**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

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# FORM 8-K

**CURRENT REPORT**
**PURSUANT TO SECTION 13 OR 15(d) OF THE**
**SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **March 14, 2024**

**GERON CORPORATION**
(Exact name of registrant as specified in its charter)

| **Delaware** | **000-20859** | **75-2287752** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**919 E. HILLSDALE BLVD., SUITE 250**
**FOSTER CITY, CALIFORNIA 94404**

(Address of principal executive offices, including zip code)

**(650) 473-7700**
(Registrant's telephone number, including area code)

**N/A**
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.001 par value | GERN | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01 Other Events.**

On March 14, 2024, Geron Corporation (the "Company") issued a press release announcing the results of the U.S. Food and Drug Administration Oncologic Drugs Advisory Committee, virtually held on March 14, 2024, in connection with the Company's New Drug Application for imetelstat for the treatment of transfusion-dependent 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. A copy of the press release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release |
| 104 | Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document) |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GERON CORPORATION

Date: March 14, 2024

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Executive Vice President, Chief Legal Officer and Corporate Secretary

**Geron Announces FDA Oncologic Drugs Advisory Committee Votes in Favor of the Clinical Benefit/Risk Profile of Imetelstat for the Treatment of Transfusion-Dependent Anemia in Patients with Lower-Risk MDS**

- **FDA Oncologic Drugs Advisory Committee voted 12 to 2 in favor of the clinical benefit/risk profile of imetelstat based on results from the IMerge Phase 3 clinical trial**
- **There are significant unmet needs across key TD LR-MDS patient populations, including difficult-to-treat subgroups that are underserved by currently available treatment options**
- **June 16, 2024 PDUFA target action date for imetelstat NDA for the treatment of TD anemia in adult patients with LR-MDS**

**FOSTER CITY, Calif., March 14, 2024** -- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company developing investigational first-in-class telomerase inhibitor, imetelstat, to treat hematologic malignancies, today announced that the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 12 to 2 in favor of the clinical benefit/risk profile of imetelstat for the treatment of transfusion-dependent (TD) anemia in adult patients with low-to-intermediate-1 risk myelodysplastic syndromes (LR-MDS) who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESAs).

“We are pleased with the Committee’s decision to recognize the positive clinical benefit/risk profile of imetelstat for the treatment of transfusion-dependent anemia in adult patients with lower-risk MDS. There are few treatment options and significant unmet medical need remains for these patients, particularly among those with difficult-to-treat subtypes of this blood cancer,” said Faye Feller, M.D., Geron’s Executive Vice President, Chief Medical Officer. “We believe that imetelstat has the potential to be an important new medicine for patients and look forward to continuing our collaboration with the FDA as they complete their review of our New Drug Application.”

The ODAC reviewed the results from the IMerge Phase 3 clinical trial. The primary endpoint of red blood cell transfusion independence (RBC-TI) for at least eight consecutive weeks was significantly higher with imetelstat vs. placebo ($p<0.001$), with median RBC-TI duration approaching one year for imetelstat ≥8-week RBC-TI responders. In addition, 28% of imetelstat-treated patients compared to 3% on placebo obtained a statistically significant improvement in the key secondary endpoint of at least 24-week RBC-TI. For those patients achieving ≥24-week RBC-TI, the median duration was 80 weeks. Clinically meaningful RBC-TI was achieved across key MDS subgroups irrespective of ring sideroblast (RS) status, baseline transfusion burden and International Prognostic Scoring (IPSS) risk category. Additionally, a sustained increase in mean hemoglobin levels in imetelstat-treated patients was observed over time compared to placebo patients. Consistent with prior imetelstat clinical experience, the most common Grade 3-4 adverse events were thrombocytopenia (62%) and neutropenia (68%) that were generally manageable and of short duration.

The FDA assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 16, 2024 for Geron’s 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 ESAs. The ODAC provides the FDA with independent opinions and recommendations from outside medical experts, patients and caregivers, though the recommendations are not binding. Geron plans to commercially launch imetelstat in the U.S. upon potential FDA approval.

**About IMerge Phase 3**

The Phase 3 portion of the IMerge Phase 2/3 trial 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 hypomethylating agent 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 RBC-TI). Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks (24-week RBC-TI), the duration of RBC-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, the Middle East and Asia.

**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 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) few treatment options and significant unmet needs across key TD LR-MDS patient populations, including difficult-to-treat subgroups that are underserved by currently available treatment; (ii) that imetelstat has the potential to be an important new medicine and Geron’s plans to work with the FDA as they complete their review of the NDA; (iii) plans to commercially launch in the U.S. upon potential approval by the FDA (PDUFA date June 16, 2024); (iv) that imetelstat has the potential to demonstrate disease-modifying activity in patients; (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 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 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.

**CONTACT:**

Aron Feingold
Vice President, Investor Relations and Corporate Communications

Kristen Kelleher
Associate Director, Investor Relations and Corporate Communications

investor@geron.com
media@geron.com

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