Geron Corporation Reports Third Quarter 2024 Financial Results and Recent Business Highlights

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Achieved $28.2 million in RYTELO™ (imetelstat) net product revenue in first full quarter of sales

Received $250 million in gross proceeds from synthetic royalty and debt financings with Royalty Pharma and Pharmakon Advisors, with access to an additional $125 million in debt

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 third quarter of 2024 and recent business highlights.

“This has been a transformative year for Geron, following our first FDA approval and commercial launch of RYTELO in June. The initial full quarter of product revenue from our U.S. launch exceeded our expectations and demonstrates strong execution as a commercial company. These results also reflect the high unmet need in lower-risk MDS and the compelling value proposition of RYTELO for hematologists and patients, giving us confidence in future continued demand and momentum for RYTELO,” said John A. Scarlett, M.D., Geron’s Chairman and Chief Executive Officer. “We were also pleased to announce this morning the completion of important synthetic royalty and debt financing transactions with Royalty Pharma and Pharmakon Advisors. We believe that the favorable terms in these transactions reflect the significant commercial potential of RYTELO and provide us with critical flexibility to fuel continued growth and invest in our future.”

Recent Business Highlights

- Strong execution in the first full quarter of U.S. launch, with net product revenue for RYTELO (imetelstat) of $28.2 million in the third quarter of 2024.
- In November 2024, completed synthetic royalty and debt financing transactions to strengthen our cash position and further solidify our balance sheet while providing strategic flexibility to invest in our future. We entered into a synthetic royalty agreement with Royalty Pharma providing $125 million of capital in exchange for tiered royalty payments. We also entered into a 5-year, senior term loan agreement with Pharmakon for

up to $250 million, from which we have drawn a first tranche of $125 million, a portion of which was used to fully repay amounts owed under our existing loan with Hercules Capital, Inc. and Silicon Valley Bank ($86.5 million), which has now been terminated, with the ability to borrow another $125 million prior to the end of 2025, subject to specified conditions.

- Jim Ziegler appointed as Executive Vice President, Chief Commercial Officer in September 2024, to spearhead Geron's global commercial strategy and operations, lead the commercial organization and be responsible for driving growth of RYTELO. Mr. Ziegler brings more than 25 years of commercial experience in the biopharmaceutical industry, spanning leadership, strategic and operational roles in both large and smaller organizations.
- New data to be presented at upcoming American Society for Hematology (ASH) Annual Meeting highlights the potential of imetelstat in myeloid hematologic malignancies (please view **ASH press release** for more details).

Upcoming Milestones

- We expect review of the Marketing Authorization Application (MAA) for RYTELO in lower-risk MDS by the Committee for Medicinal Products for Human Use (CHMP) could be completed in late 2024 or early 2025, with potential approval by the European Commission in the first half of 2025. We are continuing to prepare for the potential launch of RYTELO in the EU, and subject to regulatory approval, are planning to commercialize RYTELO in select EU markets commencing in 2026.
- We expect an interim analysis from the Phase 3 IMpactMF trial in patients with relapsed/refractory MF may occur in early 2026 (when approximately 35% of planned enrolled patients have died) and the final analysis may occur in early 2027 (when approximately 50% of planned enrolled patients have died), based on our most recent planning assumptions for enrollment and death rates in the trial.

Third Quarter 2024 Financial Results

As of September 30, 2024, we had approximately $378.9 million in cash, cash equivalents, restricted cash and marketable securities. On a pro forma basis, including gross proceeds from the upfront payment under the Royalty Pharma Agreement and the first tranche of the Pharmakon loan and after repayment of our existing debt, we had approximately $542.4 million in cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2024.

Net Loss

For the three and nine months ended September 30, 2024, the Company reported a net loss of $26.4 million, or $0.04 per share, and $149.2 million, or $0.23 per share, respectively, compared to $44.8 million, or $0.08 per share and $132.2 million, or $0.23 per share, respectively, for the three and nine months ended September 30, 2023.

Revenues

Total product revenue, net for the three and nine months ended September 30, 2024, was $28.2 million and $29.0 million, respectively.

Total net revenue for the three and nine months ended September 30, 2024, was $28.3 million and $29.5 million, respectively, compared to $164,000 and $214,000 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 nine months ended September 30, 2024, were $56.5 million and $183.1 million, respectively, compared to $47.8 million and $139.9 million for the same periods in 2023.

Cost of goods sold was approximately $456,000 and $473,000 for the three and nine months ended September 30, 2024, respectively, which consisted of costs to manufacture and distribute RYTELO.

Research and development expenses for the three months and nine months ended September 30, 2024, were $20.2 million and $80.3 million, respectively, and $29.4 million and $92.1 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.

Selling, general and administrative expenses for the three and nine months ended September 30, 2024, were $35.9 million, and $102.4 million, respectively, and $18.4 million and $47.7 million for the same periods in 2023. The increase in selling, general and administrative expenses primarily reflects higher commercial launch expenses, and increases in headcount and related expenses in connection with the U.S. launch of RYTELO.

Interest income was $4.9 million and $14.4 million for the three and nine months ended September 30, 2024, respectively, compared to $5.0 million and $13.6 million for the same periods in 2023. The decrease in interest income for the three months ended September 30, 2024, compared to the same period in 2023 was due to a decrease in interest rates. The increase in interest income for the nine months ended September 30, 2024, compared to the same period in 2023 primarily reflects a larger marketable securities portfolio with the receipt of net cash proceeds from the underwritten offering completed in March 2024, as well as higher yields from recent marketable securities purchases.

Interest expense was $3.0 million and $9.8 million for the three and nine months ended September 30, 2024,

respectively, compared to $2.1 million and $6.0 million for the same periods in 2023. The increase in interest expense primarily reflects rising interest rates.

2024 Financial Guidance

For fiscal year 2024, we expect total operating expenses to be in the range of approximately $260 million to $270 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 (including the $250 million gross proceeds received under the Pharmakon loan and Royalty Pharma agreements), together with anticipated revenues from U.S. sales of RYTELO, will be sufficient to fund our projected operating requirements for at least the next 12 months from the date of this press release. We believe that our projected financial resources will be sufficient to support commercial launch of RYTELO in the U.S. and potential launch in the EU, complete the Phase 3 IMpactMF trial in relapsed/refractory MF, invest in supply chain redundancy for RYTELO, and fund our general working capital requirements.

Conference Call

Geron will host a conference call at 8:00 a.m. ET on Thursday, November 7, 2024, to discuss business updates and third 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/539655875**

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.

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 ClinicalTrials.gov/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 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; (ii) the Company's confidence in future continued demand and momentum for RYTELO; (iii) the Company's view that the terms in the recently closed synthetic royalty and debt financing transactions reflect the significant commercial potential of RYTELO and provide the Company with critical flexibility to fuel continued growth and invest in its future; (iv) 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; (v) that the interim analysis of IMpactMF is expected in early 2026 and the final analysis is expected in early 2027; (vi) the Company's projections and expectations regarding the sufficiency of its financial resources to fund its projected operating requirements for at least the next 12 months from the date of this release, including the sufficiency and use of the Company's financial resources to support specified activities, and the assumptions underlying such projections and expectations; (vii) the Company's projections for total operating expenses for fiscal 2024; (viii) that inhibiting telomerase activity aims to potentially reduce proliferation and induce death of malignant cells; (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 certain 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; (j) whether Geron stays in compliance with and satisfies its obligations under its debt and royalty financing agreements; and (i) whether the European Commission will approve RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia and whether the FDA and European Commission 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 June 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 table follows.

GERON CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Product revenue, net	$ 28,209	$ -	$ 28,989	$ -
Royalties	62	164	468	214
	28,271	164	29,457	214
Operating expenses:				
Cost of goods sold	456	-	473	-
Research and development	20,153	29,426	80,305	92,135
Selling, general and administrative	35,877	18,350	102,361	47,734
Total operating expenses	56,486	47,776	183,139	139,869
Loss from Operations	(28,215)	(47,612)	(153,682)	(139,655)
Interest income	4,877	4,965	14,448	13,556
Interest expense	(3,046)	(2,066)	(9,798)	(5,991)
Other income and (expense), net	(63)	(92)	(188)	(64)

Net loss	$ (26,447)	$ (44,805)	$ (149,220)	$ (132,154)
Basic and diluted net loss per share:				
Net loss per share	$ (0.04)	$ (0.08)	$ (0.23)	$ (0.23)
Shares used in computing net loss per share	662,158,182	579,508,305	639,933,612	562,445,577

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	September 30, 2024 (Unaudited)	December 31, 2023 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	$ 62,198	$ 71,138
Current marketable securities	279,430	263,676
Other current assets	56,429	6,534
Total current assets	398,057	341,348
Noncurrent marketable securities	37,312	43,298
Property and equipment, net	1,595	1,177
Deposits and other assets	7,986	8,253
	$ 444,950	$ 394,076
Current liabilities	$ 137,933	$ 108,070
Noncurrent liabilities	14,733	38,057
Stockholders' equity	292,284	247,949
	$ 444,950	$ 394,076

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