Geron Corporation Reports First Quarter 2023 Financial Results and Business Highlights

May 11, 2023

Planned submission of U.S. New Drug Application on track for June 2023

Additional data and analyses from IMerge Phase 3 expected to be presented at upcoming medical meetings further strengthen differentiating qualities of imetelstat

Preparations for potential commercial launch in the U.S. ongoing

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

“We believe that imetelstat has a compelling commercial value proposition and is well-positioned to become a standard of care in lower risk MDS, based on unprecedented broad durability of transfusion independence in the IMerge Phase 3 trial and high unmet need in this patient population,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “We are on track to submit a New Drug Application in the U.S. next month and are preparing for a potential U.S. commercial launch in the first half of 2024. Further, we are planning to submit a Marketing Authorization Application in the EU in the second half of 2023 and preparing for an EU commercial launch by the end of 2024.”

Dr. Scarlett also noted, “We also continue to make progress on recruiting and enrolling patients into IMpactMF, the first and only Phase 3 study of JAK inhibitor relapsed/refractory myelofibrosis patients with a primary endpoint of overall survival. If this trial is successful, we expect imetelstat to become a transformational agent for these patients.”

Dr. Scarlett added, “As of the end of the quarter, we had over $400 million on the balance sheet, which we believe provides the financial resources to operate the company through the end of the third quarter of 2025. This means we expect to launch in lower risk MDS without being compromised by lack of funding, while also supporting IMpactMF and our other ongoing earlier stage programs.”

Financial Resources to Support Potential Commercial Launch of Imetelstat in Lower Risk Myelodysplastic Syndromes (MDS)

As of March 31, 2023, the Company had $409.2 million in cash and marketable securities. In January 2023, the Company closed an underwritten public offering of common stock and pre-funded warrant, plus the full exercise of the underwriters’ option to purchase additional shares of common stock, for net cash proceeds of $213.3 million, after deducting the underwriting discount and other offering expenses. In addition, the Company received $59.8 million upon the cash exercise of outstanding warrants in the first quarter of 2023. Based on the Company’s current operating plans and expectations regarding the timing of regulatory approval and commercialization of imetelstat in the United States (U.S.) in the first half of 2024, Geron projects that its existing financial resources will be sufficient to fund its projected operating requirements through the end of the third quarter of 2025.

First Quarter 2023 Financial Results

For the first quarter of 2023, the Company reported a net loss of $38.1 million, or $0.07 per share, compared to $30.1 million, or $0.09 per share, for the first quarter of 2022.

Revenues for the first quarter of 2023 were $21,000 compared to $123,000 for the same period in 2022. Royalty revenues in 2023 and 2022 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 2023 were $40.1 million, compared to $28.8 million for the same period in 2022. Research and development expenses for the first quarter of 2023 were $27.2 million, compared to $22.1 million for the same period in 2022. The increase in research and development expenses for the three months ended March 31, 2023, compared to the same period in 2022, primarily reflects higher clinical trial costs related to supporting IMerge Phase 3 and IMpactMF and increased personnel-related expenses for additional headcount. General and administrative expenses for the first quarter of 2023 were $12.9 million compared to $6.7 million for the same period in 2022. The increase in general and administrative expenses for the three months ended March 31, 2023, compared to the same period in 2022, primarily reflects new costs for commercial preparatory activities and higher personnel-related expenses for additional headcount.

Interest income for the first quarter of 2023 was $3.9 million, compared to $112,000 for the same period in 2022. The increase in interest income for the three months ended March 31, 2023, compared to the same period in 2022, primarily reflects higher yields

on the Company's marketable securities as a result of rising interest rates, as well as a larger investment portfolio with the cash proceeds from the January 2023 offering and warrant exercises in the first quarter of 2023.

Interest expense for the first quarter of 2023 was $1.9 million, compared to $1.5 million for the same period in 2022. The increase in interest expense for the three months ended March 31, 2023, compared to the same period in 2022, primarily reflects higher interest rates. Under the terms of the loan agreement, the interest-only payment period was extended by 12 months from April 2023 to April 2024 as a result of achieving positive top-line results from IMerge Phase 3 in January 2023. Currently, the Company has $50.0 million in principal debt outstanding.

Projected 2023 Financial Guidance Reaffirmed

For fiscal year 2023, under generally accepted accounting principles (GAAP), the Company continues to expect total expenses in the range of approximately $210 million to $220 million, which includes non-cash items such as: stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization. The Company expects non-GAAP total expenses for fiscal year 2023 to be in the range of approximately $200 million to $210 million. This guidance excludes estimated non-cash items such as: stock-based compensation expense, amortization of debt discounts and issuance costs, as well as depreciation and amortization.

The fiscal year 2023 financial guidance reflects costs to support planned regulatory submissions in 2023; continued support of ongoing clinical trials, IMerge Phase 3, IMpactMF, IMproveMF and IMpress, as well as preclinical studies in lymphoid malignancies and discovery research for a next generation telomerase inhibitor; manufacturing commercial inventory of imetelstat; preparations for potential U.S. commercial launch of imetelstat in lower risk MDS; projected increases in headcount and interest payments on outstanding debt.

As of March 31, 2023, the Company had 120 employees. The Company plans to grow to a total of approximately 150 to 160 employees by year-end 2023.

Conference Call

Geron will host a conference call at 10:30 a.m. ET on Thursday, May 11, 2023 to discuss business updates, expected upcoming milestones 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://conferencingportals.com/event/SmvIMvWL.

About Imetelstat

Imetelstat is a novel, first-in-class 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 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 MF whose disease has relapsed after or is refractory to janus associated kinase (JAK) inhibitor treatment.

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 RBC-TI lasting at least eight weeks, which is 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 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

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 biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. The Company's investigational first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize-winning science in a treatment that may alter the underlying drivers of disease. Geron currently has a Phase 3 clinical trial underway evaluating imetelstat in each of: (i) lower risk myelodysplastic syndromes (LR MDS), and (ii) relapsed/refractory myelofibrosis (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) that for IMerge Phase 3, Geron plans: to submit a New Drug Application in the U.S. in June 2023 and a Marketing Authorization Application in the EU in the second half of 2023, and is preparing for a potential launch in lower risk MDS in the U.S. in the first half of 2024, and in the EU by the end of 2024; (ii) that imetelstat has the potential to demonstrate disease-modifying activity in patients; (iii) that for fiscal year 2023, under GAAP the Company expects total expenses to be in the range of $210 to $220 million, and non-GAAP total expenses to be in the range of $200 to $210 million; (iv) that the Company believes the over $400 million currently on the balance sheet provides the financial resources to operate the Company through the end of the third quarter of 2025; (v) that IMpactMF has registrational intent; and (vi) 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 the current or evolving effects of the COVID-19 pandemic and/or geopolitical events and resulting global economic and financial disruptions will materially and adversely impact Geron's business and business prospects, its financial condition and the future of imetelstat; (b) whether Geron overcomes all of the potential delays and other adverse impacts caused by the current or evolving effects of the COVID-19 pandemic and/or geopolitical events, as well as all the 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 in (i) and (iii) to (iv) above; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether imetelstat has demonstrated sufficient safety and efficacy and clinical benefit in IMerge Phase 3 to enable regulatory approval; (e) whether any future safety or efficacy results cause the benefit-risk profile of imetelstat to become unacceptable; (f) whether imetelstat actually demonstrates disease-modifying activity in patients and the ability to target the malignant stem and progenitor cells of the underlying disease; (g) 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 in (i) and (iii) to (iv) above; (h) whether regulatory authorities require an additional imetelstat lower risk MDS clinical trial for approval, or post-approval; (i) 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 lower risk MDS or the IMpactMF trial; (j) whether the follow-up period of 12 months for the IMerge Phase 3 primary analysis was sufficient to demonstrate safety and efficacy, including transfusion independence and clinical benefit, and obtain regulatory approval; and (k) for IMerge Phase 3, the FDA may require Geron to submit additional information or require advisory committee procedures that could cause a regulatory approval, if any, to be delayed. 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, 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.

Non-GAAP Financial Measure

To supplement our financial results and guidance presented in accordance with GAAP, the Company is presenting non-GAAP total expenses, which excludes stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization, from GAAP total expenses. The Company believes this non-GAAP financial measure, when considered together with other financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Geron's results from period to period and to projected forward-looking guidance, and to identify operating trends in Geron's business. The exclusion of non-cash items, such as stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization, does not directly or immediately relate to the operational performance for the periods presented. This non-GAAP financial measure is in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Geron encourages investors to carefully consider the Company's results under GAAP, as well as the supplemental non-GAAP financial information, to more fully understand Geron's

business.

Financial table follows.

GERON CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	UNAUDITED Three Months Ended March 31, 2023	2022
Revenues:		
Royalties	$ 21	$ 123
Operating expenses:		
Research and development	27,219	22,099
General and administrative	12,894	6,699
Total operating expenses	40,113	28,798
Loss from operations	(40,092)	(28,675)
Interest income	3,853	112
Interest expense	(1,922)	(1,479)
Other income and (expense), net	39	(56)
Net loss	$ (38,122)	$ (30,098)
Basic and diluted net loss per share:		
Net loss per share	$ (0.07)	$ (0.09)
Shares used in computing net loss per share	544,459,004	332,066,889

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	March 31, 2023 (Unaudited)	December 31, 2022 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	$ 113,142	$ 57,209
Current marketable securities	267,964	115,901
Other current assets	5,917	7,136
Total current assets	387,023	180,246
Noncurrent marketable securities	28,100	—
Property and equipment, net	1,066	793
Deposits and other assets	8,688	9,536
	$ 424,877	$ 190,575
Current liabilities	$ 43,911	$ 76,694
Noncurrent liabilities	54,911	33,883
Stockholders' equity	326,055	79,998
	$ 424,877	$ 190,575

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2022.

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Source: Geron Corporation