GERON CORP
Form 8-K
January 27, 2014

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): **January 22, 2014**

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

Delaware	**0-20859**	**75-2287752**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

149 COMMONWEALTH DRIVE, SUITE 2070
MENLO PARK, CALIFORNIA 94025
(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 (see General Instruction A.2. below):

¨ 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))

Item 7.01 Regulation FD Disclosure.

In November 2012, Dr. Ayalew Tefferi (the investigator), of Mayo Clinic, initiated an investigator-sponsored clinical trial to evaluate imetelstat in patients with myelofibrosis and other myeloid malignancies (the Myelofibrosis IST). Mayo Clinic has informed Geron Corporation (the Company or Geron) that effective January 22, 2014, the Myelofibrosis IST has been closed to new patient enrollment, and that the remaining patients in the study will continue to receive imetelstat treatment and be followed under the Myelofibrosis IST protocol. The Company believes that approximately 79 patients have been enrolled in the Myelofibrosis IST, including nine patients with blast-phase myelofibrosis and nine patients with refractory anemia with ringed sideroblasts (RARS), a subpopulation of myelodysplastic syndromes, and that approximately 20 patients have discontinued from the study since its inception.

In December 2013 at the American Society of Hematology Annual Meeting, the investigator presented preliminary data from the first two cohorts of patients in the Myelofibrosis IST, including preliminary efficacy data for 22 patients and preliminary safety data for 33 patients. Based on this preliminary efficacy and safety data, the Company plans to initiate a Geron-sponsored, multi-center, Phase 2 clinical trial of imetelstat in patients with myelofibrosis in the first half of 2014. The Company also believes that the total accrued patients in the Myelofibrosis IST will be adequate for gathering additional and updated safety and efficacy data to support the imetelstat development program.

The Company expects that the investigator will present at a future medical conference additional and updated safety and efficacy data, including longer-term durability, for those patients previously reported and for additional remaining patients in the Myelofibrosis IST.

The information contained in this Item 7.01 to this Current Report shall be deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 7.01 to this Current Report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Use of Forward-Looking Statements

Except for statements of historical fact, 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, including without limitation, statements regarding: the remaining patients in the Myelofibrosis IST continuing to receive imetelstat treatment; the Company s planned Phase 2 clinical trial of imetelstat and the timing thereof; and other statements that are not historical facts. These forward-looking statements are generally identified by words such as expect, plan, will, and other similar expressions. In addition, any statements that refer to expectations, projections, or other characterizations of future events or circumstances are forward-looking statements. These 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 regarding: that Geron could be unable to initiate the planned Phase 2 clinical trial of imetelstat in a timely manner or at all; Geron s reliance on the conduct of and data from the Myelofibrosis IST; Geron s reliance on the investigator to continue to treat and follow patients in the Myelofibrosis IST; the fact that preliminary efficacy and safety data that the Company has reported from the Myelofibrosis IST may be materially different from the final data generated in the trial; that one or more of the efficacy or safety outcomes in the Myelofibrosis IST may materially change as patient treatment continues and additional and updated patient data becomes available; that adverse safety events could cause the benefit-risk profile for imetelstat to become unacceptable; and those other risks and uncertainties inherent in the development of potential therapeutic products such as successful company-sponsored clinical trial results; technical, scientific and regulatory challenges; sufficient capital resources; limitations on Geron s freedom to operate arising from intellectual property of others; and challenges or enforcement of Geron s intellectual property rights. More detailed additional information and factors that could cause actual results to differ materially from those in the forward-looking statements is contained in Geron s periodic reports filed with the Securities and Exchange Commission primarily under the heading Risk Factors, including in Geron s quarterly report on Form 10-Q for the quarter ended September 30, 2013. Undue reliance should not be placed on Geron s forward-looking statements. 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 27, 2014	By:	/s/ Stephen N. Rosenfield Stephen N. Rosenfield Executive Vice President, General Counsel and Corporate Secretary