



Geron Corporation Reports Second Quarter 2024 Financial Results and Business Highlights

August 8, 2024

U.S. commercial launch of RYTELO™ (imetelstat) began in June 2024 for patients with lower-risk myelodysplastic syndromes (LR-MDS) with transfusion-dependent anemia who are relapsed/refractory to or ineligible for erythropoiesis-stimulating agents (ESAs), regardless of ring sideroblast (RS) status

NCCN Guidelines® updated to include the use of RYTELO in both RS+ and RS- patients for second-line treatment of symptomatic anemia in patients with lower-risk MDS and for first-line treatment of patients who are ESA ineligible (serum EPO >500 mU/mL)

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 and business highlights for the second quarter of 2024.

"We are thrilled to have begun the launch of RYTELO, our first commercial product, in June, and are encouraged by the early success we are seeing and the reception from the medical community over these first six weeks," said John A. Scarlett, M.D., Geron's Chairman and Chief Executive Officer. "Our field teams have mobilized efficiently and have already interacted with approximately 60% of our top decile 1-4 accounts across the community and academic settings. This has contributed to gratifying uptake – as of July 31, 2024, we estimate that approximately 160 patients have received RYTELO, which is encouraging given the very early stage of this launch. Further, the MDS NCCN Guidelines, which guide clinical decision-making, prescriber behavior and reimbursement decisions, were updated at the end of July to include RYTELO as a Category 1 and 2A treatment of symptomatic anemia in patients with lower-risk MDS. With the introduction of RYTELO as a new therapeutic option, we are seeing increasing dialogue among hematologists rethinking treatment approaches for eligible patients with lower-risk MDS with transfusion-dependent anemia, regardless of ring sideroblast status, and we believe that RYTELO can become part of the standard-of-care for these patients."

Business Highlights

- Received approval on June 6, 2024 from the U.S. Food & Drug Administration (FDA) of RYTELO for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (LR-MDS) with transfusion-dependent (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 (ESAs).
- Launched RYTELO commercially in the U.S., with both dosage strengths available for prescribers to order from specialty distributors as of June 27, 2024.
- The National Comprehensive Cancer Network® (NCCN®) updated the MDS NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) to include RYTELO for the treatment of symptomatic anemia in patients with LR-MDS. For both RS+ and RS- patients, RYTELO has a Category 1 designation for second-line treatment regardless of first-line treatment and a Category 2A designation for first-line treatment of patients who are ESA ineligible (serum EPO >500 mU/mL).
- Achieved approximately 70% enrollment in the Phase 3 IMpactMF trial of imetelstat as of August 2024, which has a primary endpoint of overall survival, in patients with myelofibrosis (MF) who are relapsed/refractory to JAK-inhibitors. As previously disclosed, based on the most recent planning assumptions for enrollment and death rates in the trial, an interim analysis is expected in early 2026 (when approximately 35% of planned enrolled patients have died) and final analysis is expected in early 2027 (when approximately 50% of planned enrolled patients have died).
- Expanded the dose level 4 cohort (imetelstat 9.4 mg/kg) in the Part 1 dose-finding stage of the Phase 1 IMproveMF study evaluating imetelstat as a combination therapy with ruxolitinib in patients with frontline MF. This followed a unanimous decision by the study's Safety Evaluation Team (SET), who in July 2024 reviewed data from the first three patients in the dose level 4 cohort and identified no dose-limiting toxicities.

Second Quarter 2024 Financial Results

As of June 30, 2024 the Company had approximately \$430.4 million in cash, cash and equivalents and marketable securities.

Net Loss

For the three and six months ended June 30, 2024, the Company reported a net loss of \$67.4 million, or \$0.10 per share, and \$122.8 million, or \$0.19 per share, respectively, compared to \$49.2 million, or \$0.09 per share and \$87.3 million, or \$0.16 per share, respectively, for the three and six months ended June 30, 2023.

Revenues

Total product revenue, net for the three and six months ended June 30, 2024, was approximately \$780,000.

Total net revenues for the three and six months ended June 30, 2024, were \$882,000 and \$1.2 million, compared to \$29,000 and \$50,000 for the same periods in 2023. The increase in revenue is due to product revenue from U.S. sales of RYTELO, which was available for prescribers to order from specialty distributors as of June 27, 2024.

Operating Expenses

Total operating expenses for the three and six months ended June 30, 2024 were \$70.2 million and \$126.7 million, compared to \$52.0 million and \$92.1 million for the same periods in 2023.

Cost of goods sold was approximately \$17,000 for the three and six months ended June 30, 2024, which consisted of costs to manufacture and distribute RYTELO.

Research and development expenses for the three months and six months ended June 30, 2024 were \$30.8 million and \$60.2 million, respectively, and \$35.5 million and \$62.7 million, for the same periods in 2023. The decrease is primarily due to IMerge Phase 3 operations moving into the long-term follow-up stage.

Selling, general and administrative expenses for the three and six months ended June 30, 2024 were \$39.4 million, and \$66.5 million, respectively, and \$16.5 million and \$29.4 million for the same periods in 2023. The increase in selling, general and administrative expenses primarily reflects higher commercial launch expenses, increases in headcount and stock-based compensation expense recognized due to the vesting of performance-based stock options upon FDA approval of RYTELO.

Interest income was \$5.3 million and \$9.6 million for the three and six months ended June 30, 2024, compared to \$4.7 million and \$8.6 million for the same periods in 2023. The increase in interest income primarily reflects a larger marketable securities portfolio with the receipt of net cash proceeds from the underwritten offering completed in March 2024, as well as higher yields from recent marketable securities purchases.

Interest expense was \$3.3 million and \$6.8 million for the three and six months ended June 30, 2024, compared to \$2.0 million and \$3.9 million for the same periods in 2023. The increase in interest expense primarily reflects rising interest rates. Currently, we have \$80.0 million in principal debt outstanding. Interest expense reflects interest owed under the loan agreement, as well as amortization of associated debt issuance costs and debt discounts using the effective interest method and accrual for an end of term charge.

2024 Financial Guidance

For fiscal year 2024, we expect total operating expenses to be in the range of approximately \$270 million to \$280 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 our current operating plans and assumptions, we believe that our existing cash, cash equivalents, and marketable securities, together with projected revenues from U.S. sales of RYTELO, will be sufficient to fund our projected operating requirements into the second quarter of 2026.

As of June 30, 2024, we had 220 full-time employees. We plan to grow to a total of approximately 230-260 employees by year-end 2024.

Conference Call

Geron will host a conference call at 8:00 a.m. ET on Thursday, August 8, 2024, to discuss business updates and second quarter 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/182024239>

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.

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.

Geron aims to ensure broad access to RYTELO for eligible patients. Accordingly, our REACH4RYTELO™ Patient Support Program provides a range of resources that support access and affordability to eligible patients prescribed RYTELO.

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 FDA-approved for the treatment of adult patients with lower-risk 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 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 ClinicalTrials.gov/study/NCT04576156.

About IMproveMF

IMproveMF is a single arm, open label, two-part Phase 1 study to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of imetelstat in combination with ruxolitinib as a frontline treatment in patients with intermediate-2 or high-risk MF (frontline MF). In both parts, patients will receive ruxolitinib followed by imetelstat, a dosing schedule that showed synergistic and additive effects of the two agents in preclinical experiments. Part 1 will enroll up to 20 frontline MF patients who, at the time of enrollment, have received an optimized dose of ruxolitinib, to which imetelstat treatment will be added at increasing dose levels based on safety and tolerability. The primary purpose of Part 1 is to identify a safe dose for treating frontline MF patients with a combination of imetelstat and ruxolitinib. If a safe dose is identified in Part 1, participants in Part 2 will be JAK inhibitor naïve and will receive treatment with ruxolitinib after screening and enrollment at a starting dose based on standard-of-care or local prescribing information. Treatment with single-agent ruxolitinib will continue for at least 12 weeks, including four consecutive weeks at a stable dose prior to the addition of imetelstat. Part 2 is designed to confirm the safety profile of imetelstat in combination with ruxolitinib and to evaluate for preliminary clinical activity of the combination.

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 (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 views, estimates and expectations concerning the commercial launch of RYTELO, including estimates of accounts reached and patients receiving RYTELO; (ii) the potential impact on clinical decision-making, prescriber behavior and reimbursement decisions of the inclusion of RYTELO in the NCCN Guidelines as a Category 1 and 2A treatment of symptomatic anemia in patients with lower-risk MDS; (iii) the Company seeing increasing dialogue among hematologists rethinking treatment approaches for eligible patients with lower-risk MDS with transfusion-dependent anemia, regardless of ring sideroblast status, and the Company's belief that RYTELO can become part of the standard-of-care for these patients; (iv) that the interim analysis of ImpactMF is expected in early 2026 and the final analysis is expected in early 2027; (v) the Company's projections and expectations regarding the sufficiency of its cash resources and expected available resources to fund its projected operating requirements into Q2 2026, and the assumptions underlying such projections and expectations; (vi) the Company's projections for total operating expenses for fiscal 2024 and employee headcount as of the end of 2024; (vii) that inhibiting telomerase activity aims to potentially reduce proliferation and induce death of malignant cells; (viii) that Geron aims to ensure broad access to RYTELO; (ix) that ImpactMF has registrational intent; and (x) 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 patients with LR-MDS with transfusion dependent anemia; (b) 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; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether any future safety or efficacy results of imetelstat treatment cause the benefit-risk profile of imetelstat to become unacceptable; (e) whether imetelstat actually demonstrates disease-modifying activity in patients and the ability to target the malignant stem and progenitor cells of the underlying disease; (f) that Geron may seek to raise substantial additional capital in order to continue the development and commercialization of imetelstat; (g) whether Geron meets its post-marketing requirements and commitments in the U.S. for RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia; (h) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials that impact commercialization of RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia or the continuation of the ImpactMF trial; (i) 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 (j) whether the EMA will approve RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia and whether the FDA and EMA will approve imetelstat for other indications on the timelines expected, or at all. 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 March 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 table follows.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
<i>(In thousands, except share and per share data)</i>				
Revenues:				
Product revenue, net	\$ 780	\$ -	\$ 780	\$ -
Royalties	102	29	406	50
	<u>882</u>	<u>29</u>	<u>1,186</u>	<u>50</u>
Operating expenses:				
Cost of goods sold	17	-	17	-
Research and development	30,779	35,490	60,152	62,709
Selling, general and administrative	39,419	16,490	66,484	29,384
Total operating expenses	<u>70,215</u>	<u>51,980</u>	<u>126,653</u>	<u>92,093</u>
Loss from Operations	(69,333)	(51,951)	(125,467)	(92,043)
Interest income	5,332	4,738	9,571	8,591
Interest expense	(3,319)	(2,003)	(6,752)	(3,925)
Other income and (expense), net	(63)	(11)	(125)	28
Net loss	<u>\$ (67,383)</u>	<u>\$ (49,227)</u>	<u>\$ (122,773)</u>	<u>\$ (87,349)</u>
Basic and diluted net loss per share:				
Net loss per share	\$ (0.10)	\$ (0.09)	\$ (0.19)	\$ (0.16)
Shares used in computing net loss per share	<u>653,904,978</u>	<u>547,280,946</u>	<u>628,699,214</u>	<u>553,772,809</u>

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30,	December 31,
	2024	2023
	(Unaudited)	(Note 1)
<i>(In thousands)</i>		
Current assets:		
Cash, cash equivalents and restricted cash	\$ 118,068	\$ 71,138
Current marketable securities	245,789	263,676
Other current assets	9,451	6,534
Total current assets	<u>373,308</u>	<u>341,348</u>
Noncurrent marketable securities	66,505	43,298
Property and equipment, net	1,626	1,177
Deposits and other assets	7,960	8,253
	<u>\$ 449,399</u>	<u>\$ 394,076</u>
Current liabilities	\$ 103,540	\$ 108,070
Noncurrent liabilities	39,164	38,057
Stockholders' equity	306,695	247,949
	<u>\$ 449,399</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, 2023.

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Source: Geron Corporation