



Geron Corporation Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Business Highlights

February 26, 2025

Achieved \$47.5 million in RYTELO™ (imetelstat) net product revenue in Q4 2024 and \$76.5 million since commercial launch at the end of June 2024, following FDA approval

Expect to reach profitability without additional financing if current internal sales and operating expenses expectations are met

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a commercial-stage biopharmaceutical company aiming to change lives by changing the course of blood cancer, today reported financial results for the fourth quarter and full year 2024 and recent business highlights.

"2024 was a terrific year for Geron and for RYTELO, our first-in-class telomerase inhibitor, which we believe represents a highly differentiated treatment with blockbuster potential in the high unmet need, lower-risk MDS patient population. We also continued to progress our development efforts in relapsed/refractory myelofibrosis, which could potentially double our commercial opportunity if our IMpactMF Phase 3 trial reads out positively and we are approved in this indication. From a financial perspective, we ended the year with a strong cash position, and Q3 and Q4 revenues exceeded our expectations. Heading into 2025, we are excited by the strategic and leadership changes we put in place early in the launch, which we believe will position us to increase our revenue growth trajectory and more fully capture the significant commercial opportunity over the next several quarters," said John A. Scarlett, M.D., Geron's Chairman and Chief Executive Officer.

Recent Business Highlights

- Continued execution on U.S. commercial launch, with net product revenue for RYTELO (imetelstat) of \$47.5 million in the fourth quarter of 2024 and \$76.5 million since launch at the end of June 2024, following approval by the U.S. Food and Drug Administration (FDA).
- Received positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) in December 2024 recommending approval of RYTELO for the treatment of certain adult patients with transfusion-dependent anemia due to lower-risk MDS. Subject to receiving regulatory approval, which is expected in the first half of 2025, Geron is preparing to commercialize RYTELO in select EU countries in 2026.
- Achieved approximately 80% enrollment in the Phase 3 IMpactMF trial evaluating imetelstat in patients with relapsed/refractory myelofibrosis (R/R MF). Based on our current planning assumptions for enrollment and event (death) rates in the trial, we now expect the interim analysis for overall survival may occur in the second half of 2026 (when approximately 35% of planned enrolled patients have died) and the final analysis may occur in the second half of 2028 (when approximately 50% of planned enrolled patients have died).
- Presented new data at the 66th American Society for Hematology (ASH) Annual Meeting in December 2024, including analyses of IMerge Phase 3 data suggesting clinical activity of imetelstat in patients with lower-risk MDS regardless of type or number of prior therapies and Phase 1 findings from IMproveMF suggesting tolerability of imetelstat in combination with ruxolitinib as a potential frontline therapy in patients with MF.

Fourth Quarter 2024 Financial Results

As of December 31, 2024, we had approximately \$502.9 million in cash, cash equivalents, restricted cash and marketable securities.

Net Loss

For the three and twelve months ended December 31, 2024, the Company reported a net loss of \$25.4 million, or \$0.04 per share, and \$174.6 million, or \$0.27 per share, respectively, compared to \$52.0 million, or \$0.09 per share, and \$184.1 million, or \$0.32 per share, respectively, for the three and twelve months ended December 31, 2023.

Revenues

Total product revenue, net for the three and twelve months ended December 31, 2024, was \$47.5 million and \$76.5 million, respectively. There was no product revenue in the prior year periods, given that RYTELO was approved by the FDA in June 2024.

Total net revenue for the three and twelve months ended December 31, 2024, was \$47.5 million and \$77.0 million, respectively, compared to \$23,000 and \$237,000 for the same periods in 2023. Total net revenue includes license fees and royalties in addition to any product revenue, net. The increase in revenue is due to product revenue from U.S. sales of RYTELO, which was approved by the FDA in June 2024.

Operating Expenses

Total operating expenses for the three and twelve months ended December 31, 2024, were \$67.6 million and \$250.7 million, respectively, compared to \$54.3 million and \$194.2 million for the same periods in 2023.

Cost of goods sold was approximately \$783,000 and \$1.3 million for the three and twelve months ended December 31, 2024, respectively, which consisted of costs to manufacture and distribute RYTELO, compared to nil in the prior year periods.

Research and development expenses for the three and twelve months ended December 31, 2024, were \$23.4 million and \$103.7 million, respectively, and \$32.9 million and \$125.0 million, for the same periods in 2023. The decrease is primarily due to manufacturing and quality costs that were capitalized in the current period due to FDA approval of RYTELO, compared to being expensed in the prior period. The decrease is partially offset by an increase in labor costs due to higher headcount and incentive and stock-based compensation expense recognized due to the vesting of performance-based stock options upon FDA approval of RYTELO.

Selling, general and administrative expenses for the three and twelve months ended December 31, 2024, were \$43.4 million, and \$145.7 million, respectively, and \$21.4 million and \$69.1 million for the same periods in 2023. The increase in general and administrative expenses in 2024 as compared to 2023 primarily reflects higher personnel-related expenses related to increased headcount to support commercial launch of RYTELO in the U.S. and stock-based compensation expense recognized upon FDA approval of RYTELO due to the vesting of performance-based stock options.

Interest income was \$5.2 million and \$19.6 million for the three and twelve months ended December 31, 2024, respectively, compared to \$4.6 million and \$18.2 million for the same periods in 2023. The increase in interest income in 2024 compared to 2023 primarily reflects a larger marketable securities portfolio due to the receipt of net cash proceeds from the underwritten offering completed in March 2024, as well as higher yields from marketable securities purchases. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Interest expense was \$8.7 million and \$18.5 million for the three and twelve months ended December 31, 2024, respectively, compared to \$2.3 million and \$8.3 million for the same periods in 2023. The increase in interest expense primarily reflects \$5.3 million in non-cash interest expense related to our agreement with Royalty Pharma and an increased principal debt balance under the Pharmakon loan agreement and the Hercules loan agreement which was repaid in the fourth quarter of 2024. Interest expense reflects interest owed under the loan agreements, interest expense recognized under the Royalty Pharma agreement, as well as amortization of associated debt issuance costs and debt discounts using the effective interest method and accrual for an end of term charge.

Loss on extinguishment of debt

We recorded a loss on the extinguishment of debt of \$1.7 million for the twelve months ended December 31, 2024. The loss is related to the settlement of debt outstanding under the terminated Hercules loan agreement.

2025 Financial Guidance

For fiscal year 2025, we expect total operating expenses to be in the range of approximately \$270 million to \$285 million, which includes non-cash items such as stock-based compensation expense, amortization of debt discounts and issuance costs, and depreciation and amortization.

We expect to reach profitability without additional financing if our current internal sales and operating expense expectations are met. 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 U.S. sales of RYTELO, will be sufficient to fund our projected operating requirements for the foreseeable future.

Conference Call

Geron will host a conference call at 8:00 a.m. ET on Wednesday, February 26, 2024, to discuss business updates and fourth quarter and full year 2024 financial results.

A live webcast of the conference call and related presentation will be available on the Company's website at www.geron.com/investors/events. An archive of the webcast will be available on the Company's website for 30 days.

Participants may access the webcast by registering online using the following link, <https://events.q4inc.com/attendee/332361629>

About RYTELO (imetelstat)

RYTELO (imetelstat) is an FDA-approved oligonucleotide telomerase inhibitor for the treatment of adult patients with low-to-intermediate-1 risk myelodysplastic syndromes (LR-MDS) with transfusion-dependent 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 (ESAs). It is indicated to be administered as an intravenous infusion over two hours every four weeks.

A marketing authorization application for RYTELO is under review by the European Commission as a monotherapy treatment for

adult patients with transfusion-dependent anemia due to very low, low or intermediate risk myelodysplastic syndromes (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.

RYTELO is a first-in-class treatment that works by inhibiting telomerase enzymatic activity. Telomeres are protective caps at the end of chromosomes that naturally shorten each time a cell divides. In LR-MDS, abnormal bone marrow cells often express the enzyme telomerase, which rebuilds those telomeres, allowing for uncontrolled cell division. Developed and exclusively owned by Geron, RYTELO is the first and only telomerase inhibitor approved by the U.S. Food and Drug Administration.

About Geron

Geron is a commercial-stage biopharmaceutical company aiming to change lives by changing the course of blood cancer. Our first-in-class telomerase inhibitor RYTELO™ (imetelstat) is approved in the United States for the treatment of certain adult patients with lower-risk myelodysplastic syndromes (LR-MDS) with transfusion dependent anemia. We are also conducting a pivotal Phase 3 clinical trial of imetelstat in JAK-inhibitor relapsed/refractory myelofibrosis (R/R MF), as well as studies in other myeloid hematologic malignancies. Inhibiting telomerase activity, which is increased in malignant stem and progenitor cells in the bone marrow, aims to reduce proliferation and induce death of malignant cells. To learn more, visit www.geron.com or follow us on [LinkedIn](#).

About ImpactMF Phase 3

ImpactMF is an open label, randomized, controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 320 patients with intermediate-2 or high-risk myelofibrosis (MF) who are relapsed after or refractory to prior treatment with a JAK inhibitor, also referred to as relapsed/refractory MF. Patients will be randomized to receive either imetelstat or best available therapy. The primary endpoint is overall survival (OS). Key secondary endpoints include symptom response, spleen response, progression free survival, complete remission, partial remission, clinical improvement, duration of response, safety, pharmacokinetics, and patient reported outcomes. ImpactMF is currently enrolling patients. For further information about ImpactMF, including enrollment criteria, locations and current status, visit <https://www.clinicaltrials.gov/study/NCT04576156>.

IMPORTANT SAFETY INFORMATION ABOUT RYTELO

WARNINGS AND PRECAUTIONS

Thrombocytopenia

RYTELO can cause thrombocytopenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased platelets occurred in 65% of patients with MDS treated with RYTELO.

Monitor patients with thrombocytopenia for bleeding. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer platelet transfusions as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Neutropenia

RYTELO can cause neutropenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased neutrophils occurred in 72% of patients with MDS treated with RYTELO.

Monitor patients with Grade 3 or 4 neutropenia for infections, including sepsis. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Infusion-Related Reactions

RYTELO can cause infusion-related reactions. In the clinical trial, infusion-related reactions occurred in 8% of patients with MDS treated with RYTELO; Grade 3 or 4 infusion-related reactions occurred in 1.7%, including hypertensive crisis (0.8%). The most common infusion-related reaction was headache (4.2%). Infusion-related reactions usually occur during or shortly after the end of the infusion.

Premedicate patients at least 30 minutes prior to infusion with diphenhydramine and hydrocortisone as recommended and monitor patients for one hour following the infusion as recommended. Manage symptoms of infusion-related reactions with supportive care and infusion interruptions, decrease infusion rate, or permanently discontinue as recommended.

Embryo-Fetal Toxicity

RYTELO can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RYTELO and for 1 week after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 32% of patients who received RYTELO. Serious adverse reactions in >2% of patients included sepsis (4.2%) and fracture (3.4%), cardiac failure (2.5%), and hemorrhage (2.5%). Fatal adverse reactions occurred in 0.8% of patients who received RYTELO, including sepsis (0.8%).

Most common adverse reactions ($\geq 10\%$ with a difference between arms of $>5\%$ compared to placebo), including laboratory abnormalities, were decreased platelets, decreased white blood cells, decreased neutrophils, increased AST, increased alkaline phosphatase, increased ALT, fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache.

Please see RYTELO (imeteostat) full Prescribing Information, including Medication Guide, available at https://pi.geron.com/products/US/pi/rytelo_pi.pdf.

Use of Forward-Looking Statements

Except for the historical information contained herein, this press release contains forward-looking statements made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such statements, include, without limitation, those regarding: (i) the Company’s belief that RYTELO represents a highly differentiated treatment with blockbuster potential in the high unmet need, lower-risk MDS patient population; (ii) the Company’s belief that if the Phase 3 IMPactMF trial in R/R MF reads out positively and imeteostat is approved in this indication, it could potentially double the Company’s commercial opportunity; (iii) the Company’s belief that the strategic and leadership changes it put in place early in the launch will position it to increase its revenue growth trajectory and more fully capture the significant commercial opportunity over the next several quarters; (iv) the Company’s expectations about the U.S. launch of RYTELO, its execution as a commercial company, the high unmet need in lower-risk MDS, and the compelling value proposition of RYTELO for hematologists and patients; (v) the Company’s expectations for the timing and completion of regulatory review and approval of RYTELO in the EU and, subject to regulatory approval, the Company’s plans to commercialize RYTELO in select EU markets commencing in 2026; (vi) that the interim analysis of IMPactMF is expected in the second half of 2026 and the final analysis is expected in the second half of 2028; (vii) the Company’s projections for total operating expenses for fiscal 2025; (viii) the Company’s expectations that it will reach profitability without additional financing if its current internal sales and operating expense expectations are met; (ix) the Company’s projections and expectations regarding the sufficiency of its existing financial resources, together with U.S. sales of RYTELO, to fund its projected operating requirements for the foreseeable future; (x) that inhibiting telomerase activity aims to potentially reduce proliferation and induce death of malignant cells; (xi) that IMPactMF has registrational intent; and (xii) other statements that are not historical facts, constitute forward-looking statements. These forward-looking statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. These risks and uncertainties, include, without limitation, risks and uncertainties related to: (a) whether Geron is successful in commercializing RYTELO (imeteostat) for the treatment of certain patients with lower-risk MDS with transfusion dependent anemia; (b) whether the European Commission, or EC, approves RYTELO for the treatment of patients with lower-risk MDS with transfusion dependent anemia and whether the FDA and EC will approve imeteostat for other indications on the timelines expected, or at all; (c) Geron’s plans to commercialize RYTELO in the European Union, or EU; (d) whether Geron overcomes potential delays and other adverse impacts caused by enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to have the financial resources for and meet expected timelines and planned milestones; (e) whether regulatory authorities permit the further development of imeteostat on a timely basis, or at all, without any clinical holds; (f) whether any future safety or efficacy results of RYTELO treatment cause its benefit-risk profile to become unacceptable; (g) whether imeteostat actually demonstrates disease-modifying activity in patients and the ability to target the malignant stem and progenitor cells of the underlying disease; (h) whether Geron meets its post-marketing requirements and commitments for RYTELO; (i) whether there are failures or delays in manufacturing or supplying sufficient quantities of RYTELO (imeteostat) or other clinical trial materials that impact commercialization of RYTELO or the continuation of the IMPactMF trial; (j) that the projected timing for the interim and final analyses of the IMPactMF trial may vary depending on actual enrollment and death rates in the trial; and (k) whether Geron stays in compliance with and satisfies its obligations under its debt and royalty financing agreements. Additional information on the above risks and uncertainties and additional risks, uncertainties and factors that could cause actual results to differ materially from those in the forward-looking statements are contained in Geron’s filings and periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors” and elsewhere in such filings and reports, including Geron’s quarterly report on Form 10-Q for the quarter ended September 30, 2024, and subsequent filings and reports by Geron. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Geron disclaims any obligation to update these forward-looking statements to reflect future information, events, or circumstances.

Financial tables follow.

GERON CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
<i>(In thousands, except share and per share data)</i>				

	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	\$ 47,507	\$ —	\$ 76,495	\$ —
Royalties	31	23	499	237
	<u>47,538</u>	<u>23</u>	<u>76,994</u>	<u>237</u>
Operating expenses:				
Cost of goods sold	783	—	1,256	—
Research and development	23,433	32,911	103,738	125,046
Selling, general and administrative	43,371	21,401	145,732	69,135
Total operating expenses	<u>67,587</u>	<u>54,312</u>	<u>250,726</u>	<u>194,181</u>
Loss from operations	(20,049)	(54,289)	(173,732)	(193,944)
Interest income	5,159	4,595	19,607	18,152
Interest expense	(8,707)	(2,321)	(18,504)	(8,312)
Other income and (expense), net	(48)	41	(236)	(23)
Loss on extinguishment of debt	(1,707)	—	(1,707)	—
Net loss	<u>\$ (25,352)</u>	<u>\$ (51,974)</u>	<u>\$ (174,572)</u>	<u>\$ (184,127)</u>
Basic and diluted net loss per share:				
Net loss per share	<u>\$ (0.04)</u>	<u>\$ (0.09)</u>	<u>\$ (0.27)</u>	<u>\$ (0.32)</u>
Shares used in computing net loss per share	<u>664,199,550</u>	<u>594,977,503</u>	<u>646,033,247</u>	<u>570,645,405</u>

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	December 31, 2024	December 31, 2023
	(Unaudited)	(Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	\$ 80,876	\$ 71,138
Current marketable securities	327,550	263,676
Other current assets	82,566	6,534
Total current assets	<u>490,992</u>	<u>341,348</u>
Noncurrent marketable securities	94,519	43,298
Property and equipment, net	1,310	1,177
Deposits and other assets	6,960	8,253
	<u>\$ 593,781</u>	<u>\$ 394,076</u>
Current liabilities	\$ 88,298	\$ 108,070
Noncurrent liabilities	225,163	38,057
Stockholders' equity	280,320	247,949
	<u>\$ 593,781</u>	<u>\$ 394,076</u>

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2024.

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Source: Geron Corporation