Geron Corporation Reports Business Highlights and Third Quarter 2023 Financial Results

November 2, 2023

Imetelstat is currently under regulatory review by the FDA and EMA for the treatment of transfusion-dependent anemia in adult patients with lower risk MDS

Planning is ongoing for a potential commercial launch in the U.S. in mid-2024

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 highlights and financial results for the third quarter of 2023.

“This quarter, we continued to make important progress and build momentum along our planned path to develop and commercialize imetelstat, which is now the first telomerase inhibitor to be under review by both the FDA and EMA for potential regulatory approval,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “We see lower risk MDS as a very compelling commercial opportunity, with few durable treatment options and significant need for large patient segments such as patients without sideroblasts (RS-) and those with high transfusion burden. We believe, if approved, that imetelstat could play a meaningful role in this treatment landscape.”

Dr. Scarlett continued, “We believe that we are in a strong position to execute upon a potential launch in the U.S., bolstered by an experienced leadership team and with our talented commercial and medical affairs leadership teams fully onboarded. Additionally, with approximately $382 million on the balance sheet as of the end of the quarter, and expected available resources, we have the financial resources to fund a potential successful launch in the U.S. and our planned operations through the end of Q3 2025.”

Business Highlights

- Received acceptance from the U.S. Food & Drug Administration (FDA) of the New Drug Application (NDA) submitted for imetelstat for the treatment of transfusion-dependent anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS), or lower risk MDS, 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. In addition, the FDA informed the Company that it is currently planning to hold an advisory committee meeting as part of the NDA review.
- Submitted the Marketing Authorization Application (MAA) for imetelstat in the same lower risk MDS indication as in the NDA and received validation from the European Medicines Agency (EMA) that the application is under regulatory review by the European Committee for Medicinal Products for Human Use (CHMP) under the centralized procedure. Review of the MAA is expected to be completed by the end of 2024.
- Presented encore data and analyses from the IMerge Phase 3 clinical trial evaluating imetelstat in patients with lower risk MDS at the Society of Hematologic Oncology Annual Meeting. New analyses from this trial are also planned at the American Society of Hematology (ASH) Annual Meeting, on which a separate press release will be issued.
- Escalated to the second dose cohort in the Phase 1 ImproveMF study evaluating imetelstat as a combination therapy with ruxolitinib in patients with frontline myelofibrosis (MF) following a unanimous decision by the study’s Safety Evaluation Team (SET), who reviewed the first cohort (3 patients) data and identified no dose-limiting toxicities.
- Appointed Michelle Robertson as Executive Vice President, Chief Financial Officer and Treasurer, following Olivia Bloom’s retirement. Ms. Robertson brings to Geron over 30 years of financial and commercial operations experience. Prior to joining, she served as the Chief Financial Officer and Treasurer of Editas Medicine, a CRISPR genome editing company, where she raised $500M in capital over three years to support the company’s research transition into late-stage clinical development. Before that, she served as Chief Financial Officer of Momenta Pharmaceuticals, Inc. from 2018 until 2020, leading the finance team through a strategic restructure, before its acquisition by Johnson & Johnson. Prior to joining Momenta, Ms. Robertson held multiple finance and commercial operations roles of increasing responsibility.

Third Quarter 2023 Financial Results

As of September 30, 2023, the Company had $381.9 million in cash, cash equivalents, and marketable securities. In the third quarter of 2023, the Company received $28.3 million upon the cash exercise of outstanding warrants. As of September 30, 2023, warrants remaining outstanding are exercisable for potential future proceeds of $3.2 million. 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, 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 requirements through the end of Q3 2025.

Revenues for the three and nine months ended September 30, 2023, were $164,000 and $214,000, respectively, compared to $297,000 and $493,000 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 nine months ended September 30, 2023, were $47.8 million and $139.9 million, respectively, compared to $40.2 million and $97.1 million for the comparable 2022 periods.

Research and development expenses for the three and nine months ended September 30, 2023, were $29.4 million and $92.1 million, respectively, compared to $24.6 million and $67.3 million for the comparable 2022 periods. The increase in research and development expenses for the three and nine months ended September 30, 2023, compared to the same periods in 2022 primarily reflects higher clinical trial costs related to supporting IMerge Phase 3 and IMpactMF, increased personnel-related expenses for additional headcount, higher consulting costs to support regulatory submissions and greater imetelstat manufacturing costs in preparation for potential commercialization in lower risk MDS.

General and administrative expenses for the three and nine months ended September 30, 2023, were $18.4 million and $47.7 million, respectively, compared to $15.6 million and $29.8 million for the comparable 2022 periods. The increase in general and administrative expenses for the three and nine months ended September 30, 2023, compared to the same periods in 2022, primarily reflects new costs for commercial preparatory activities and higher personnel-related expenses for additional headcount.

Interest income was $5.0 million and $13.6 million for the three and nine months ended September 30, 2023, respectively, compared to $852,000 and $1.3 million for the same periods in 2022. The increase in interest income for the three and nine months ended September 30, 2023, compared to the same periods 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 public offering and warrant exercises in the first nine months of 2023.

Interest expense was $2.0 million and $6.0 million for the three and nine months ended September 30, 2023, respectively, compared to $1.8 million and $4.9 million for the same periods in 2022. The increase in interest expense for the three and nine months ended September 30, 2023, compared to the same periods in 2022, primarily reflects higher interest rates. Currently, the Company has $50.0 million in principal debt outstanding.

Projected 2023 Financial Guidance

For fiscal year 2023, under generally accepted accounting principles (GAAP), the Company continues to expect total expenses in the range of approximately $200 million to $210 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 2023 financial guidance reflects costs to support regulatory submissions with the FDA and EMA in 2023; continued support of ongoing clinical trials, IMerge Phase 3, IMpactMF, ImproveMF, and the investigator-led Impress trial, as well as preclinical studies in lymphoid malignancies and discovery research for a next generation telomerase inhibitor; manufacturing of 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 September 30, 2023, the Company had 137 employees. The Company plans to grow to a total of approximately 160 employees by year-end 2023.

Conference Call

Geron will host a conference call at 9:00 am ET on Thursday, November 2, 2023 to discuss business updates and third quarter 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://conferencingportals.com/event/UqsyjoKj.

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 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 (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 (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) continued progress and momentum in the Company's planned development and commercialization of imetelstat; (ii) the potential commercial opportunity for imetelstat and that it could play a meaningful role in the treatment of patients without sideroblasts (RS-) and those with high transfusion burden; (iii) plans for a potential launch in lower risk MDS in the U.S. by the end of the first half of 2024 and for the MAA review to be completed by the end of 2024; (iv) the Company's projections and expectations regarding the sufficiency of its cash resources and expected available resources to fund its projected operating requirements through the end of Q3 2025, and the assumptions underlying such projections and expectations; (v) the PDUFA action date of June 16, 2024 and the FDA's plans to hold an advisory committee meeting as part of the NDA review; (vi) the Company's plans to present additional data at ASH; (vii) the Company's projections for total expenses for fiscal 2023 and employee headcount as of the end of 2023; (viii) that imetelstat has the potential to demonstrate disease-modifying activity in patients; (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 health pandemics and/or geopolitical events and any resulting economic and financial disruptions will materially and adversely impact Geron's business and business prospects, results of operations and financial condition; (b) 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; (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, efficacy and clinical benefit in IMerge Phase 3 to enable regulatory approval; (e) whether any future safety or efficacy results of imetelstat treatment 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 noted herein; (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 continuation of the IMpactMF trial; (j) 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 (k) whether the FDA and EMA will approve imetelstat for the treatment of transfusion-dependent anemia in patients with lower risk 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.

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,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Royalties	$ 164	$ 297	$ 214	$ 493
Operating expenses:				
Research and development	29,426	24,603	92,135	67,308
General and administrative	18,350	15,642	47,734	29,784
Total operating expenses	47,776	40,245	139,869	97,092
Loss from operations	(47,612)	(39,948)	(139,655)	(96,599)
Interest income	4,965	852	13,556	1,294
Interest expense	(2,066)	(1,817)	(5,991)	(4,877)
Other income and expense, net	(92)	(138)	(64)	916
Net loss	$ (44,805)	$ (41,051)	$ (132,154)	$ (99,266)
Basic and diluted net loss per share:				
Net loss per share	$ (0.08)	$ (0.10)	$ (0.23)	$ (0.26)
Shares used in computing net loss per share	579,508,305	405,237,474	562,445,577	380,659,049

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	September 30, 2023	December 31, 2022
	(Unaudited)	**(Note 1)**
Current assets:		
Cash, cash equivalents and restricted cash	$ 31,245	$ 57,209
Current marketable securities	282,818	115,901
Other current assets	21,022	7,136
Total current assets	355,085	180,246
Noncurrent marketable securities	67,821	—
Property and equipment, net	1,231	793
Deposits and other assets	8,880	9,536
	$ 413,017	$ 190,575
Current liabilities	$ 89,386	$ 76,694
Noncurrent liabilities	33,017	33,883
Stockholders' equity	290,614	79,998
	$ 413,017	$ 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