Geron Corporation Reports Business Highlights and Fourth Quarter and Full Year 2023 Financial Results

February 28, 2024

June 16, 2024 PDUFA date for imetelstat NDA for the treatment of transfusion-dependent anemia in adult patients with lower-risk MDS

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company developing investigational first-in-class telomerase inhibitor, imetelstat, to treat hematologic malignancies, today reported business highlights and financial results for the fourth quarter and full year 2023.

“Geron’s progress and execution throughout 2023 has paved the way for a potentially transformational 2024, as we plan for the transition to becoming a commercial company,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “We believe that we are in a strong position for value creation, based on our differentiated product candidate, the potential for significant commercial opportunities in transfusion-dependent, lower-risk MDS and relapsed/refractory MF, the excellence and experience of our employees, and the strength of our balance sheet to support a potential U.S. launch.”

2023 Business Highlights

Transfusion-Dependent Lower-Risk Myelodysplastic Syndromes (TD LR-MDS)

- In January 2023, Geron reported positive top-line results from the pivotal IMerge Phase 3 clinical trial evaluating imetelstat in patients with TD LR-MDS. Additional data including subgroup analyses and patient-reported outcomes were subsequently reported at the European Hematology Association Annual Meeting in June 2023 and at the American Society of Hematology Annual Meeting and published in *The Lancet* in December 2023.
- In August 2023, the U.S. Food & Drug Administration (FDA) accepted the New Drug Application (NDA) for imetelstat for the treatment of TD anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes, who have failed to respond, or have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESAs). The FDA assigned a Prescription Drug User Fee Act (PDUFA) action date of June 16, 2024 to the NDA.
- On January 30, 2024, the FDA provided notice in the Federal Register that it has scheduled a public Oncologic Drugs Advisory Committee to be held virtually on March 14, 2024, as part of the imetelstat NDA review.
- In September 2023, the European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for imetelstat in the same proposed indication as the NDA.

Myelofibrosis

- In December 2023, Geron achieved fifty percent enrollment in the Phase 3 IMpactMF clinical trial investigating imetelstat versus best available therapy (BAT) in patients with intermediate-2 or high-risk Myelofibrosis (MF) who are relapsed/refractory myelofibrosis (R/R MF) to Janus kinase (JAK) inhibitor treatment.
- In January 2024, dosing in the Phase 1 IMproveMF study evaluating imetelstat as a combination therapy with ruxolitinib in patients with intermediate-2 or high-risk MF (frontline MF) was escalated to the third of four doses following a decision by the study’s independent Safety Evaluation Team (SET).

Corporate

- In November 2023, Geron appointed Gaurav Aggarwal, M.D., a prominent investor in the life sciences sector for more than two decades who has a history of expertise in financial and corporate strategy, as well as business development, to Geron’s Board of Directors.
- In August and September 2023, respectively, Geron appointed Scott Samuels as Executive Vice President, Chief Legal Officer and Corporate Secretary, and Michelle Robertson as Executive Vice President, Chief Financial Officer and Treasurer. Both Mr. Samuels and Ms. Robertson join Geron with a track record of excellence in commercial-stage biopharmaceutical companies.

Anticipated Upcoming Milestones

- U.S. commercial launch of imetelstat upon potential FDA approval (PDUFA date June 16, 2024) for the treatment of transfusion-dependent anemia in adult patients with LR-MDS who have failed to respond, or have lost response to, or are ineligible for ESAs.
- Review of the imetelstat MAA for the same indication as the NDA expected to be completed in early 2025. Subject to approval by the European Commission, EU commercial launch of imetelstat could occur in 2025.
- Interim analysis from the Phase 3 IMpactMF trial in R/R MF expected in the first half of 2025, with a final analysis from the

study expected in the first half of 2026.

U.S. Commercial Preparation

Throughout 2023, Geron completed several long-lead time pre-commercial activities, including securing a global trademark for the imetelstat brand name; finalizing third party logistics, our distribution network, patient support providers; and onboarding highly experienced commercial and medical affairs teams. Other pre-commercial preparations for the U.S. are ongoing, including enhancing and/or establishing company processes and systems to support an expected commercial launch, refining our market research in TD LR-MDS, and engaging in marketing, commercial access, payer, and reimbursement preparatory efforts.

Fourth Quarter and Full Year 2023 Financial Results

As of December 31, 2023, the Company had $378.1 million in cash, cash equivalents, and marketable securities. During 2023, the Company received net cash proceeds of $213.3 million from the underwritten public offering of common stock and pre-funded warrants completed in January 2023, $105.9 million of cash proceeds from the exercise of outstanding warrants, and $29.7 million in net proceeds drawn down under the Loan Agreement with Hercules and SVB in the fourth quarter of 2023. Based on the Company's current operating plans and expectations regarding the expected timing of regulatory approval and commercialization of imetelstat in the U.S. in the first half of 2024, Geron projects that its existing financial resources, together with projected revenues from U.S. sales of imetelstat, proceeds from the exercise of outstanding warrants, and funding under the Company's loan facility, will be sufficient to fund its projected operating expenses into the third quarter of 2025.

Revenues for the three and twelve months ended December 31, 2023, were $23,000 and $237,000, respectively, compared to $103,000 and $596,000 for the comparable 2022 periods. Revenues in both years primarily reflect estimated royalties from sales of cell-based research products from the Company's divested stem cell assets.

Total operating expenses for the three and twelve months ended December 31, 2023, were $54.3 million and $194.1 million, respectively, compared to $42.0 million and $139.1 million for the comparable 2022 periods.

Research and development expenses for the three and twelve months ended December 31, 2023, were $32.9 million and $125.0 million, respectively, compared to $28.2 million and $95.5 million for the comparable 2022 periods. The increase in research and development expenses for the three and twelve months ended December 31, 2023, compared to the same periods in 2022, primarily reflects higher clinical trial costs related to supporting the Company's IMerge and IMpactMF Phase 3 clinical trials, increased personnel-related expenses for additional headcount in preparation for transition to a commercial-stage company, higher consulting costs to support regulatory submissions, and greater manufacturing costs in preparation for potential commercialization.

General and administrative expenses for the three and twelve months ended December 31, 2023, were $21.4 million and $69.1 million, respectively, compared to $13.8 million and $43.6 million for the comparable 2022 periods. The increase in general and administrative expenses for the three and twelve months ended December 31, 2023, compared to the same periods in 2022, primarily reflects additional costs for commercial preparatory activities and higher personnel-related expenses for additional headcount in preparation for transition to a commercial-stage company.

Interest income was $4.6 million and $18.2 million for the three and twelve months ended December 31, 2023, respectively, compared to $1.2 million and $2.5 million for the same periods in 2022. The increase in interest income for the three and twelve months ended December 31, 2023, compared to the same periods in 2022, primarily reflects higher yields on the Company's marketable securities as a result of higher interest rates, as well as a larger investment portfolio with the cash proceeds from the January 2023 public offering and warrant exercises in 2023.

Interest expense was $2.3 million and $8.3 million for the three and twelve months ended December 31, 2023, respectively, compared to $2.0 million and $6.8 million for the same periods in 2022. The increase in interest expense for the three and twelve months ended December 31, 2023, compared to the same periods in 2022, primarily reflects higher interest rates. Currently, the Company has $80.0 million in principal debt outstanding and $45.0 million available under its existing loan facility, subject to achievement of specified milestones or approval of the lenders.

Projected 2024 Financial Guidance

For fiscal year 2024, the Company expects 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.

The fiscal year 2024 financial guidance reflects costs to support regulatory processes with the FDA and EMA in 2024; continued support of ongoing clinical trials; manufacturing of commercial inventory of imetelstat; continued build out of our commercial organization to support the potential U.S. commercial launch of imetelstat S; continued increases in headcount in preparation for transition to a commercial-stage company; and interest payments on outstanding debt.

As of December 31, 2023, the Company had 141 full-time employees. Subject to approval of imetelstat in the U.S., the Company plans to grow to a total of approximately 270 employees by year-end 2024.

Conference Call

Geron will host a conference call at 8:00 am ET on Wednesday, February 28, 2024, to discuss business updates and fourth quarter and full year 2023 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/964382933.

About Imetelstat

Imetelstat is a novel, first-in-class investigational telomerase inhibitor exclusively owned by Geron and being developed in hematologic malignancies. Data from non-clinical studies and clinical trials of imetelstat provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in myeloid hematologic malignancies, resulting in malignant cell apoptosis and suggesting potential disease-modifying activity. Imetelstat has been granted Fast Track designation by the U.S. Food and Drug Administration for both the treatment of adult patients with transfusion dependent anemia due to Low or Intermediate-1 risk MDS that is not associated with del(5q) who are refractory or resistant to an erythropoiesis stimulating agent, and for adult patients with Intermediate-2 or High-risk myelofibrosis (MF) whose disease has relapsed after or is refractory to janus associated kinase (JAK) inhibitor treatment. Imetelstat is currently not approved by any regulatory authority.

About IMerge Phase 3

The Phase 3 portion of the IMerge Phase 2/3 study is a double-blind, 2:1 randomized, placebo-controlled clinical trial to evaluate imetelstat in patients with IPSS Low or Intermediate-1 risk (lower risk) transfusion dependent MDS who were relapsed after, refractory to, or ineligible for, erythropoiesis stimulating agent (ESA) treatment, had not received prior treatment with either a HMA or lenalidomide and were non-del(5q). To be eligible for IMerge Phase 3, patients were required to be transfusion dependent, defined as requiring at least four units of packed red blood cells (RBCs), over an eight-week period during the 16 weeks prior to entry into the trial. The primary efficacy endpoint of IMerge Phase 3 is the rate of red blood cell transfusion independence (RBC-TI) lasting at least eight weeks, defined as the proportion of patients without any RBC transfusion for at least eight consecutive weeks since entry to the trial (8-week TI). Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks (24-week TI), the duration of TI and the rate of hematologic improvement erythroid (HI-E), which is defined under 2006 IWG criteria as a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. A total of 178 patients were enrolled in IMerge Phase 3 across North America, Europe, Middle East and Asia.

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 MF who are relapsed after or refractory to prior treatment with a JAK inhibitor, also referred to as R/R MF. Patients will be randomized to receive either imetelstat or BAT. 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.

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.

About Geron

Geron is a late-stage clinical biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our first-in-class investigational telomerase inhibitor, imetelstat, harnesses Nobel Prize-winning science in a treatment that may alter the underlying drivers of disease. The New Drug Application (NDA) for imetelstat for the treatment of transfusion dependent anemia in patients with lower-risk myelodysplastic syndromes (TD LR-MDS) who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESAs), based on the results from the Phase 3 IMerge clinical trial, is currently under review by the United States Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of June 16, 2024. In addition, an MAA is under review in the European Union for the same proposed indication. Furthermore, Geron currently has an ongoing pivotal Phase 3 clinical trial evaluating imetelstat in relapsed/refractory myelofibrosis (R/R MF). To learn more, visit www.geron.com or follow us on LinkedIn.

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 potential for a transformational year for the Company in 2024, the Company's plans to transition to becoming a commercial company, and the potential for value creation and significant commercial opportunities; (ii) plans for a potential launch in TD LR-MDS in the U.S. upon potential approval by the FDA (PDUFA date June 16, 2024), and for the MAA review to be completed in early 2025, and subject to approval by the European Commission, that EU commercial launch could occur in 2025; (iii) that the interim analysis of IMPpactMF is expected in the first half of 2025 and the final analysis is expected in the first half of 2026; (iv) the Company's projections and expectations regarding the sufficiency of its cash resources and expected available resources to fund its projected operating requirements into Q3 2025, and the assumptions underlying such projections and expectations; (v) the Company's projections for total operating expenses for fiscal 2024 and employee headcount as of the end of 2024; (vi) that imetelstat has the potential to demonstrate disease-modifying activity in patients; (vii) that IMpactMF has registrational intent; and (viii) 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 overcomes all of the 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 to meet the expected timelines, planned milestones and expenses noted herein; (b) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (c) whether imetelstat has demonstrated sufficient safety, efficacy and clinical benefit in IMerge Phase 3 to enable regulatory approval; (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 complete the development and commercialization of imetelstat to meet the expected timelines, planned milestones and expenses noted herein; (g) whether regulatory authorities require an additional clinical trial for approval of imetelstat in TD LR-MDS, or post-approval; (h) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials that impact a commercial launch in TD LR-MDS 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 FDA and EMA will approve imetelstat for the treatment of TD LR-MDS or 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 September 30, 2023 and future 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

	(Unaudited) Three Months Ended December 31,		Year Ended December 31,	
(In thousands, except share and per share data)	**2023**	**2022**	**2023**	**2022**
Revenues:				
Royalties	$ 23	$ 103	$ 237	$ 596
Operating expenses:				
Research and development	32,911	28,210	125,046	95,518
General and administrative	21,401	13,844	69,135	43,628
Total operating expenses	54,312	42,054	194,181	139,146
Loss from operations	(54,289)	(41,951)	(193,944)	(138,550)
Interest income	4,595	1,235	18,152	2,529
Interest expense	(2,321)	(2,005)	(8,312)	(6,822)
Other income and expense, net	41	86	(23)	1,002
Net loss	$ (51,974)	$ (42,635)	$ (184,127)	$ (141,901)

Basic and diluted net loss per share:

Net loss per share	$ (0.09)	$ (0.10)	$ (0.32)	$ (0.37)
Shares used in computing net loss per share	594,977,503	408,143,890	570,645,405	380,784,846

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	December 31, 2023	December 31, 2022
Current assets:		
Cash, cash equivalents and restricted cash	$ 71,138	$ 57,209
Current marketable securities	263,676	115,901
Other current assets	6,534	7,136
Total current assets	341,348	180,246
Noncurrent marketable securities	43,298	—
Property and equipment, net	1,177	793
Deposits and other assets	8,253	9,536
	$ 394,076	$ 190,575
Current liabilities	$ 108,070	$ 76,694
Noncurrent liabilities	38,057	33,883
Stockholders' equity	247,949	79,998
	$ 394,076	$ 190,575

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Source: Geron Corporation