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): **May 16, 2019**

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:

☐ 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 May 16, 2019, Geron issued two press releases; one entitled "Geron Provides Imetelstat Program Update" and the other entitled "Geron Announces Two Presentations On Imetelstat at Upcoming European Hematology Association Annual Congress." A copy of each of the press releases is attached as Exhibit 99.1 and Exhibit 99.2, respectively, 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, "Geron Provides Imetelstat Program Update"
99.2	Press release, "Geron Announces Two Presentations On Imetelstat at Upcoming European Hematology Association Annual Congress"

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: May 16, 2019

By: /s/ Stephen N. Rosenfield

Name: Stephen N. Rosenfield

Title: Executive Vice President, Chief Legal Officer and Corporate Secretary

EXHIBIT 99.1

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Geron Provides Imetelstat Program Update

Conference Call Scheduled for 9:00 a.m. ET today

MENLO PARK, Calif., May 16, 2019 -- Geron Corporation (Nasdaq: GERN) today provided an update to its 2019 corporate objectives for the imetelstat program.

“2019 is off to a good start with the imetelstat IND transfer now complete, enabling us to move forward with the planned opening of the Phase 3 clinical trial in lower risk myelodysplastic syndromes for screening and enrollment, which we continue to expect by mid-year 2019,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “Our new development team has refined our regulatory strategies for myelofibrosis, which we plan to discuss at an End of Phase 2 meeting with the FDA by the end of the first quarter of 2020. We will be performing analyses to support these strategies, and we believe the results of these analyses will enhance the potential of determining a timely and cost-effective regulatory strategy for imetelstat in relapsed/refractory myelofibrosis.”

Imetelstat IND Sponsorship Transfer to Geron

As of May 14, 2019, Geron assumed the imetelstat investigational new drug (IND) sponsorship from Janssen. With the IND transfer complete, Geron is proceeding with start-up activities for the Phase 3 portion of IMerge and continues to expect the Phase 3 portion of IMerge to be open for screening and enrollment by mid-year. Geron expects to complete the transition of the imetelstat program by the end of the third quarter of 2019, including assuming the remaining non-clinical, manufacturing, and ex-U.S. clinical operational responsibilities from Janssen.

Planned Phase 3 Portion of IMerge Expected to Open Mid-Year

IMerge is a two-part clinical trial of imetelstat in transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (lower risk MDS). The second part of IMerge is designed as a Phase 3 double-blind, randomized, placebo-controlled trial in approximately 170 patients, which will evaluate imetelstat in transfusion dependent patients with non-del(5q) lower risk MDS who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA) and have not received treatment with either a hypomethylating agent (HMA) or lenalidomide. The Company expects the trial to be conducted at multiple medical centers globally, including North America, Europe, Middle East and Asia.

In preparation for the Phase 3 portion of IMerge and other potential future clinical trials of imetelstat, Geron is purchasing inventories of drug substance, drug product and raw materials for imetelstat manufacturing from Janssen. The Company expects this inventory to be sufficient to supply the Phase 3 portion of IMerge, as well as initial supply for potential future clinical trials of imetelstat in other indications. In addition, Geron is re-establishing its drug manufacturing supply chain and expects to have engaged all necessary contract manufacturing vendors by the end of the third quarter.

Planning End of Phase 2 Meeting for Relapsed/Refractory Myelofibrosis (MF)

Geron is revising its objective to communicate a decision regarding late-stage development in relapsed/refractory myelofibrosis (MF) by the end of the third quarter of 2019. This revision is based on recently refined strategies for potential regulatory approval proposed by the Company's new development team, as well as the time required to perform analyses necessary to support these strategies for discussions with regulatory authorities. The Company believes the results of these analyses will enhance the potential for reaching agreement with the U.S. Food and Drug Administration (FDA) on a timely and cost-effective regulatory strategy for imetelstat in relapsed/refractory MF.

The Company now plans to conduct an End of Phase 2 (EOP2) meeting with the FDA by the end of the first quarter of 2020. Subsequent to this meeting, the Company expects to provide a decision regarding late-stage development of imetelstat in relapsed/refractory MF.

Building a Robust Internal Development Team

Since the beginning of the year, Geron has recruited senior leadership with extensive oncology and drug development experience in key functional areas for its development team. In addition, several new hires with prior experience with the imetelstat program have recently joined the Company. The Company's successful recruiting efforts are building internal capabilities and leadership in clinical operations, clinical sciences and development, translational research, biostatistics, pharmacovigilance and drug safety, quality, regulatory and manufacturing.

This growing internal expertise will support the Company's current and future development plans, including the planned opening of the Phase 3 portion of IMerge for screening and enrollment, and evaluating potential additional indications for imetelstat, as well as the ability to evaluate other hematology-oncology assets to expand the Company's pipeline in the future.

Revised 2019 Financial Guidance

For fiscal year 2019, the Company has increased its total operating expense guidance to a range from $80 to $85 million, of which approximately $20 to $25 million represents one-time costs. The projected increase from the Company's prior total operating expense guidance primarily reflects the purchase of additional inventories of drug substance, drug product and raw materials for imetelstat manufacturing from Janssen in 2019 of approximately $10 million, and expected higher clinical operational costs of approximately $5 million.

As of May 15, 2019, the Company has 31 employees, and now plans to grow to a total of approximately 45 to 50 employees by year-end 2019, of whom half will be research and development personnel.

Current Ongoing Clinical Trials of Imetelstat

Patients currently enrolled in ongoing imetelstat clinical trials will continue to be supported through the respective trial protocols, including treatment and follow-up.

<u>Phase 2 Portion of IMerge</u>

The first part of IMerge was designed as a Phase 2, open label, single arm study to assess the efficacy and safety of imetelstat. The primary efficacy endpoint is 8-week RBC-TI rate, which is defined as the proportion of patients achieving red blood cell transfusion independence during any consecutive eight weeks since entry into the trial.

Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the rate of hematologic improvement-erythroid (HI-E), defined as a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. To be eligible for the Phase 2 or Phase 3 portion of IMerge, patients are required to be transfusion dependent, defined as requiring at least four units of packed RBCs over an eight-week period during the 16 weeks before entry into the trial. The Phase 2 portion of IMerge is closed to new patient enrollment.

As reported at the American Society of Hematology Meeting in December 2018, the 8-week RBC-TI rate in a combined cohort of 38 patients in the Phase 2 portion of IMerge was 37% (14/38) using a clinical data cut-off date of October 26, 2018. Based on the most recent clinical cut-off date, used to prepare the IMerge clinical data for the transition of the imetelstat program, the confirmed 8-week RBC-TI rate in the combined cohort is 42% (16/38).

IMbark

IMbark was designed as a Phase 2 clinical trial to evaluate two starting dose levels of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in patients with Intermediate-2 or High-risk MF who have relapsed after or are refractory to prior treatment with a janus kinase (JAK) inhibitor. The co-primary efficacy endpoints for the trial are spleen response rate and symptom response rate. Key secondary endpoints are safety and overall survival (OS). IMbark is closed to new patient enrollment.

As reported at the American Society of Hematology Meeting in December 2018, the median OS in the 9.4 mg/kg dosing arm of IMbark was 29.9 months using a data cut-off date of October 22, 2018. Based on the most recent clinical cut-off date, used to prepare the IMbark clinical data for the transition of the imetelstat program, the median OS in the 9.4 mg/kg dosing arm is 28.1 months.

Conference Call

Geron will host a conference call to discuss the imetelstat program update at 9:00 a.m. ET on Thursday, May 16, 2019, which will also include a discussion of future presentations of imetelstat clinical data.

Participants may access the conference call live via telephone by dialing domestically +1 (877) 303-9139 or internationally +1 (760) 536-5195. The conference ID is 1264477. A live, listen-only webcast will also be available on the Company's website at www.geron.com/investors/events. If you are unable to listen to the live call, an archived webcast will be available on the Company's website for 30 days.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic myeloid malignancies. Early clinical data suggest imetelstat may have disease-modifying activity through the suppression of malignant progenitor cell clone proliferation, which allows potential recovery of normal hematopoiesis. Ongoing clinical studies of imetelstat include a Phase 2/3 trial, called IMerge, in lower risk myelodysplastic syndromes (MDS) and a Phase 2 trial, called IMbark, in Intermediate-2 or High-risk myelofibrosis. Imetelstat has been granted Fast Track designation by the United States Food and Drug Administration for the treatment of patients with transfusion-dependent anemia due to lower risk MDS who are non-del(5q) and refractory or resistant to an erythroid stimulating agent.

About Geron

Geron is a late-stage clinical biopharmaceutical company focused on the development and potential commercialization 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 such statements, include, without limitation, those regarding: (i) that patient screening and enrollment for the Phase 3 portion of IMerge will be open by mid-year 2019; (ii) that the imetelstat program transition will be complete by the end of the third quarter of 2019; (iii) that the Phase 3 portion of IMerge will be conducted at multiple medical centers globally; (iv) that the inventory being purchased from Janssen will be sufficient to supply the Phase 3 portion of IMerge and initial supply for potential future clinical trials of imetelstat; (v) that Geron expects to have engaged all necessary contract manufacturing vendors by the end of the third quarter 2019; (vi) that Geron will conduct an EOP2 meeting with the FDA regarding relapsed/refractory MF by the end of the first quarter of 2020 and subsequently will provide its decision regarding late-stage development of imetelstat for that indication; (vii) Geron's belief that the results of the analyses to support strategies for potential regulatory approval will enhance the potential for reaching agreement with the FDA on a timely and cost-effective regulatory strategy for imetelstat in relapsed/refractory MF; (viii) that the Company's total operating expenses will be $80 to $85 million in 2019, and other financial projections and expectations; (ix) that the Company will grow to a total of 45 to 50 employees by year-end 2019; (x) that Geron's growing internal expertise will support its current and future development plans; (xi) that Geron has the ability to evaluate potential additional indications for imetelstat and other hematology-oncology assets to expand its pipeline in the future; (xii) that imetelstat may have disease-modifying activity; 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 the Company overcomes all the: (a) challenges of completing the transition of the imetelstat program from Janssen, and (b) clinical safety and efficacy, technical, scientific, manufacturing and regulatory challenges to enable the screening and enrollment of the Phase 3 portion of IMerge to open by mid-year 2019; (ii) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (iii) whether imetelstat is safe and efficacious, and whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (iv) whether the transition of the imetelstat program to the Company can be completed by the end of the third quarter of 2019; (v) whether Geron can re-establish the imetelstat manufacturing supply chain; (vi) whether the inventory being purchased from Janssen is sufficient to supply the Phase 3 portion of IMerge and initial supply for potential future clinical trials of imetelstat; (vii) whether Geron is able to perform the analyses and complete the required activities in order to conduct an EOP2 meeting by the end of the first quarter of 2020; (viii) whether the results of the analyses will be sufficient to enable Geron to reach agreement with the FDA on a timely and cost-effective regulatory strategy, and to make a decision, regarding late-stage development in relapsed/refractory MF; (ix) the need for future capital; (x) whether Geron is successful in engaging all necessary contract manufacturing vendors by the end of the third quarter 2019; (xi) whether Geron has underestimated its 2019 operating expenses or has not anticipated contingencies that may require more expenditures; (xii) whether Geron is able to hire the additional personnel to grow to 45 to 50 employees by the end of the year; (xiii) Geron's potential inability to successfully retain or recruit key personnel to support its current and future development plans or to otherwise successfully manage its growth; and (xiv) whether imetelstat demonstrates disease-modifying activity. 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 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, 2019. 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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Geron Announces Two Presentations on Imetelstat
at Upcoming European Hematology Association Annual Congress

MENLO PARK, Calif., May 16, 2019 -- Geron Corporation (Nasdaq: GERN) today announced that two abstracts containing clinical data and analyses related to imetelstat, the Company's first-in-class telomerase inhibitor, have been accepted for presentation at the 24th European Hematology Association (EHA) Annual Congress to be held in Amsterdam, the Netherlands, from June 13-16, 2019. The abstracts are available on the EHA website at www.ehaweb.org/congress.

"We appreciate the opportunity to present additional data and analyses at EHA from the ongoing imetelstat clinical trials," said John A. Scarlett, M.D., Geron's Chairman and Chief Executive Officer. "In the Phase 2 portion of IMerge, the 8-week transfusion independence rate increased compared to the data presented last December, supporting the initiation of the Phase 3 portion of IMerge that we plan to open for screening and enrollment by mid-year 2019. For IMbark, the analyses reported in the abstract suggest that treatment with imetelstat is associated with a lower risk of death compared to best available therapy from closely matched real-world data from patients with Intermediate-2 or High-risk myelofibrosis after JAK inhibitor failure."

Updated Efficacy and Safety Data from the Phase 2 Portion of IMerge

Abstract Title: ***Treatment with Imetelstat Provides Durable Transfusion Independence (TI) in Heavily Transfused Non-del(5q) Lower Risk MDS (LR-MDS) Relapsed/Refractory (R/R) to Erythropoiesis Stimulating Agents (ESAs)***

The abstract, accepted for an oral presentation, reports updated efficacy and safety data from 38 patients treated with imetelstat in Part 1 of IMerge, a Phase 2 clinical trial in transfusion dependent, non-del(5q) lower risk myelodysplastic syndromes (MDS) patients who are relapsed or refractory to ESAs and naïve to hypomethylating agent (HMA) and lenalidomide treatment. The primary efficacy endpoint is 8-week RBC-TI rate, which is defined as the proportion of patients achieving red blood cell transfusion independence during any consecutive eight weeks since entry into the trial.

In the preliminary data set used to prepare the abstract, the 8-week RBC-TI rate was 45% (17/38). Based on the most recent clinical cut-off date, used to prepare the IMerge clinical data for the transition of the imetelstat program, the 8-week RBC-TI rate is 42% (16/38), which is an increase of two new responders compared to the 8-week RBC-TI rate of 37% (14/38) reported at the American Society of Hematology Annual Meeting in December 2018. The most frequently reported adverse events were manageable and reversible grade ≥3 cytopenias.

The abstract states these data support initiation of Part 2 of IMerge, the Phase 3 placebo-controlled trial, which is planned to be open for screening and enrollment by mid-year 2019.

Oral Presentation Details:
Session Title: Improvements in MDS Treatment
Session Date: Saturday, June 15
Session Time: 11:30 – 11:45 a.m. CET
Abstract Code: S837

The oral presentation is expected to provide more mature efficacy and safety data for the Phase 2 portion of IMerge.

Analysis of Overall Survival Data from IMbark

Abstract Title: ***Favorable Overall Survival of Imetelstat-Treated Relapsed/Refractory Myelofibrosis Patients Compared with Closely Matched Real World Data***

This abstract, accepted for a poster presentation, provides a new analysis of the overall survival (OS) benefit in patients treated with imetelstat 9.4 mg/kg during the IMbark Phase 2 clinical trial, compared to real-world data (RWD) from patients who had discontinued from a JAK inhibitor (JAKi). For this analysis, historical RWD were collected from a single-center study of patients who had discontinued ruxolitinib. A closely matched cohort of these patients was identified using guidelines for inclusion and exclusion criteria as defined in the IMbark clinical protocol, and consisted of patients who had discontinued JAKi due to lack or loss of response and were subsequently treated with best available therapy (BAT) at the Moffitt Cancer Center. For comparability between the IMbark data and the RWD, several baseline clinical patient characteristics, such as, platelet count, spleen size, time from diagnosis to JAKi therapy discontinuation, MF type and others, were selected to assess the average treatment effect of imetelstat or BAT. Using propensity score approaches, median overall survival in the imetelstat-treated patients from IMbark was calculated to be 30.69 months compared to a median overall survival that was calculated to be 12.04 months in patients treated with BAT at the Moffitt Cancer Center (hazard ratio 0.35, p<.0019). These analyses suggest that treatment with imetelstat is associated with a lower risk of death compared to BAT from closely matched RWD from patients with Intermediate-2 or High-risk MF after JAKi failure.

Poster Presentation Details:
Session Title: Myeloproliferative neoplasms—Clinical
Session Date: Saturday, June 15
Session Time: 5:30 – 7:00 p.m. CET
Abstract Code: PS1456

In accordance with EHA policies, abstracts submitted to the EHA Annual Congress are embargoed from the time of submission. To be eligible for presentation at the EHA Annual Congress, any additional data or information to be presented at the Annual Congress may not be made public before the presentation. The slide presentation and poster will be available at www.geron.com/r-d/publications following the EHA Annual Congress presentations.

Post-EHA Event with Key Opinion Leaders

On June 25, 2019, Geron plans to host a webcasted event after the EHA Annual Congress. At the event, authors from each of the imetelstat abstracts will reprise the respective presentations from the EHA Annual Congress. A press release with event details, including how to access a webcast link, will be available on Geron's website at the beginning of June.

About Imetelstat

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