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

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): **June 6, 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 June 6, 2024, Geron Corporation (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has approved RYTELO™ (imetelstat) for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent (TD) anemia requiring four or more red blood cell units over eight weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated June 6, 2024
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: June 7, 2024

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

Geron Announces FDA Approval of RYTELO™ (imetelstat), a First-in-Class Telomerase Inhibitor, for the Treatment of Adult Patients with Lower-Risk MDS with Transfusion-Dependent Anemia

- *Approval across ESA ineligible and ESA relapsed/refractory patients with LR-MDS with transfusion-dependent anemia, regardless of ring sideroblast (RS) status*
- *Durable and sustained red blood cell transfusion independence, increases in hemoglobin levels and reduction in transfusion burden observed across key LR-MDS subgroups in the IMerge Phase 3 clinical trial; the most common Grade 3/4 adverse reactions were thrombocytopenia and neutropenia, which were generally manageable and short-lived*
- *Lower-risk MDS is a progressive blood cancer with high unmet need, where many patients with anemia become dependent on red blood cell transfusions, which can be associated with clinical consequences and decreased quality of life*
- *Conference call with Geron management scheduled at 8am ET on Friday, June 7, 2024*

FOSTER CITY, Calif., June 6, 2024 – Geron Corporation (Nasdaq: GERN), a commercial-stage biopharmaceutical company aiming to change lives by changing the course of blood cancer, today announced that the U.S. Food and Drug Administration (FDA) has approved RYTELO™ (imetelstat) for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent (TD) anemia requiring four or more red blood cell units over eight weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

“With the approval and availability of RYTELO, we believe eligible patients with lower-risk MDS can potentially experience meaningful clinical benefit, particularly the potential for greater than 24 weeks of freedom from the burden of red blood cell transfusions and symptomatic anemia,” said John A. Scarlett, M.D., Geron’s Chairman and Chief Executive Officer. “The approval of RYTELO as the first telomerase inhibitor is a testament to the power of our science and the passion of our people to innovate in the field of blood cancer. As we celebrate today’s momentous milestone, I would like to thank the patients and families, advocates, clinicians, study coordinators and site personnel, scientists, and Geron employees and collaborators past and present whose participation was integral to this achievement and to supporting our transformation into a commercial company.”

Lower-risk myelodysplastic syndromes (LR-MDS) is a blood cancer that often progresses to require increasingly intensified management of key symptoms such as anemia and resulting fatigue. These symptomatic LR-MDS patients frequently become red blood cell transfusion dependent, which has been shown to be associated with short- and long-term clinical consequences that reduce quality of life and shorten survival[1]. There is a high unmet need for many LR-MDS patients, particularly those with characteristics having poorer prognosis. Current treatment options for those failing ESA are limited to select sub-populations and there is an unmet need for treatments that can provide extended and continuous red blood cell transfusion independence.

Approval Based on Results from IMerge Phase 3 Clinical Trial

“For patients with lower-risk MDS and anemia who are transfusion dependent, we have very few options today and often cycle through available therapies, making the approval of RYTELO potentially practice changing for us,” said Rami Komrokji, MD, Vice Chair, Malignant Hematology Department, Moffitt Cancer Center, who was an investigator of the pivotal IMerge clinical trial. “What is exciting about RYTELO is the totality of the clinical benefit across LR-MDS patients irrespective of ring sideroblast status or high transfusion burden, including sustained and durable transfusion independence and increases in hemoglobin levels, all within a well-characterized safety profile

of generally manageable cytopenias. The treatment goal for patients with LR-MDS and anemia is transfusion-independence and before today, this wasn't possible for many patients."

The FDA approval of RYTELO is based on results from the IMerge Phase 3 clinical trial, published in *The Lancet*. The IMerge trial met its primary and key secondary endpoints, with RYTELO demonstrating significantly higher rates of red blood cell transfusion independence (RBC-TI) versus placebo for at least eight consecutive weeks (RYTELO 39.8% [95% CI 30.9–49.3]; placebo 15.0% [7.1–26.6]; p<0.001) and for at least 24 weeks (RYTELO 28.0% [95% CI 20.1-37.0]; placebo 3.3% [95% CI 0.4-11.5]; p<0.001). RBC-TI was durable and sustained in the RYTELO treated population, with a median RBC-TI duration for 8-week responders and 24-week responders of approximately 1 year and 1.5 years, respectively.

In an exploratory analysis of RYTELO-treated patients achieving ≥8-week RBC-TI, median increases in hemoglobin were 3.6 g/dL for RYTELO and 0.8 g/dL for placebo. Clinically meaningful efficacy results were observed across key MDS subgroups irrespective of ring sideroblast (RS) status, baseline transfusion burden and IPSS risk category.

In the IMerge trial, the safety profile of RYTELO was well-characterized with generally manageable and short-lived thrombocytopenia and neutropenia, which are familiar side effects for hematologists who are experienced with managing cytopenias. The most common Grade 3/4 adverse reactions were neutropenia (72%) and thrombocytopenia (65%), which lasted a median duration of less than two weeks, and in more than 80% of patients were resolved to Grade $\leq$ 2 in under four weeks. Cytopenias were generally manageable with dose modifications. The intravenous administration of RYTELO every four weeks aligns to routine blood count monitoring for these patients.

The most common adverse reactions (incidence ≥10% with a difference between arms of >5% compared to placebo), including laboratory abnormalities, were decreased platelets (thrombocytopenia) , decreased white blood cells, decreased neutrophils (neutropenia), increased aspartate aminotransferase (AST), increased alkaline phosphatase (ALP), increased alanine aminotransferase (ALT), fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache. Clinically relevant adverse reactions in < 5% of patients who received RYTELO included febrile neutropenia, sepsis, gastrointestinal hemorrhage, and hypertension.

Conference Call Details

A conference call with Geron management is scheduled at 8am Eastern Time on Friday June 7, 2024 to discuss the FDA approval and launch of RYTELO. To access the webcast and slides, please visit the Investors & Media page. Participants may access the webcast by registering online using the following link, https://events.q4inc.com/attendee/923992744.

About RYTELO™ (imetelstat)
RYTELO™ (imetelstat) is an FDA-approved oligonucleotide telomerase inhibitor for the treatment of adult patients with low-to-intermediate-1 risk myelodysplastic syndromes (LR-MDS) with transfusion-dependent anemia requiring four or more red blood cell units over eight weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESAs). It is indicated to be administered as an intravenous infusion over two hours every four weeks.

RYTELO is a first-in-class treatment that works by inhibiting telomerase enzymatic activity. Telomeres are protective caps at the end of chromosomes that naturally shorten each time a cell divides. In LR-MDS, abnormal bone marrow cells often express the enzyme telomerase, which rebuilds those telomeres, allowing for uncontrolled cell division. Developed and exclusively owned by Geron, RYTELO is the first and only telomerase inhibitor approved by the U.S. Food and Drug Administration.

Geron aims to ensure broad access to RYTELO for eligible patients. Accordingly, our REACH4RYTELO™ Patient Support Program provides a range of resources that support access and affordability to eligible patients prescribed RYTELO.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombocytopenia

RYTELO can cause thrombocytopenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased platelets occurred in 65% of patients with MDS treated with RYTELO.

Monitor patients with thrombocytopenia for bleeding. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer platelet transfusions as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Neutropenia

RYTELO can cause neutropenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased neutrophils occurred in 72% of patients with MDS treated with RYTELO.

Monitor patients with Grade 3 or 4 neutropenia for infections, including sepsis. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Infusion-Related Reactions

RYTELO can cause infusion-related reactions. In the clinical trial, infusion-related reactions occurred in 8% of patients with MDS treated with RYTELO; Grade 3 or 4 infusion-related reactions occurred in 1.7%, including hypertensive crisis (0.8%). The most common infusion-related reaction was headache (4.2%). Infusion-related reactions usually occur during or shortly after the end of the infusion. Premedicate patients at least 30 minutes prior to infusion with diphenhydramine and hydrocortisone as recommended and monitor patients for one hour following the infusion as recommended. Manage symptoms of infusion-related reactions with supportive care and infusion interruptions, decrease infusion rate, or permanently discontinue as recommended.

Embryo-Fetal Toxicity

RYTELO can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RYTELO and for 1 week after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 32% of patients who received RYTELO. Serious adverse reactions in >2% of patients included sepsis (4.2%) and fracture (3.4%), cardiac failure (2.5%), and hemorrhage (2.5%). Fatal adverse reactions occurred in 0.8% of patients who received RYTELO, including sepsis (0.8%).

Most common adverse reactions (≥10% with a difference between arms of >5% compared to placebo), including laboratory abnormalities, were decreased platelets, decreased white blood cells, decreased

neutrophils, increased AST, increased alkaline phosphatase, increased ALT, fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache.

Please see RYTELO (imetelstat) full Prescribing Information, including Medication Guide, available at https://pi.geron.com/products/US/pi/rytelo_pi.pdf.

About Geron

Geron is a commercial-stage biopharmaceutical company aiming to change lives by changing the course of blood cancer. Our first-in-class telomerase inhibitor RYTELO™ (imetelstat) is FDA-approved for the treatment of adult patients with lower-risk MDS with transfusion dependent anemia. We are also conducting a pivotal Phase 3 clinical trial of imetelstat in JAK-inhibitor relapsed/refractory myelofibrosis (R/R MF), as well as studies in other hematologic malignancies. Inhibiting telomerase activity, which is increased in malignant stem and progenitor cells in the bone marrow, aims to potentially reduce proliferation and induce death of malignant cells. 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) Geron's belief that eligible patients with lower-risk MDS can potentially experience meaningful clinical benefit with RYTELO, particularly the potential for greater than 24 weeks of freedom from the burden of red blood cell transfusions and symptomatic anemia; (ii)an unmet need for new treatments for patients with LR-MDS that can provide extended and continuous red blood cell transfusion independence; (iii) that RYTELO could be practice-changing for hematologists who treat patients with lower-risk MDS and anemia who are transfusion dependent; (iv) the potential for RYTELO to offer a totality of clinical benefit across LR-MDS patients irrespective of ring sideroblast status or high transfusion burden, including sustained and durable transfusion independence and increases in hemoglobin levels, all within a well-characterized safety profile of generally manageable cytopenias; (v) that inhibiting telomerase activity aims to potentially reduce proliferation and induce death of malignant cells; (vi) that Geron aims to ensure broad access to RYTELO; (vii) that imetelstat has the potential to demonstrate disease-modifying activity in patients; (viii) that IMpactMF has registrational intent; and (ix) 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 is successful in commercializing RYTELO (imetelstat) for the treatment of patients with LR-MDS with transfusion dependent anemia; (b) whether Geron overcomes 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 meet expected timelines and planned milestones; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (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 continue the development and commercialization of imetelstat; (g) whether Geron meets its post-marketing requirements and commitments in the U.S. for RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia; (h) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials that impact commercialization of RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia 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 EMA will approve RYTELO for the treatment of patients with LR-MDS with transfusion dependent anemia and whether the FDA and EMA will approve imetelstat for 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 March 31, 2024, 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.

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