Geron Corporation Reports First Quarter 2025 Financial Results and Recent Business Highlights

May 7, 2025

Reported $39.4 million in RYTELO® (imetelstat) net product revenue in Q1 2025; revenue impacted by inventory dynamics, with Q1 demand relatively flat

Granted marketing authorization of RYTELO by the European Commission (EC); planning for commercial launch in select EU countries 2026

Reached approximately 85% enrollment in the Phase 3 IMpactMF clinical trial for treatment of relapsed/refractory myelofibrosis; interim analysis remains expected in 2H 2026

Company to host conference call and webcast today, May 7 at 8:00 a.m. ET

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 first quarter of 2025 and recent business highlights.

"We are confident in the long-term potential of RYTELO as an important therapeutic for eligible patients with lower-risk-MDS and are sharply focused on maximizing the U.S. commercial opportunity," said Dawn Carter Bir, Interim President and Chief Executive Officer of Geron. "We have received positive feedback from clinicians who have utilized RYTELO, supporting its strong therapeutic profile. We've identified specific opportunities and are making focused investments that we believe will strengthen the U.S. commercial trajectory. We expect our increased commercial investments to bolster uptake across a broader group of prescribers and drive long-term demand. We are also expanding our medical affairs efforts to support increased awareness and education. Looking ahead, our Phase 3 IMpactMF trial evaluating overall survival with imetelstat in patients with JAKi relapsed/refractory myelofibrosis (R/R MF), which we believe represents a tremendous expansion opportunity, is progressing well and the event-driven interim analysis is still expected in the second half of 2026."

Recent Business Highlights

- Continued first year of U.S. commercialization of RYTELO, with net product revenue of $39.4 million in the first quarter of 2025. Demand for RYTELO in the 13-week period through the week ending March 28 increased 1% compared to the prior 13 weeks.
- Received marketing authorization for RYTELO from the European Commission (EC) as a monotherapy for the treatment of adult patients with transfusion-dependent (TD) anemia due to very low, low, or intermediate risk myelodysplastic syndromes (lower-risk MDS or LR-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 (ESAs).
    - Launch planning is underway and Geron expects to commercialize RYTELO in select EU countries commencing in 2026.
- Reached 85% enrollment in Phase 3 IMpactMF clinical trial evaluating imetelstat in patients with JAKi R/R MF. We continue to expect an interim analysis readout for overall survival in the second half of 2026 (when approximately 35% of patient events have occurred), and final analysis in the second half of 2028 (when approximately 50% of patient events have occurred).
    - The Company believes there is a significant market opportunity for imetelstat to treat JAKi R/R MF patients based on its unique mechanism of action, strong clinical data to date, and the substantial size of the addressable patient population, if the trial is positive and imetelstat is approved in this indication.
    - Clinical data from the Phase 2 study showed a strong signal regarding prolonged survival and resolution of bone marrow fibrosis in patients treated with imetelstat, suggesting the potential for disease modification.

First Quarter 2025 Financial Results

As of March 31, 2025, Geron had approximately $457.5 million in cash, cash equivalents, restricted cash and marketable securities, compared to $502.9 million as of December 31, 2024.

Net Loss

For the three months ended March 31, 2025, the Company reported a net loss of $19.8 million, or $0.03 per share, compared to $55.4 million, or $0.09 per share, for the three months ended March 31, 2024.

Revenues

Total product revenue, net for the three months ended March 31, 2025, was $39.4 million. There was no product revenue in the prior year period, as RYTELO was approved by the FDA in June 2024. The decline in net product revenue compared to the three months ended December 31, 2024, which was $47.5 million, was primarily due to inventory drawdown among RYTELO distributors from the fourth quarter of 2024 into the first quarter of 2025.

Total net revenue for the three months ended March 31, 2025, was $39.6 million, compared to $0.3 million for the same period in 2024. 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 months ended March 31, 2025, were $56.3 million, compared to $56.4 million for the same period in 2024.

Cost of goods sold was approximately $1.2 million for the three months ended March 31, 2025, which consisted of costs to manufacture and distribute RYTELO, compared to nil in the prior year period.

Research and development expenses for the three months ended March 31, 2025, were $15.1 million, compared to $29.4 million for the same period in 2024. The decrease was primarily due to the wind down of clinical trial costs associated with a decrease of activity in our Phase 3 IMerge MDS study after FDA approval of RYTELO in 2024, as well as manufacturing and quality costs that were capitalized in the current period now that RYTELO is approved, versus being expensed in the prior year period.

Selling, general and administrative expenses for the three months ended March 31, 2025, were $40.0 million, compared to $27.1 million for the same period in 2024. The increase in general and administrative expenses in 2025 as compared to 2024 primarily reflects higher personnel expenses related to increased headcount to support commercialization of RYTELO in the U.S.

Interest income was $5.2 million for the three months ended March 31, 2025, compared to $4.2 million for the same period in 2024. The increase in interest income in 2025 compared to 2024 primarily reflects a larger marketable securities portfolio, with the receipt of net cash proceeds from synthetic royalty and debt financings in November 2024. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Interest expense was $8.2 million for the three months ended March 31, 2025, compared to $3.4 million for the same period in 2024. The increase in interest expense primarily reflects $4.8 million in non-cash interest expense related to our synthetic royalty agreement and an increased principal debt balance under our loan agreement and a prior loan agreement, which was repaid in the fourth quarter of 2024. Interest expense reflects interest expense recognized under the synthetic royalty agreement, interest owed under the loan agreements, 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.

2025 Financial Guidance

For fiscal year 2025, the Company maintains its previously announced expectations of 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.

Based on the current operating plans and assumptions, the Company believes that existing cash, cash equivalents, and marketable securities, together with anticipated net revenues from U.S. sales of RYTELO, will be sufficient to fund projected operating requirements for the foreseeable future.

Conference Call

Geron will host a conference call at 8:00 a.m. ET on Wednesday, May 7, 2025, to discuss business updates and first quarter 2025 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,

About RYTELO (imetelstat)

RYTELO is an oligonucleotide telomerase inhibitor approved in the U.S. 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.

In addition, RYTELO is approved in the European Union as a monotherapy for the treatment of adult patients with transfusion-dependent anemia due to very low, low or intermediate risk myelodysplastic syndromes 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 and the European Commission.

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 and the European Union 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 hematologic malignancies. Inhibiting telomerase activity, which is increased in malignant stem and progenitor cells in the bone marrow, aims to potentially reduce proliferation and induce death of malignant cells. To learn more, visit www.geron.com or 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 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 (≥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 (imetelstat) 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 beliefs regarding the long-term potential of RYTELO as an important therapeutic for eligible patients with lower-risk MDS; (ii) the strength of RYTELO's therapeutic profile; (iii) the Company's beliefs, plans and expectations regarding specific opportunities and investments the Company is making, and the expected success of these efforts to strengthen the U.S. commercial trajectory and increase awareness and education across prescribers; (iv) the Company's beliefs and expectations regarding uptake of RYTELO across a broader group of prescribers and long-term demand, including as a result of the Company's increased commercial investments; (v) the Company's beliefs regarding the significant market opportunity for imetelstat to treat JAKi R/R MF patients if the Phase 3 IMpactMF trial is positive and imetelstat is approved in this indication; (vi) the Company's beliefs regarding the progress and status of the Phase 3 IMpactMF trial and expected timing for the interim analysis occurring in the second half of 2026 and the final analysis in the second half of 2028; (vii) the Company's plans and expectations regarding the timing for commercializing RYTELO in select EU countries in 2026; (viii) imetelstat's potential for disease modification; (ix) the Company's projections for total operating expenses for fiscal year 2025; (x) the Company's expectations that it will reach profitability without additional financing if its current internal sales and operating expense expectations are met; (xi) 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; (xii) that inhibiting telomerase activity aims to potentially reduce proliferation and induce death of malignant cells; (xiii) that IMpactMF has registrational intent; and (xiv) 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 (imetelstat) for the treatment of certain patients with lower-risk MDS with transfusion dependent anemia and achieves market acceptance across the breadth of the eligible patient segments in RYTELO's approved indication; (b) whether the FDA and European Commission will approve imetelstat for other indications on the timelines expected, or at all; (c) Geron's plans to commercialize RYTELO in the European Union, or EU and risks related to operating outside of the U.S.; (d) whether Geron overcomes potential delays and other adverse impacts that may be 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 imetelstat 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 imetelstat 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 (imetelstat) 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 synthetic 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 annual report on Form 10-K for the year ended December 31, 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

(In thousands, except share and per share data)	Three Months Ended March 31,	
	2025	**2024**
	(Unaudited)	**(Unaudited)**
Revenues:		

Product revenue, net	$ 39,436	$ —
Royalties	167	304
	39,603	304
Operating expenses:		
Cost of goods sold	1,206	—
Research and development	15,078	29,373
Selling, general and administrative	40,023	27,065
Total operating expenses	56,307	56,438
Loss from operations	(16,704)	(56,134)
Interest income	5,152	4,239
Interest expense	(8,200)	(3,433)
Other income and (expense), net	(83)	(62)
Net loss	$ (19,835)	$ (55,390)
Basic and diluted net loss per share:		
Net loss per share	$ (0.03)	$ (0.09)
Shares used in computing net loss per share	665,905,469	603,493,451

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	**March 31, 2025**	**December 31, 2024**
	(Unaudited)	**(Note 1)**
Current assets:		
Cash, cash equivalents and restricted cash	$ 85,610	$ 80,876
Current marketable securities	313,132	327,550
Other current assets	97,027	82,566
Total current assets	495,769	490,992
Noncurrent marketable securities	58,795	94,519
Property and equipment, net	1,147	1,310
Deposits and other assets	6,739	6,960
	$ 562,450	$ 593,781
Current liabilities	$ 63,034	$ 88,298
Noncurrent liabilities	231,178	225,163
Stockholders' equity	268,238	280,320
	$ 562,450	$ 593,781

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