

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): **July 31, 2017**

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

0-20859
(Commission File Number)

75-2287752
(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:

- 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))

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 July 31, 2017, Geron Corporation issued a press release entitled "Geron Announces Updates to Imetelstat Clinical Development." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated July 31, 2017.

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: August 1, 2017

By: /s/ Olivia Bloom
Name: Olivia K. Bloom
Title: Executive Vice President, Finance,
Chief Financial Officer and
Treasurer

EXHIBIT INDEX

Exhibit No. **Description**

[99.1](#) [Press release, dated July 31, 2017.](#)

Press Release, Dated July 31, 2017

Geron Announces Updates to Imetelstat Clinical Development

Conference Call Scheduled for 8:00 a.m. ET on Tuesday, August 1

MENLO PARK, Calif., July 31, 2017 -- Geron Corporation (Nasdaq: GERN) today announced updates to the clinical development plans for IMerge and IMbark, the ongoing trials of the telomerase inhibitor imetelstat in lower risk myelodysplastic syndromes (MDS) and relapsed or refractory myelofibrosis (MF), respectively, being conducted by Janssen Research & Development, LLC. For IMerge, Part 1 will be expanded to enroll additional patients in a refined MDS population to confirm the clinical benefit and safety observed from current results. For IMbark, the trial remains unchanged. Geron expects that the IMbark protocol-specified primary analysis, the completion of which triggers a future Continuation Decision by Janssen, will begin no later than the third quarter of 2018.

IMerge

Original Trial Design

IMerge (NCT02598661) is a Phase 2/3 clinical trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk MDS who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). The clinical trial is in two parts: Part 1 is a Phase 2, open-label, single-arm design in approximately 30 patients and Part 2 is designed to be a Phase 3, randomized, controlled trial in approximately 170 patients. The primary efficacy endpoint is the rate of red blood cell (RBC) transfusion independence (TI) lasting at least 8 weeks.

Trial Status Update

In Part 1 of IMerge, 32 patients were enrolled, of which a subset of 13 patients had not received prior treatment with either a hypomethylating agent (HMA) or lenalidomide and did not have a del(5q) chromosomal abnormality. As of May 2017, the 13-patient subset showed an increased durability and rate of transfusion independence compared to the overall trial population (≥ 8 -week RBC-TI: 53.8% vs 34.4%). The safety profile in Part 1 was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. The most common adverse events were cytopenias, which were manageable, and included grade 3/4 neutropenia and thrombocytopenia.

Based on these data from the 13-patient subset, the Joint Steering Committee has decided to amend Part 1 of the protocol to enroll approximately 20 additional patients who are non-del5q and naïve to HMA and lenalidomide treatment in order to increase the experience and confirm the benefit-risk profile of imetelstat dosed at 7.5 mg/kg every four weeks in this refined target patient population. Enrollment into the expanded Part 1 is expected to begin in the fourth quarter of 2017.

Separately, a data package and proposed refinements to the trial design for Part 2 of IMerge were previously provided to the FDA following an internal data review completed by Janssen in April, and related interactions are ongoing. Feedback from ongoing FDA interactions, data from the expanded Part 1, and other imetelstat program information, including the protocol-specified primary analysis for IMbark, are expected to inform Janssen's decision of whether to move forward to Part 2 of IMerge.

Detailed results for the original 32 patients in Part 1 of IMerge, including key secondary endpoints of hematologic improvement and rate of RBC-TI lasting at least 24 weeks, as well as duration of response and detailed safety information, will be submitted for presentation at a major medical conference.

IMbark

Trial Status Update

IMbark (NCT02426086) is a Phase 2 trial in patients with Intermediate-2 or High Risk MF who have relapsed after or are refractory to prior treatment with a JAK inhibitor. The trial continues without modification, and patients remaining in the treatment phase may continue to receive imetelstat. All safety and efficacy assessments will be conducted as planned in the protocol, which includes an assessment of a potential survival benefit associated with imetelstat treatment. To date, median overall survival has not yet been reached in either the 4.7 mg/kg or 9.4 mg/kg dosing arm. Enrollment of new patients to the trial remains suspended because the total number of patients enrolled to date is adequate to perform the protocol-specified primary analysis. Geron expects Janssen to perform an internal data review in the first quarter of 2018 to enable a potential protocol amendment to allow the long-term treatment and follow-up of patients, including for survival, beyond the current April 2018 per-protocol end-of-study date.

Continuation Decision

The Joint Steering Committee has agreed that the timing of the protocol-specified primary analysis for IMbark will begin upon the earlier of either a pre-specified number of deaths occurring in the trial or the end of the third quarter of 2018. Following completion of this primary analysis, which includes an assessment of potential survival benefit associated with imetelstat treatment, Janssen will notify Geron whether it elects to maintain the license rights and continue the development of imetelstat in any indication, i.e., the Continuation Decision.

Conference Call

At 8:00 a.m. EDT on August 1, 2017, Geron's management will host a conference call to discuss these updates to imetelstat clinical development. Participants can access the conference call live via telephone by dialing 877-303-9139 (U.S.); +1-760-536-5195 (international). The conference ID number is 42220500. A live audio-only webcast is also available through the company's website at www.geron.com in the Investors section under Events and at <http://edge.media-server.com/m/p/oqg6hyn5>. The audio webcast of the conference call will be available for replay approximately one hour following the live broadcast through September 1, 2017.

About Imetelstat

Imetelstat (GRN163L; JNJ-63935937) is a potent and specific inhibitor of telomerase that is administered by intravenous infusion. This first-in-class compound, discovered by Geron, is a specially designed and modified short oligonucleotide, which targets and binds directly with high affinity to the active site of telomerase. Preliminary clinical data suggest imetelstat has disease-modifying activity by inhibiting the progenitor cells of the malignant clones associated with hematologic malignancies in a relatively select manner. Most commonly reported adverse events in imetelstat clinical studies include fatigue, gastrointestinal symptoms and cytopenias. Imetelstat has not been approved for marketing by any regulatory authority.

About the Collaboration with Janssen

On November 13, 2014, Geron entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc., to develop and commercialize imetelstat for oncology, including hematologic myeloid malignancies, and all other human therapeutics uses. Under the terms of the agreement, Geron received an upfront payment of \$35 million and is eligible to receive additional payments up to a potential total of \$900 million for the achievement of development, regulatory and commercial milestones, as well as royalties on worldwide net sales. All regulatory, development, manufacturing and promotional activities related to imetelstat are being managed through a joint governance structure, with Janssen responsible for these activities. The joint governance structure includes a Joint Steering Committee with equal membership from both companies.

About Geron

Geron is a clinical stage biopharmaceutical company focused on the collaborative development of a first-in-class telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. For more information about Geron, visit www.geron.com.

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 statements in this press release regarding: (i) continued conduct by Janssen of IMbark and/or IMerge and any future clinical trials of imetelstat; (ii) amending the protocol for Part 1 of IMerge to expand enrollment in a refined target patient population; (iii) the timing for enrollment to begin for the expanded Part 1 of IMerge; (iv) potential feedback from ongoing FDA interactions; (v) any future presentation of data from current clinical trials of imetelstat by Janssen at a major medical conference; (vi) that Janssen will conduct an internal data review for IMbark in the first quarter of 2018 to enable a potential protocol amendment to allow long-term treatment and follow-up of patients; (vii) potential outcomes of any data reviews conducted by Janssen for IMbark or IMerge; (viii) the safety and efficacy of imetelstat; (ix) that median overall survival may be reached in IMbark; (x) the timing of the protocol-specified primary analysis for IMbark; (xi) that the number of patients enrolled to date in IMbark is adequate to perform the protocol-specified primary analysis and that approximately 20 additional patients in IMerge will be sufficient for decision-making; (xii) potential receipt by Geron of additional payments up to a potential total of \$900 million for the achievement of development, regulatory and commercial milestones, and royalties from sales of imetelstat; and (xiii) other statements that are not historical facts, constitute 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 related to: (i) whether Janssen decides to continue to conduct IMerge and/or IMbark; (ii) whether imetelstat is safe and efficacious and will succeed in IMbark and/or IMerge by overcoming all of the clinical safety and efficacy, technical, scientific, manufacturing and regulatory challenges; (iii) whether the FDA or other health authorities permit IMbark and/or IMerge to continue to proceed under the existing protocols or any amendments thereto; (iv) Janssen’s ability to collect additional and more mature data from current clinical trials of imetelstat; (v) Geron’s dependence on Janssen for the development, regulatory approval, manufacture and commercialization of imetelstat, including the risks that if Janssen were to breach or terminate the collaboration agreement or otherwise fail to successfully develop and commercialize imetelstat and in a timely manner, or at all, Geron would not obtain the anticipated financial and other benefits of the collaboration agreement with Janssen and the clinical development or commercialization of imetelstat could be delayed or terminated; (vi) whether any future efficacy or safety results from any clinical trial of imetelstat may cause the benefit/risk profile of imetelstat to become unacceptable; and (vii) whether patent coverage of imetelstat enables Janssen to successfully commercialize imetelstat. Additional information on the above-stated 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 periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors,” including Geron’s quarterly report on Form 10-Q for the quarter ended March 31, 2017. 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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