Geron Corporation Reports First Quarter 2024 Financial Results and Business Highlights

May 2, 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 financial results and business highlights for the first quarter 2024.

“Since the FDA ODAC’s 12 to 2 vote in favor of the clinical benefit/risk profile of imetelstat for the treatment of transfusion-dependent anemia in patients with lower-risk MDS in March, we have continued working with the FDA as they complete their review of our New Drug Application, which has a June 16, 2024 PDUFA target action date,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “We are actively preparing for a successful launch of imetelstat in the U.S., if approved, including most recently onboarding our sales force last month, refining our market research and completing buildout of our enterprise capabilities and systems to support our transition from a clinical to commercial-stage company.”

U.S. Commercial Preparation

Geron has now completed onboarding its commercial team, with the buildout of the full sales organization in April. Other commercial preparations for the U.S. are ongoing and on target, including enhancing and/or establishing company processes and systems to support an expected commercial launch, refining market research in TD LR-MDS, and engaging in marketing, commercial access, payer, and reimbursement preparatory efforts.

Clinical Development Update

The Phase 3 IMpactMF clinical trial, which has a primary endpoint of overall survival, is ongoing in myelofibrosis patients who are relapsed/refractory to JAK inhibitors. Last month, the data monitoring committee evaluated unblinded data and recommended the clinical trial continue. In addition, the Company reviewed enrollment rates and blinded death rates, which are lower than anticipated based on initial planning assumptions. Accordingly, guidance is being updated to extend the timelines by half a year, with the interim analysis now expected in early 2026 and the final analysis expected in early 2027.

First Quarter 2024 Financial Results

As of March 31, 2024, the Company had approximately $465 million in cash and marketable securities, including proceeds from an underwritten public offering of common stock and a pre-funded warrant in March 2024 for net proceeds of approximately $141 million.

For the first quarter of 2024, the Company reported a net loss of $55.4 million, or $0.09 per share, compared to $38.1 million, or $0.07 per share, for the first quarter of 2023.

Revenues for the first quarter of 2024 were $304,000, compared to $21,000 for the same period in 2023. Royalty revenues in 2024 and 2023 primarily reflect estimated royalties from sales of cell-based research products from the Company’s divested stem cell assets.

Total operating expenses for the first quarter of 2024 were $56.4 million, compared to $40.1 million for the same period in 2023. Research and development expenses for the first quarter of 2024 were $29.4 million, compared to $27.2 million for the same period in 2023. The increase in research and development expenses for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects the net result of higher manufacturing costs due to the timing of imetelstat manufacturing batches and increased personnel-related expenses for additional headcount. We expect research and development expenses to remain consistent in the future as we support IMpactMF, IMproveMF and IMpress, as well as the long-term treatment and follow-up of remaining patients in IMerge. General and administrative expenses for the first quarter of 2024 were $27.1 million, compared to $12.9 million for the same period in 2023. The increase in general and administrative expenses for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects new costs for commercial preparatory activities and higher personnel-related expenses for additional headcount.

Interest income for the first quarter of 2024 was $4.2 million, compared to $3.9 million for the same period in 2023. The increase in interest income for the three months ended March 31, 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 for the first quarter of 2024 was $3.4 million, compared to $1.9 million for the same period in 2023. The increase in interest expense for the three months ended March 31, 2024, compared to the same period in 2023, primarily reflects higher interest rates. Currently, we have $80.0 million in principal debt outstanding. Interest expense reflects interest owed under our loan facility.

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; build out of our commercial organization to support the potential U.S. commercial launch of imetelstat in the U.S.; increases in headcount in preparation for transition to a commercial-stage company; and interest payments on outstanding debt.

Based on our current operating plans and our assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of our outstanding warrants, and potential future drawdowns under our loan facility, will be sufficient to fund our projected operating requirements into the second quarter of 2026.

As of March 31, 2024, we had 162 full-time employees, prior to the onboarding of our salesforce in April 2024. Subject to approval of imetelstat in the U.S., the Company plans to grow to a total of approximately 250-300 employees by year-end 2024.

Conference Call

Geron will host a conference call at 8:00 a.m. ET on Thursday, May 2, 2024, to discuss business updates and first 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/934891352**

About Imetelstat

Imetelstat is a novel, first-in-class investigational telomerase inhibitor exclusively owned by Geron and being developed by Geron 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. 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 kinase (JAK) inhibitor treatment. Imetelstat is currently not approved by any regulatory authority.

About IMpactMF

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 refractory to prior treatment with a JAK inhibitor, also referred to as 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.

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 U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of June 16, 2024. In addition, the European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for the same proposed indication and is under review. 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 Company's work with the FDA to complete the review of the NDA for imetelstat in lower-risk MDS; (ii) preparations for a potential launch in TD LR-MDS in the U.S. upon potential approval by the FDA (PDUFA date June 16, 2024); (iii) that the interim analysis of IMpactMF is expected in early 2026 and the final analysis is expected in early 2027; (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 Q2 2026, 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 annual report on Form 10-K for the year ended December 31, 2023, 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

UNAUDITED

(In thousands, except share and per share data)	Three Months Ended March 31, 2024	2023
Revenues:		
Royalties	$ 304	$ 21
Operating expenses:		
Research and development	29,373	27,219
General and administrative	27,065	12,894
Total operating expenses	56,438	40,113
Loss from operations	(56,134)	(40,092)
Interest income	4,239	3,853
Interest expense	(3,433)	(1,922)
Other income and (expense), net	(62)	39
Net loss	$ (55,390)	$ (38,122)

Basic and diluted net loss per share:		
Net loss per share	$ (0.09)	$ (0.07)
Shares used in computing net loss per share	603,493,451	544,459,004

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	**March 31, 2024**	**December 31, 2023**
	(Unaudited)	**(Note 1)**
Current assets:		
Cash, cash equivalents and restricted cash	$ 190,880	$ 71,138
Current marketable securities	253,288	263,676
Other current assets	7,341	6,534
Total current assets	451,509	341,348
Noncurrent marketable securities	20,782	43,298
Property and equipment, net	1,681	1,177
Deposits and other assets	8,102	8,253
	$ 482,074	$ 394,076
Current liabilities	$ 123,158	$ 108,070
Noncurrent liabilities	14,048	38,057
Stockholders' equity	344,868	247,949
	$ 482,074	$ 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.

Aron Feingold

Vice President, Investor Relations and Corporate Communications

Kristen Kelleher

Associate Director, Investor Relations and Corporate Communications

investor@geron.com

media@geron.com

Source: Geron Corporation