill the post-marketing requirements and commitments established by the FDA, or that may be or are 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.

Furthermore, in connection with our marketing authorization for RYTELO in the EU for certain patients with TD anemia due to lower-risk MDS, we are subject to post-marketing requirements to submit final results from certain ongoing non-clinical and clinical studies and the completion of certain quality-related activities and studies. We are also 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, discover 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, or failure to complete post-marketing requirements on the timeline required, may result in administrative, civil or criminal penalties. This could also result in 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, among others. If RYTELO is approved outside the U.S. and the EU, 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 ongoing or future clinical trials may result in a delay in obtaining, or our failure to obtain, regulatory approval for RYTELO in lower-risk MDS in any jurisdictions other than the U.S. and the EU, or for other indications in any jurisdictions. Failure to obtain approval could significantly harm our business and business prospects, render our significant clinical development expenditures unrecoverable, and might cause us to cease operations.

Securing marketing approval requires the submission of extensive non-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy to the satisfaction of such regulatory authorities, as well as information about the product manufacturing process and any inspections of manufacturing facilities conducted by regulatory authorities through the filing of a New Drug Application, or NDA, in the U.S. and a Marketing Authorization Application, or MAA, in the EU. Although RYTELO is approved in the U.S. and the EU in lower-risk MDS, there can be no assurance that we will receive regulatory approval for the commercialization of RYTELO for lower-risk MDS in any other jurisdiction or for any new indications. In addition, given our determination to discontinue the Phase 3 IMpactMF trial, we will be unable to pursue any regulatory approvals for the relapsed/refractory MF indication and the development of imetelstat for the treatment of other myeloid hematologic malignancies is only in the early states; accordingly, we do not expect to receive any regulatory approvals to market RYTELO for any additional indications for a number of years, if ever.

Any marketing approval that we may receive for RYTELO in any other jurisdiction or for any other indication may also be limited or subject to restrictions or post-approval commitments and requirements 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, and from the EC in March 2025, 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 further 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, if needed, the price of our common stock, 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.

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 EC 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 ten years of exclusivity in the U.S. and EU, 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. On March 7, 2025, the EC granted marketing authorization for RYTELO as an orphan medicinal product indicated for the treatment of adult patients with TD anemia due to very low, low or intermediate risk MDS without an isolated deletion 5q cytogenetic (non-del 5q) abnormality and who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy.

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 if such products are able to demonstrate superiority to RYTELO.

We may lose orphan drug exclusivity in the U.S. for certain reasons, including if the FDA 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. In the EU, orphan designation may be lost before marketing authorization if it is established that the criteria for orphan designation are no longer met. Failure to maintain orphan designation status would lead to the inability to obtain or the loss of associated regulatory exclusivity.

Even if we maintain orphan drug exclusivity for RYTELO in the U.S., the exclusivity may not effectively protect RYTELO from all competition because different drugs with different active moieties can be approved for the same condition or a drug containing the same active moiety or principal molecular structure can be approved for a different indication. Even after an orphan drug product is approved, such as the approval of RYTELO in the U.S. in June 2024 for certain patients with lower-risk MDS, the FDA can subsequently grant orphan designation to a different drug with the same active moiety for the same condition, if the FDA 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, allow competitive products to enter the market, and 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, orphan drug designation will neither shorten the development time nor regulatory review time for RYTELO in the US and other comparable jurisdictions, and it does not give RYTELO advantages in the regulatory review or approval process. Notably, there have been legal challenges to aspects of FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, including whether two drugs are the same drug product. Future challenges could lead to changes that affect the protections potentially afforded to our products in ways that are difficult to predict.

Similarly, in the EU, orphan market exclusivity may not effectively protect RYTELO from all competition. Following the authorization of RYTELO as an orphan medicinal product by the EC in March 2025 for certain patients with lower-risk MDS, the EC can subsequently approve similar orphan medicinal products for the same therapeutic indication or if we are unable to supply RYTELO in sufficient quantities or if a similar medicinal product with the same orphan indication is shown to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. If it is established that the criteria for orphan designation are no longer met inter alia where it is shown that the product is sufficiently profitable, EU orphan market exclusivity may be reduced to six instead of 10 years, allowing similar medicinal products for the same therapeutic indication to the market sooner. In the EU, orphan drug designation for any additional indication we may pursue for RYTELO does confer certain regulatory advantages—such as protocol assistance—but it does not shorten development timelines or accelerate the EMA's overall review process.

In December 2025, the European Commission, Parliament and Council reached a political agreement on the Pharma Package, which includes proposed changes to the EU orphan medicinal product framework that may modify the length of orphan market exclusivity and change the way in which market exclusivity is awarded to drugs with more than one approved orphan indication. The Pharma Package is subject to formal adoption by the European Parliament and Council and, if adopted, could alter the exclusivity protections currently available for our orphan designated products in the EU, including by reducing orphan market exclusivity from the current 10 years to 9 years, with a 2-year extension for so-called "breakthrough orphan medicinal products", and introducing the concept of "global orphan marketing authorization", which would prevent separate orphan market exclusivity for second or further orphan therapeutic indications. Although the final text has not yet been published and RYTELO for the treatment of MDS is and remains regulated under the current regulatory framework, our activities, including authorization of future indications may be affected by the new legislation if adopted.

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 the U.S. for lower-risk MDS, the top-line results from IMerge Phase 3 are not necessarily predictive of RYTELO's activity in other indications.

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 and the EC in March 2025 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. For example, in October 2026, we announced our decision to discontinue our Phase 3 IMpactMF clinical trial. The decision to discontinue the Phase 3 IMpactMF trial was based on a recommendation from an independent DMC following the DMC's conclusion that the trial was unlikely to meet the primary endpoint of overall survival. Given the discontinuation of the Phase 3 IMpactMF trial, we will be unable to pursue any regulatory approvals for the relapsed/refractory MF indication and we will otherwise not receive any return on our recoup our investment in the relapsed/refractory MF indication. Moreover, the development of imetelstat for the treatment of other myeloid hematologic malignancies is in the early stages and we do not expect to receive any regulatory approvals to market RYTELO for any additional indications for a number of years, if ever. Accordingly, we will remain wholly dependent on the commercialization of RYTELO in lower-risk MDS for the foreseeable future.

Regulatory authorities have substantial discretion in the approval process and can delay, limit or deny approval of RYTELO in other jurisdictions or indications, 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, as was the case in our Phase 3 IMpactMF trial;

- 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 international regulatory authorities that regulatory approval for RYTELO should be narrowed or made more restrictive than our current approvals in the U.S. and the EU for lower-risk MDS or any future indication for which approval is sought, if any;
- disagreement regarding the formulation, labeling and/or the specifications for RYTELO;
- the failure of the quality or stability of RYTELO to meet acceptable regulatory standards;
- 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, good clinical practices, or 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.

Any of these events may result in a failure to further develop, obtain regulatory approval for or commercialize RYTELO in any jurisdiction or in any indication other than lower-risk MDS in the U.S. and the EU, which could severely and adversely affect our business and business prospects.

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.

RISKS RELATED TO COMPLIANCE WITH HEALTHCARE LAWS

Our relationships with healthcare providers, including physicians and third-party payors, the methods by which we promote RYTELO, and the content of our promotional materials and programs, are subject to applicable promotional, anti-kickback, fraud and abuse, and other healthcare laws and regulations, and our failure to comply with these laws could expose us to criminal sanctions, civil penalties, exclusion from federal health care programs, contractual damages, reputational harm and may adversely affect our business and financial results.

The FDA strictly regulates the promotional claims that may be made about drug products. In particular, FDA asserts that 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 our promotional materials or methods were found to have violated the Food, Drug, and Cosmetic Act, or False Claims Act, we could be subject to Warning or Untitled Letters, or to significant civil, criminal, or 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.

Healthcare professionals, including but not limited to physicians, nurses, medical directors, hospitals, pharmacies, pharmacy benefit managers, group purchasing organizations, wholesalers, insurers, and all individuals employed by such entities (collectively, HCPs), and patients, caregivers, patient advocacy organizations, or medical societies, may influence the recommendation and prescription of RYTELO. There is ongoing government focus on the relationships between the pharmaceutical industry and HCPs or others who can influence the prescription or recommendation of products, and common industry activities that we may engage in such as speaker programs, advisory boards, consulting agreements with HCPs, relationships with charitable foundations providing copayment assistance, and relationships with patient organizations and patients continue to receive increased governmental attention.

Our arrangements with HCPs and others who have the ability to influence the recommendation and prescription of RYTELO may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations, 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. Additionally, some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction.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” of the 2025 Form 10-K.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. For example, to help patients afford our products, we have a patient assistance program and also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients in affording pharmaceuticals have become the subject of scrutiny under the AKS and other federal and state laws in recent years. If we or our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. A government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

While we maintain a comprehensive compliance program designed with the goal of ensuring that our practices and the activities of our third party contractors and employees fall within the scope of available statutory exceptions and regulatory safe harbors whenever possible, and otherwise comply with applicable laws, it is possible that government authorities may disagree with our assessment, find fault with the conduct of our employees or contractors or conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, or could result in related shareholder lawsuits, any of which would adversely affect our business, financial condition, results of operations and prospects.

Foreign, 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.

RISKS RELATED TO THE FURTHER DEVELOPMENT OF IMETELSTAT

We cannot be certain that we will be able to continue to develop imetelstat or advance it in clinical trials, or that we will be able to receive regulatory approval for imetelstat 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 approved product, and our ability to generate revenue from product sales and achieve sustained 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. and the EU, we are developing imetelstat for the treatment of several myeloid hematologic malignancies. However, besides the relapsed/refractory MF indiction, which was being evaluated in the now discontinued Phase 3 IMpactMF trial, the development of imetelstat for the treatment of other myeloid hematologic malignancies is only in the early stages. 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:

- generate sufficient safety and efficacy data from the IMproveMF, IMpress and IMAGINE clinical trials, to support any application for regulatory approval, 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, if and 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 and for territories outside of the U.S. in compliance with applicable laws;
- recruit and retain sufficient qualified and experienced personnel to support the development and commercialization of RYTELO in potential other approved indications and other jurisdictions outside of the U.S. and the EU;
- achieve acceptance of RYTELO treatment by patients and the relevant medical communities;
- compete effectively with other approved treatments in lower-risk MDS;
- obtain appropriate coverage and reimbursement levels for the cost of 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 in the U.S., EU 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 and business prospects.

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 OS as a trial endpoint, which inherently requires prolonged periods of clinical observation and follow-up, including the need for a certain number of events, or deaths, to occur prior to the interim or final analysis in that trial of OS;
- use of trial endpoints, including patient-reported outcomes, that necessitate a comprehensive analysis of the resulting data to determine trial outcomes;
- obtaining and/or maintaining regulatory clearances in the U.S. or other jurisdictions 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 DMCs 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, fluctuations in interest rates, prospects of a recession, government shutdowns, changes in tariffs or other trade restrictions, 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, GCP, or other regulatory requirements, or not performing data collection or analyses in a timely or accurate manner.

As an example of the above, we recently announced our decision to discontinue our Phase 3 IMpactMF clinical trial evaluating imetelstat in patients with relapsed/refractory MF. The decision to discontinue the Phase 3 IMpactMF trial was based on a recommendation from an independent DMC following the DMC's conclusion that the trial was unlikely to meet the primary endpoint of overall survival.

In addition to the above, recent actions by the current administration in the U.S. to limit federal agency budgets and personnel have resulted in reductions in the FDA's budget and employees, which may lead to slower response times, longer review periods, delayed inspections or other disruptions that we cannot currently predict. Failures or delays with respect to any of the foregoing events and such disruptions in the timely review and processing of our regulatory submissions and inspections 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 may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could halt or limit its further commercialization, delay or prevent its regulatory approval in any other jurisdiction or indication, or cause us to delay or terminate our clinical trials.

While the FDA and the EC granted approval of RYTELO based on the data included in our NDA and MAA, respectively, including data from the Phase 3 IMerge trial, we cannot be certain whether the results as 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 U.S., 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, 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 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 and EC could withdraw or restrict regulatory approval for RYTELO in the U.S. and EU, respectively, for lower-risk MDS;
- additional information supporting the benefit-risk profile of RYTELO 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 the EC in the EU, 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 of 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, as well as any data disclosed as a result of an interim analysis, may not predict success in later clinical trials or the final analysis, and we cannot assure you that any ongoing or future clinical trials of imetelstat will lead to similar results and data that could potentially enable us to obtain any 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, as was the case in our Phase 3 IMpactMF clinical trial. 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. For example, notwithstanding the improvement in overall survival and potential disease-modifying activity observed in our Phase 2 IMbark clinical trial, we recently announced our decision to discontinue our Phase 3 IMpactMF clinical trial following an independent DMC’s conclusion that the trial was unlikely to meet the primary endpoint of overall survival. As a result, we will be unable to expand RYTELO’s indication to use to the relapsed/refractory MF indication and we will otherwise not receive any return on or recoup our investment in the relapsed/refractory MF indication.

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. 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 could have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, if needed, and our business and business prospects. In this regard, given the discontinuation of the Phase 3 IMpactMF trial, we will be unable to pursue any regulatory approvals for the relapsed/refractory MF indication and we will otherwise not receive any return on our recoup our investment in the relapsed/refractory MF indication, which has harmed our business and business prospects, including our prospects for sustained profitability in the near term.

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. 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, such as was the case with the DMC's conclusion based on its review of the available data in IMpactMF, which could halt the commercialization of RYTELO, hinder the potential success of IMproveMF, IMpress or IMAGINE, or cause us to abandon further development of imetelstat entirely.

Top-line or interim 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 OS. 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 whether 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, if needed, 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 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 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, as such delays may impede our ability to generate necessary supplemental clinical evidence, fulfill post-marketing commitments or requirements, or provide regulatory authorities with timely safety and efficacy data needed to support ongoing approval or future development.

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. 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, 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, active pharmaceutical ingredient, or API, and drug product and other supplies, and the cost of procuring the foregoing, any of which may be impacted by a number of factors, including the effects of macroeconomic or other global conditions, such as ongoing military conflicts, increased tariffs, renegotiation of existing international trade agreements, escalating trade tensions and other trade restrictions;
- 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.

In addition, the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the U.S., Israel and Iran have had and may continue to have further global economic consequences, including continued disruptions of the global supply chain and energy markets. For example, disruptions or perceived risks to energy supply routes, including shipping through key transit points, have resulted in increased fuel and energy prices and could continue

to do so for an extended period, which could disrupt our existing supply chain and increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results. See also the risk factor entitled "*Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our costs and negatively impact net revenues from sales of RYTELO.*"

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 RYTELO could be interrupted or 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 the API 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 and drug product, and we rely on a single source to supply the API for RYTELO. Failure by such third-party manufacturers to perform in a timely manner and in compliance with all regulatory requirements, or at all, or the termination of one of our supply agreements before we have retained and established an acceptable alternative supplier, could lead to delays or shortages in drug supply, perhaps substantially, that are necessary for our clinical activities and commercialization of RYTELO. For example, one of our third-party manufacturers received a warning letter from the FDA due to certain deficiencies in the manufacturer's process and facilities that were not in compliance with FDA requirements and regulations governing the manufacturing, processing, packing and holding of drug product. While not related to the production of RYTELO, if the warning letter is not timely remediated by the manufacturer, it could lead to delays or shortages in drug supply, or the inability to manufacture or ship drug supply necessary for non-clinical and clinical activities, and commercialization.

In addition, we plan to retain additional third-party manufacturers to provide redundancy in our supply chain; however, we may be unable to do so on a timely basis on terms that are acceptable to us, or at all. We expect to rely on third-party manufacturers to produce and deliver sufficient quantities of RYTELO and other materials to support our commercialization of RYTELO 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 providing the quantities of RYTELO required to meet commercial and clinical needs;
- capacity limitations and scheduling constraints experienced by third-party manufacturers due to scheduling, maintenance 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 our commercial needs or before we establish an acceptable alternative supplier;
- 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 the warning letter issued to 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, including manufacturing, warehousing, and distribution 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 or adding alternative manufacturers may be prolonged, difficult and expensive, 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 or alternative manufacturer on acceptable terms, or at all.

RISKS RELATED TO OUR OPERATING RESULTS AND FINANCIAL POSITION

We have a history of net losses 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, 2026, our accumulated deficit was approximately $1.9 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. Although we began commercializing RYTELO in June 2024, the commercial potential of and our ability to successfully commercialize RYTELO remains unproven, and our limited operating history as a commercial company makes our future operating results difficult to predict. We expect that our sales revenue may continue to vary from period to period as a result of the evolving effects of our commercialization strategy in lower-risk MDS and as our commercialization efforts otherwise progress. If we do not generate sufficient revenue from commercial sales of RYTELO, or if we experience unforeseen events or choose to make other investments in our business, we may continue to experience negative cash flow as we fund our operations and imetelstat clinical development activities and research programs, and continue with the commercialization of RYTELO, including as a result of our obligation to pay royalty payments under the Royalty Pharma Agreement and service our debt obligations. We will need to generate significant revenues to achieve consistent future profitability, and we may never achieve consistent future profitability. Even if we report a profit in future periods, 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 limited historical sales data of RYTELO in lower-risk MDS since its approval by the FDA in June 2024, 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 have in the past been below the expectations of securities analysts and investors, and sales of RYTELO have been and may in the future be below prior sequential or prior period sales, our own guidance and/or the expectations of securities analysts and investors. To the extent that we do not meet our guidance, our financial projections or estimates, or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. For example, following releases of earnings for both of the quarters and years ended December 31, 2025 and 2024, our stock price declined significantly both times. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their common stock. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the overall level of demand for RYTELO in its approved indication, including across the breadth of the eligible patient segments;
- 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 have taken or 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 royalty 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, 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 further decline, perhaps significantly.

Our financial projections and estimates are subject to significant risks, assumptions, and uncertainties, and our actual results may differ materially.

Our financial projections and estimates are subject to significant risks, assumptions, and uncertainties, and our actual results may differ materially. These projections and estimates include estimates of the total addressable market for RYTELO, assumptions regarding patient market share and duration of therapy for patients receiving RYTELO, as well as assumptions regarding our ability to meet demand and assumptions regarding our future costs of goods. These projections and estimates are subject to various factors beyond our control, including, for example, 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, increased costs in the supply chain, including as a result of increased tariffs, renegotiation of existing international trade agreements, escalating trade tensions and other trade restrictions, increased labor costs, changes in the regulatory environment, the impact of global health crises or macroeconomic or other global conditions, and changes in our senior management team. Our financial projections and estimates constitute forward-looking statements, are for illustrative purposes only and should not be relied upon as necessarily being indicative of future results. The assumptions and estimates underlying such financial projections and estimates are inherently uncertain and are subject to a wide variety of significant business, economic, competitive and other risks and uncertainties. Actual results may differ materially from the results contemplated by the financial projections. Our independent auditors have not studied, reviewed, compiled or performed any procedures with respect to the projections, and accordingly, they did not express an opinion or provide any other form of assurance with respect thereto. While all financial projections, estimates and targets are necessarily speculative, we believe that the preparation of financial projections involves increasingly higher levels of uncertainty the further out the projection, estimate or target extends from the date of preparation. Accordingly, there can be no assurance that the prospective results are indicative of our future performance or that actual results will not differ materially from those presented in the financial projections or estimates.

Our failure to obtain additional capital, if and 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, 2026, we had approximately $339.4 million in cash, cash equivalents, restricted cash and marketable securities. While we believe that, based on our current operating plans and assumptions, our existing cash, cash equivalents, and marketable securities, together with anticipated net revenues from sales of RYTELO, will be sufficient to fund our projected operating requirements for the foreseeable future, if we do not generate net revenues from commercial sales of RYTELO at the levels we anticipate, if we experience unforeseen events or choose to make other investments in our business, or our assumptions regarding our projected operating expenses are otherwise incorrect, we may require additional funding, which could include a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, which may not be possible. For example, changes in our operations, such as increased development, manufacturing and clinical trial expenses, or our undertaking of additional programs, business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses, may cause our operating expenses to increase, perhaps significantly, which could require us to raise additional funding. If adequate funds are not available to us when we need them, 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 receiving FDA approval of RYTELO in the U.S. in June 2024 and marketing authorization in the EU in March 2025, 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 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. or in the EU for lower-risk MDS or other potential jurisdictions or 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. For example, given our decision to discontinue our Phase 3 IMpactMF clinical trial, we will be unable to expand RYTELO's indication to use to the relapsed/refractory MF indication and we will otherwise not receive any return on or recoup our investment in the relapsed/refractory MF indication. 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 further changes in tariffs and other trade restrictions, renegotiation of existing international trade agreements or further escalation of trade tensions, inflation, fluctuations in interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts such as the ongoing Russia and Ukraine military conflict and the ongoing military conflict involving the U.S., Israel and Iran, 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 overall 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 RYTELO, including commercialization in the U.S. and 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;
- 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 commercialization arrangements with third parties, including for the commercialization and marketing of RYTELO in the EU and in any other regions outside of the U.S., if approved for commercialization in such other regions;

- expenses associated with the pending putative securities class action and shareholder derivative lawsuits and potential additional related lawsuits, as well as any other litigation;
- the extent and scope of our selling, general and administrative expenses, including expenses associated with pending and 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.

In the event we need to raise additional capital to fund our business, including pursuant to the 2026 Sales Agreement with TD Cowen (as defined below), capital lease transactions or other financing sources, such additional capital 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, fluctuations in interest rates, prospects of a recession, government shutdowns, further changes in tariffs and other trade restrictions, 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 equity and credit markets and are expected to have further global economic consequences. For example, the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the U.S., Israel and Iran have created extreme volatility and disruption in the equity and credit markets and have had and may continue to have further global economic consequences, including continued disruptions of the global supply chain and energy markets, which could continue to drive inflationary pressures and increase global recession risk. If the equity and credit markets deteriorate, 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, if needed, 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 2026 Sales Agreement, our stockholders may be diluted, and the terms may include liquidation or other preferences that could materially and adversely affect the rights of our existing stockholders. In addition, we have borrowed, and in the future may borrow, additional capital from institutional and commercial banking sources to fund 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 our 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 ROYALTY PAYMENT OBLIGATIONS

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, including by limiting our operating and financial flexibility.

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. We drew a Tranche A Loan in an aggregate principal amount of $125.0 million, or the Tranche

A Loan, on November 1, 2024. The Pharmakon Loan Agreement had also provided for two additional committed term loan tranches of up to $125.0 million in the aggregate: a Tranche B Loan of $75.0 million and a Tranche C Loan of $50.0 million. On January 5, 2026, we entered into an amendment to the Pharmakon Loan Agreement, or the Pharmakon Amendment, which extended the date for requesting the Tranche B Loan and Tranche C Loan, once available, from December 31, 2025 to July 30, 2026. Neither the Tranche B Loan nor the Tranche C Loan was drawn, and both are no longer available.

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, 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. 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. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of our 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.

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.

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 clinical development and our future growth, including 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.

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 provides 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 withdrawal event in respect to RYTELO;
- the occurrence of a material adverse change;
- 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. 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 certain restrictions on our operational flexibility.

The Royalty Pharma Agreement contains covenants that impose on us certain obligations with respect to royalty payments, diligence, reporting, indemnification and includes restrictions on intellectual property transfers and out-licenses, and certain other actions. For example, we are obligated to make royalty payments each quarter based on U.S. net sales of RYTELO at the royalty rates set forth in the Royalty Pharma Agreement, until the date when the aggregate Royalty Payments equal or exceed 1.65 times the Purchase Price, if this occurs by June 30, 2031. However, in the event we are unable to repay our obligation to Royalty Pharma before June 30, 2031, we will be required to make royalty payments equal to or exceeding 2.0 times the Purchase Price thereafter, which may negatively impact our business, financial condition and results of operations. 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 and relevant regulatory exclusivities 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, regulatory exclusivity, 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.

As a result of the Leahy-Smith America Invents Act, or 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.

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.

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 seven years in the U.S. and ten years in the EU 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.*"

In addition to orphan drug exclusivity, we expect to rely on other forms of regulatory exclusivity to protect our ability to commercialize RYTELO. In the U.S., New Chemical Entity, or NCE, exclusivity would entitle us to four years of data exclusivity and one year of market exclusivity, for a total of five years of NCE exclusivity from the date of approval of the first-approved indication. Our request for NCE exclusivity is still pending with FDA, and might not be awarded or could be awarded and then later withdrawn. In the EU, imetelstat is designated as a New Active Substance, or NAS. For this NAS, regulatory data protection entitles us to eight years of data exclusivity and two years of market exclusivity, for a total of ten years in parallel to orphan market exclusivity.

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. 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 USPTO, 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 one patent term extension of up to five years beyond its normal expiration. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. The length of the patent term extension is typically calculated as one half of the period between the effective date of an IND and the submission date of an NDA less any time the sponsor did not act with due diligence during the period, plus the time between the submission date of the NDA and the approval of that application less any time the sponsor did not act with due diligence during the period. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. We have applied to the USPTO for patent term extension of some of our patents. Currently, communication of patent term extension approval and the length of the granted extension period by the USPTO may occur up to several years from filing of an application for patent term extension. If the USPTO 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 USPTO and could differ from our calculation.

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, including:

- failure to adhere to the required filing deadlines;
- submission of a patent term extension application after the underlying patents have expired;
- failure to exercise due diligence during clinical development or regulatory review; or
- failure to otherwise meet the applicable criteria.

Moreover, the applicable authorities, including the FDA and the USPTO 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. 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 jurisdictions, 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 an SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation, upon receipt of marketing authorization, 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 an SPC may only be applied for once with respect to a product. 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 jurisdictions and territories including in 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. Accordingly, in Europe and such other similar jurisdictions and territories, we will not be able to seek patent term extension of our composition of matter patent, as it expired in September 2024. 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.

Additionally, 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 FDCA or an abbreviated new drug application, or ANDA, under Section 505(j) to obtain permission to sell a generic or follow-on 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 within 20 days after 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 after the NDA holder's receipt of the notice of Paragraph IV Certification, the expiration of the patent, certain settlements of the lawsuit, or the court reaches a decision in the infringement lawsuit in favor of the third-party. If the product has NCE exclusivity and the notice is given and the suit filed in the fifth year of exclusivity, the regulatory stay extends until 7.5 years after approval of the reference product. 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. However, 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 ANDA 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.

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.

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.

For instance, the U.S. has enacted and implemented wide-ranging patent reform legislation, including 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 USPTO, 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, regulations in other jurisdictions or 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.

In 2012, the European Patent Package, or EU Patent Package, was approved and included regulations with the goal of providing for the possibility of a single Unitary Patent covering the Contracting Member States, and a new Unified Patent Court, or UPC, for litigation of Unitary Patents and as well as European patents not opted out from the UPC system. The EU Patent Package entered into force fully in June 2023 and currently covers 18 EU Member States. As of June 1, 2023, all European patents, including those issued prior to June 1, 2023 in principle fall under the jurisdiction of the UPC and allow for the possibility of obtaining injunctions for the UPC Member States and are at risk of central revocation at the UPC in participating UPC Member States. Under the EU Patent Package, patent holders are permitted to "opt out" their European patents (but not their Unitary Patents) from 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 Member States, either obtain a Unitary Patent or validate the European patent nationally and optionally 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 European jurisdictions and/or the UPC is not fully 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 be issued with claims that cover RYTELO and our technologies.

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, inter partes review, or 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 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 stock.

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.

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 USPTO 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 delays 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 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 USPTO 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 third party observations, oppositions or invalidation trials against granted patents and/or patent applications. 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 other types of proceedings aimed at preventing us from commercializing RYTELO in the relevant jurisdiction(s);
- requiring us to obtain licenses to certain patents and patent applications;

- 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 registered trademark, RYTELO, for our product and failure to maintain such trademark could adversely affect our business.

We have a registered trademark, RYTELO, which is the commercial trade name for imetelstat, in a number of countries and regions, including in the U.S. and Europe. Our product trademark, RYTELO, is approved for use as name of the imetelstat medicinal product by the FDA and the EC. Opposition or cancellation proceedings, however, may be filed against our trademarks, and our trademarks may not survive such proceedings. If our U.S. trademark application which forms the basis for our international registration, or IR, for our commercial trade name is withdrawn or abandoned within the first five 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, and if we fail to satisfy the applicable regulatory requirements, we may not have enforceable trademark rights or registrations in such jurisdictions.

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.

In addition to patent and trademark protection, 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 entering into confidentiality agreements with our employees, consultants, collaborators and contractors. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device/pharmaceutical industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. 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.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us in countries where we do not have patent protection.

RISKS RELATED TO MANAGING OUR GROWTH AND OTHER BUSINESS OPERATIONS

Our strategic restructuring plan and the associated workforce reduction implemented in December 2025 may not result in anticipated savings and long-term value creation, could result in total costs and operating expenses that are greater than expected and could disrupt our business.

In connection with our strategic restructuring plan announced in December 2025, we implemented a workforce reduction, representing approximately one-third of our workforce prior to the reduction in headcount. We may not realize, in full or in part, the anticipated benefits on our 2026 operating expenses from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. We incurred approximately $17.0 million in restructuring and restructuring-related charges for the year ended December 31, 2025, primarily consisting of one-time employee severance payments, healthcare and related benefits, and other employee-related costs. The workforce reduction was substantially completed in the first quarter of 2026. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition could be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our workforce reduction may be disruptive to our operations, or could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our

business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future, if approved.

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. and in the EU 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.

Management transition creates uncertainties and could harm our business.

Over the past few years, we have experienced significant changes in executive leadership, and more could occur. For example, on August 6, 2025, we announced the appointment of Harout Semerjian as our President and Chief Executive Officer and a member of our board of directors, effective August 7, 2025. In addition, in October 2025, we appointed a new EVP, Chief Commercial Officer and in November 2024, we appointed a new EVP of Research and Development. Additionally, in connection with our strategic restructuring plan announced in December 2025, we implemented a workforce reduction, representing approximately one-third of our workforce prior to the reduction in headcount. Changes to company strategy, which can often times occur with the appointment of new executives and departure of prior executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management transition inherently causes some loss of institutional knowledge, which may have a disruptive impact on our ability to implement our strategy and could have a material adverse effect on our financial condition and our business and business prospects can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our results of operations and financial condition could suffer as a result.

Although we intend 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 continue to commercialize, market and sell RYTELO in the U.S. for certain patients with lower-risk MDS ourselves. At this time, we do not plan to commercialize RYTELO independently in the EU (or in any other regions outside of the U.S. where RYTELO may be approved for marketing in the future). Accordingly, we have engaged third parties for the commercialization and marketing of RYTELO in the EU, including a commercialization partner, to assist with critical activities, including reimbursement, Health Technology Assessment (HTA) submissions, market access and distribution, a contracted sales force and recording of sales, and we may otherwise seek additional collaborative 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. In addition, the terms of our Pharmakon Loan Agreement may limit our ability to enter into certain collaborative arrangements and any future debt agreements may continue or further limit our ability to enter into such agreements. 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, curtail or abandon the additional development of RYTELO;
- delay, curtail or abandon the commercialization of RYTELO in jurisdictions where it is approved;
- 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, including in connection with new Trump administration changes;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- challenges inherent in efficiently managing employees or consultants 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, military conflicts, 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.

We may experience additional risks related to operating outside of the U.S. that could materially adversely affect our business.

We conduct clinical trials outside of the U.S., and are pursuing paths to make RYTELO available to lower-risk MDS patients outside of the U.S., including in the EU, which may subject us to additional risks, including risks related to operating outside of the U.S., such as:

- we may experience unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- risks of potential noncompliance by us or by any third parties we engage 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.

For example, the current administration in the U.S. has called for substantial changes to foreign trade policy and has recently imposed significant increases in tariffs on international trade and the renegotiation of international trade agreements. We cannot predict what effects these and potential additional tariffs or renegotiation of existing international trade agreements, scope and nature of tariffs in the future, including as a result of litigation or other challenges, will have on our business, including in the context of escalating global trade and political tensions. However, such tariffs and other trade restrictions could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results. Likewise, the ongoing Russia-Ukraine military conflict and the ongoing military conflict involving the U.S., Israel and Iran have had and may continue to have further global economic consequences, including continued disruptions of the global supply chain and energy markets, which could disrupt our existing supply chain and increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results. See the risk factors titled, "*Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our costs and negatively impact net revenues from sales of RYTELO*" and "*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.*"

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 foreign jurisdictions and increase our costs. Ongoing legislative initiatives in the EU include the proposed SPC Regulation revision, the proposed Critical Medicines Act (for which a provisional political agreement was reached in May 2026), and the proposed Biotech Act. We cannot predict the impact of such changes and future regulation on our business or the results of our operations. These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our costs and negatively impact net revenues from sales of RYTELO.

There is inherent risk, based on the complex relationships among the U.S. and the countries in which we now conduct or may in the future conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. Compliance with applicable regulatory requirements regarding the export of products may create delays in the introduction of RYTELO in international markets, including in the EU, or, in some cases, prevent the export of RYTELO to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions. The U.S. and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods, including pharmaceutical and biological products. Notwithstanding the U.S. Supreme Court's recent decision invalidating tariffs imposed under the International Emergency Economic Powers Act, the magnitude and impact of tariffs are uncertain and are subject to a variety of factors, including the effective date and duration of additional tariffs, changes in the amount, scope and nature of tariffs in the future, including as a result of litigation or other challenges, any retaliatory tariffs that other countries may impose in response to tariffs levied by the United States and any mitigating actions that may become available.

The ongoing trade tensions between the U.S. and other jurisdictions have resulted in multiple rounds of tariffs and potential tariffs affecting pharmaceuticals and pharmaceutical ingredients, including finished drug products, manufacturing equipment, and related supplies. In April 2025, the U.S. government imposed a 10% baseline global tariff and in August 2025, the U.S. imposed higher "reciprocal" tariffs on numerous other territories, including EU Member States and South Korea. While the U.S. Supreme Court recently issued a ruling invalidating tariffs imposed by the Trump administration under the International Emergency Economic Powers Act, other tariffs imposed by the U.S. government remain in place, including the 10% global tariff imposed by the Trump administration under Section 122 of the Trade Act of 1974 following the U.S. Supreme Court decision. Moreover, the Bureau of Industry and Security, U.S. Department of Commerce, initiated and completed an investigation which determined certain pharmaceutical ingredients, including finished drug product, manufactured outside the U.S. pose a national security risk and should be subject to additional tariffs. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Although a significant portion of our supply chain for imetelstat is currently based in the U.S., the active pharmaceutical ingredient, or API, for imetelstat is manufactured in South Korea and our 47mg vial of RYTELO drug product is currently manufactured in Italy. In addition, in the future we may choose to utilize other contract manufacturers for different presentations of imetelstat and source materials for our supply chain from other international jurisdictions. Accordingly, such global or industry-specific tariffs, or the renegotiation of current international trade agreements, or other trade restrictions could result in additional costs on our business, including generally increasing our manufacturing costs, and may decrease our gross margins and increase our supply chain complexity. Moreover, other governments have imposed and may continue to impose retaliatory tariffs, trade restrictions or trade barriers impacting RYTELO, which could impose additional costs and complexity on our business, including with respect to our planned commercialization of RYTELO in select EU markets in 2026 or restrict our ability to sell RYTELO in the EU or in other international markets where we may obtain approval of RYTELO.

Further, the continued threats of new or increased tariffs, sanctions, trade restrictions and trade barriers as well as ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing international trade agreements, have had and may continue to have a generally disruptive impact on the global economy and, therefore, could negatively impact revenues from sales of RYTELO. Given the significant volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results is uncertain and could be significant in the future.

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.

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

Securities 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. On March 13 and March 14, 2025, we and certain of our current and former officers were named as defendants in two putative securities class action lawsuits filed in the United States District Court for the Northern District of California captioned *Dabestani v. Geron Corporation, et al.*, No. 3:25-cv-02507 and *Potvin v. Geron Corporation, et al.*, No. 3:25-cv-02563, respectively. Both lawsuits allege violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder in connection with allegedly false and misleading statements concerning the commercial potential of RYTELO. The plaintiffs allege, among other things, that we overstated RYTELO's commercial potential by making materially false and misleading statements and/or concealing material adverse facts concerning RYTELO's commercial potential, including the lack of awareness among healthcare providers for RYTELO, the burden of monitoring requirements in administering the drug, and the impacts of seasonality and existing competition on RYTELO's sales, and that our stock price dropped when we disclosed in our earnings call on February 26, 2025 that we had observed flat revenue trends over the prior few months. The plaintiffs seek damages and interest, and an award of reasonable costs, including attorneys' and experts' fees. On May 29, 2025, the Court consolidated the *Dabestani* and *Potvin* cases into one consolidated action captioned *In re Geron Corporation Securities Litigation*, or the Securities Class Action, and appointed lead plaintiffs and counsel for lead plaintiffs. On August 8, 2025, lead plaintiffs filed a consolidated amended complaint. On October 7, 2025, we filed our motion to dismiss the consolidated amended complaint. A hearing on the motion to dismiss was held on March 19, 2026, and on March 30, 2026, the Court entered an order granting our motion to dismiss without prejudice. On April 13, 2026, lead plaintiffs filed a second amended complaint. On May 18, 2026, we filed our motion to dismiss the second amended complaint. A hearing on the motion to dismiss was held on August 6, 2026, and on August 13, 2026, the Court entered an order denying our motion to dismiss.

In addition, on April 15, 2025 and April 16, 2025, three purported stockholders filed derivative complaints, each filed in the United States District Court for the Northern District of California, captioned *Bishop v. Scarlett, et al.*, No. 3:25-cv-03356, *Lerner v. Scarlett, et al.*, No. 3:25-cv-03401, and *Willis v. Scarlett, et al.*, No: 3:25-cv-03396, respectively. The three lawsuits name certain of our current and former directors and officers and allege that they breached their fiduciary duties and violated federal securities laws by issuing allegedly false and misleading statements concerning the commercial potential of RYTELO. The allegations in each of the three derivative complaints are substantially similar to the Securities Class Action. The plaintiff seeks damages and interest, and an award of reasonable costs, including attorneys' and experts' fees. The plaintiffs in *Bishop v. Scarlett, et al.* and *Willis v. Scarlett, et al.* also seek punitive damages. On May 16, 2025, the Court consolidated the three derivative complaints into one consolidated action captioned *In re Geron Corporation Derivative Litigation*, or the Consolidated Derivative Action. On June 17, 2025, the Court stayed the Consolidated Derivative Action pending a final ruling on the anticipated motion to dismiss in the Securities Class Action. On September 8, 2026, the Court extended the stay in the Consolidated Derivative Action pending the resolution of class certification in the Securities Class Action

On August 29, 2025, a purported stockholder made a demand on our board of directors to commence a civil action against certain of our current and former directors for breaching their fiduciary duties and violating the securities laws by issuing allegedly false and misleading statements concerning the commercial potential of RYTELO. On September 19, 2025, the board of directors responded that it would defer a final decision on the demand given the other pending derivative lawsuits and the Securities Class Action. On October 7, 2025, the purported stockholder filed a suit in the United States District Court for the Northern District of California, captioned *Hyung v. Bir, et al.*, No. 3:25-cv-08575 (the "*Hyung* Derivative Action"). The derivative lawsuit names certain of our current and former directors and officers. The allegations in the derivative lawsuit are substantially similar to the Securities Class Action and the Consolidated Derivative Action. The plaintiff seeks damages and an award of reasonable costs, including attorneys' and experts' fees. On June 17, 2025, the Court stayed the Hyung Derivative Action pending a final ruling on the motion to dismiss in the Securities Class Action. On September 8, 2026, the Court extended the stay in the *Hyung* Derivative Action pending resolution of class certification in the Securities Class Action. Additionally, on January 23 and February 19, 2026, respectively, two additional purported stockholders each made a similar demand on our board of directors. On March 25, 2026, our board of directors similarly responded that it would defer a final decision on the demands given the other pending derivative lawsuits and the Securities Class Action. On September 8, 2026, one of the purported stockholders filed a suit in the United States District Court for the Northern District of California, captioned *Russo v. Scarlett, et al.*, No. 3:26-cv-09979 (the "*Russo* Derivative Action"). The derivative lawsuit names certain of our current and former directors and officers. The allegations in the *Russo* Derivative Action are substantially similar to the Securities Class Action, the Consolidated Derivative Action, and the *Hyung* Derivative Action. On September 24, 2026, the plaintiffs in the *Hyung* Derivative Action and *Russo* Derivative Action filed a joint stipulation to consolidate the two derivative actions and stay the consolidated action pending the resolution of class certification in the Securities Class Action.

On September 29, 2026, a purported stockholder filed a derivative complaint in the United States District Court for the District of New Jersey, captioned *Weinstein v. Scarlett, et al.*, No. 2:26-cv-12796 (the "*Weinstein* Derivative Action"). The lawsuit names certain of our current and former directors and officers and alleges that they breached their fiduciary duties and violated federal securities laws by issuing allegedly false and misleading statements concerning the commercial potential of RYTELO. The allegations are substantially similar to the Securities Class Action, the Consolidated Derivative Action, the *Hyung* Derivative Action, and the *Russo* Derivative Action. The plaintiff seeks damages and an award of reasonable costs, including attorneys' and experts' fees. On October 19, 2026, the Court entered an order staying the *Weinstein* Derivative Action pending the resolution of class certification in the Securities Class Action.

We have also been subject to securities class action lawsuits in the past. In 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed, and we settled the other two lawsuits and a final judgment 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 were dismissed with prejudice.

It is possible that additional lawsuits might be filed, or allegations might be received from stockholders, with respect to these same matters as alleged in the pending lawsuits or other matters and also naming us and/or our officers and directors as defendants. Such lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources and may incur substantial legal fees and costs in the defense of the pending lawsuits and any related or additional lawsuits, and we may not prevail. Monitoring, initiating and defending against legal actions is also 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. Given the early stage of these lawsuits and the inherent uncertainty of litigation, we cannot predict how long it may take to resolve the pending lawsuits or the amount of costs we may incur, or the potential outcome or the possible amount of any damages we may be required to pay. A decision adverse to our interests in the pending lawsuits or in similar or related litigation, could result in the payment of substantial damages or settlements, or possibly fines, and, although we maintain liability insurance, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage. If any judgment or settlement against us and costs or expenses associated with the pending litigation exceed our insurance coverage or insurance coverage is denied, we may be forced to bear some or all of these costs and expenses directly, which could be substantial 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 commercialization 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 U.S., 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 with whom we work, 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 with whom we work collect, receive, store, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose, or otherwise process 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, including disaster recovery and business continuity procedures, 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 the initial cyber security assessments that we conduct for critical service providers and contractual duties and obligations, we have limited ability to control or monitor third parties' safeguards and actions related to such matters. 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 of loss or theft of company devices as well as 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.

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 with whom we work, 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, "hacktivists," organized criminal threats actors, or internal bad actors, personnel, 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 sensitive 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, or remediate and recover compromised systems in a timely manner.

Such incidents or threats may result in unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive information. 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 from cybersecurity threats 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 cybersecurity threats or 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 with whom we work experience or are perceived to have experienced a breach, we may experience material 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, or we may choose to voluntarily notify relevant stakeholders, or take other actions, such as providing credit monitoring and identity theft protection services, and we have done so in the past. 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. While we do maintain cyber liability insurance, our insurance coverages may not be sufficient in type or amount to cover us against any such losses, claims, or liabilities related to security breaches, cyber-attacks, cyber intrusion, or other related breaches or disruptions.

We and third parties with whom we work 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 (or the third parties with whom we work) 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 or conflict among jurisdictions. The global data protection landscape is

rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business; affect us or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal data; necessitate the acceptance of more onerous obligations in our contracts; result in liability; or impose additional costs on us. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or the EU GDPR, and the United Kingdom's GDPR, or the UK GDPR (collectively, the "GDPR"), impose strict requirements on the processing of personal data. For example, under GDPR, government regulators may impose temporary or definitive bans on data processing, fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from the EEA, the UK 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 U.S. 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, 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. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups, and 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 data 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.

In Europe, the Network and Information Security Directive ("NIS2") regulates resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2 may lead up to administrative fines of a maximum of 10 million Euros or up to 2% of the total worldwide revenue of the preceding fiscal year.

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 are contractually subject to industry standards adopted by industry groups and we are, and may become in the future, subject to such obligations. 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. We are also 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, white papers, and other statements, such as statements relating to compliance with certain certifications or self-regulatory principles concerning data privacy and security. Regulators in the U.S. are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading 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 with whom we work fail to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties with whom we work 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.

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, 2016 and September 30, 2026, our stock has traded as high as $6.38 per share and as low as $0.89 per share. Between October 1, 2025 and September 30, 2026, the price has ranged between a high of $1.95 per share and a low of $1.07 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 and market opportunity for future sales of RYTELO;
- 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 research and development of imetelstat, or adverse efficacy or safety results of, further delays in the commencement, enrollment or conduct of, discontinuation of, or further modifications or refinements to any current or potential future clinical trials, or our inability to successfully continue the development of imetelstat;
- our ability to obtain additional capital, if and when needed, to further advance our development program;
- changes in laws or regulations applicable to RYTELO, including laws or regulations concerning the commercialization of RYTELO or clinical trial requirements for approval or other regulatory developments related to RYTELO;
- 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 and maintain regulatory exclusivity for RYTELO and 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;
- 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,
- 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 general 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;
- actual or expected sales of common stock by stockholders;
- announcements of or developments concerning pending and potential future litigation;
- actions instituted by activist shareholders or others;
- other events or factors that are beyond our control; and
- the occurrence of any other risks and uncertainties discussed under the heading "Risk Factors."

In addition, as further discussed in the Risk Factor above titled "*We and certain of our current and former officers and directors have been named as defendants in securities class action lawsuits and derivative lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome*," we and certain of our current and former officers and directors have been named as defendants in securities class action and derivative lawsuits. Such lawsuits have often been instituted against companies, including us, whose securities have experienced periods of volatility in market price. The pending lawsuits and any lawsuits brought against us in the future could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on our financial condition and business operations and lead to increased volatility in our stock price and a decrease in the value of our stockholders' investment in our securities.

Our failure to maintain compliance with the continued listing requirements of the Nasdaq Global Select Market may result in our common stock being delisted from the Nasdaq Global Select Market, which could negatively impact the price of our common stock, liquidity, our ability to access the capital markets and our stockholders' ability to sell their shares.

Our common stock is currently listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol "GERN." The listing standards of Nasdaq provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of $1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. Historically, our stock price has been extremely volatile and recently, our stock has traded as low as $0.84 per share through October 30, 2026. Following our recent announcement about the decision to discontinue the Phase 3 IMpactMF trial, the market price of our common stock has experienced a severe decline and closed below $1.00 per share. While our common stock is currently listed on Nasdaq, we can give no assurance that we will be able to maintain compliance with the continued listing requirements for Nasdaq. If we fail to maintain compliance with any such continued listing requirement, there can also be no assurance that we will be able to regain compliance with any such continued listing requirement in the future or that our common stock will not be delisted in the future. If Nasdaq delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

- limited availability of market quotations for our securities;
- a determination that the common stock is a "penny stock", which would require brokers trading in the common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock;
- a limited amount of analyst coverage, if any; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Delisting from Nasdaq could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

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 imposed 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 restrict our ability to pay dividends and any future debt agreements may continue to or further restrict our ability to pay 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, CROs, 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 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. As described further below, we identified a material weakness in our internal control over financial reporting that existed as of September 30, 2025, which we remediated as of December 31, 2025. However, in the future, any testing by us conducted in connection with Section 404, or any testing by our independent registered public accounting firm, may reveal additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

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 review our internal control over financial reporting, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met.

Therefore, we cannot assure you that additional 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 continue to 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.
We have previously identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. We previously identified a material weakness in internal control related to the design and operation of certain Information Technology General Controls, or ITGCs, related to user access and program change management for our Enterprise Resource Planning and payment processing systems. Consequently, IT application controls and IT dependent manual business process controls that rely upon information from these systems, were also deemed ineffective. Although the material weakness identified did not result in any material misstatements in our consolidated financial statements for the periods presented in this Report and there were otherwise no changes to our previously issued financial statements, our management concluded that these control deficiencies existed as of September 30, 2025 and constitute a material weakness. Accordingly, our internal control over financial reporting and our disclosure controls and procedures were not effective as of September 30, 2025. While we subsequently remediated this material weakness as of December 31, 2025, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our consolidated financial statements that could result in a restatement of our previously issued financial statements and could cause us to fail to meet our periodic reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock

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

New income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign sales and earnings. Any new taxes could

adversely affect our domestic and international business operations and our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the 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. In addition, the U.S. government recently enacted legislation commonly referred to as the One Big Beautiful Bill Act, that (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years. Changes in tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future United States tax expense.

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, federal net operating losses incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal net operating losses in a taxable year is limited to 80% of taxable income in such year. 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 have occurred in the past, and future ownership changes, some of which may be outside our control, could occur in the future, as a result of shifts in our stock ownership. 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. For example, in June 2024, California enacted legislation that, with certain exceptions, suspends the use of California net operating losses to offset California income and limits the use of California business tax credits to offset California taxes, for taxable years beginning after 2023 and before 2027.

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

During the quarterly period covered by this report, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

ITEM 6. EXHIBITS

		Incorporation by Reference			
Exhibit Number	**Description**	**Exhibit Number**	**Filing**	**Filing Date**	**File No.**
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.				
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.				
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.**				
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.**				
101	The following materials from the Registrant's September 30, 2026 Quarterly Report on Form 10-Q for the quarter ended September 30, 2026 formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Condensed Consolidated Balance Sheets as of September 30, 2026 and December 31, 2025, (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2026 and 2025, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2026 and 2025, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2026 and 2025 and (v) Notes to Condensed Consolidated Financial Statements.				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

\+ Filed herewith.

** 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 Report), 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 4, 2026

By: /s/ MICHELLE ROBERTSON

MICHELLE ROBERTSON

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

EXHIBIT 31.1

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

I, Harout Semerjian, 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 4, 2026

/s/ HAROUT SEMERJIAN

HAROUT SEMERJIAN

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 4, 2026

/s/ MICHELLE ROBERTSON

MICHELLE ROBERTSON

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

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, 2026 (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 4, 2026

/s/ HAROUT SEMERJIAN

HAROUT SEMERJIAN

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, 2026 (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 4, 2026

/s/ MICHELLE ROBERTSON

MICHELLE ROBERTSON

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