

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): **January 30, 2024**

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-20859

(Commission File Number)

75-2287752

(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.

As previously disclosed, in August 2023, Geron Corporation (“Geron” or the “Company”) announced that its New Drug Application (“NDA”) for the use of 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, was accepted by the United States Food and Drug Administration (“FDA”) for review and assigned a Prescription Drug User Fee Act (“PDUFA”) action date of June 16, 2024. On January 30, 2024, the FDA provided notice in the Federal Register that it has scheduled an advisory committee meeting of the Oncologic Drugs Advisory Committee as part of the NDA review, to be held virtually on March 14, 2024, from 9:30 a.m. to 3:00 p.m. Eastern Time. The meeting will be open to the public. For additional information, please see <https://federalregister.gov/d/2024-01797>.

Use of Forward-Looking Statements

Except for the historical information contained herein, this Current Report on Form 8-K 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, including, without limitation, those regarding the PDUFA action date for Geron’s imetelstat NDA and the date of the scheduled FDA advisory committee meeting, 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: uncertainty of regulatory actions, approvals or clearances, including the risks that the PDUFA action date for the NDA may be extended and that the FDA may ultimately determine not to approve the NDA in its present form or at all; that the date for the FDA advisory committee meeting may be changed and the discussions at and outcomes of that meeting; whether imetelstat may cause, or have attributed to it, adverse events that could further delay or prevent the commencement and/or completion of clinical trials, delay or prevent its regulatory approval, or limit its commercial potential; if imetelstat is approved for marketing and commercialization, whether Geron is able to establish and maintain effective sales, marketing and distribution capabilities, obtain adequate coverage and third-party payor reimbursement, and achieve adequate acceptance in the marketplace; the future development of imetelstat, including any future efficacy or safety results that may cause the benefit risk profile of imetelstat to become unacceptable; Geron’s need for additional capital to support the development and commercialization of imetelstat and to otherwise grow Geron’s business; establishing and maintaining imetelstat manufacture and supply; the enforcement of Geron’s patent and proprietary rights; managing Geron’s business growth; and potential competition. 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 of this Current Report on Form 8-K, 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.

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: January 30, 2024

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