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): **September 26, 2018**

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 1.02 Termination of a Material Definitive Agreement.

On September 26, 2018, Janssen Biotech, Inc., a Pennsylvania corporation ("Janssen"), notified Geron Corporation ("Geron") of its termination of the exclusive collaboration and license agreement (the "Collaboration Agreement") between Geron and Janssen. Such termination will be effective September 28, 2018, and was made pursuant Section 14.5.2 of the Collaboration Agreement. Accordingly, Janssen informed Geron that it does not intend to provide a notice of continuation under the Collaboration Agreement with respect to the continued development of imetelstat by Janssen. Section 14.6.4 of the Collaboration Agreement sets forth the responsibilities of Janssen and Geron with respect to the orderly transition of the imetelstat program back to Geron for continued development by Geron.

Item 8.01 Other Events.

On September 27, 2018, Geron issued a press release entitled "Geron Announces Discontinuation of Imetelstat Collaboration by Janssen." 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 September 27, 2018.

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: September 27, 2018

By: /s/ Stephen N. Rosenfield
Name: Stephen N. Rosenfield
Title: Executive Vice President, General Counsel and Corporate Secretary

EXHIBIT 99.1

Press Release Dated September 27, 2018

geron

Geron Announces Discontinuation of Imetelstat Collaboration by Janssen

- Geron regains global rights to imetelstat program
- Highlights reported for IMerge and IMbark
- Geron plans to initiate the Phase 3 portion of IMerge
- Conference call scheduled for 8:00 a.m. ET today

MENLO PARK, Calif., September 27, 2018 -- Geron Corporation (Nasdaq: GERN) today announced that Janssen Biotech, Inc. (Janssen) has terminated the 2014 Collaboration and License Agreement (CLA) with the Company. Janssen stated in their press release issued today that they made this decision as the result of a strategic portfolio evaluation and prioritization of assets within their portfolio. As such, Geron has regained the global rights to develop and commercialize imetelstat, a first-in-class telomerase inhibitor.

"We are grateful for the collaboration with Janssen, who successfully managed two Phase 2 trials of imetelstat," said John A. Scarlett, M.D., Geron's President and Chief Executive Officer. "We believe the clinical results from IMbark provide valuable insights into the potential future development of imetelstat for an underserved relapsed and refractory myelofibrosis patient population. We also believe the combined data of 38 patients from the initial and expansion cohorts for the target patient population from the Phase 2 portion of IMerge support further development of imetelstat, and we are therefore prioritizing the initiation of the Phase 3 portion of IMerge."

Under the terms of the CLA, the effective date of the termination is September 28, 2018, after which the licensed rights to the imetelstat program, including intellectual property rights generated under the collaboration, return to Geron without any continuing economic obligations to Janssen, and Janssen has no further obligations to fund any of the current ongoing imetelstat clinical trials.

Transition of the imetelstat program to Geron is expected to occur over approximately 12 months with operational support from Janssen, including the orderly transfer of all ongoing clinical, regulatory, medical affairs, manufacturing and preclinical activities to Geron. In addition, Janssen is expected to supply imetelstat to Geron for up to 24 months during a transition period for clinical manufacturing.

Patients currently enrolled in the ongoing imetelstat clinical trials in myelofibrosis (IMbark) and myelodysplastic syndromes (IMerge) will continue to be supported through the respective trial protocols, including treatment and follow-up.

Expanded Phase 2 Portion of IMerge Data Snapshot Highlights

IMerge is a two-part clinical trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (MDS) who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA).

The first part of the trial was originally designed as a Phase 2, open-label, single-arm trial to assess the efficacy and safety of imetelstat. The second part of the trial is planned as a Phase 3 double-blind, randomized, placebo-controlled trial in approximately 170 patients. The primary efficacy endpoint is the rate of red blood cell transfusion independence, or RBC-TI rate, lasting at least 8 weeks. Key secondary endpoints include the RBC-TI rate lasting at least 24 weeks, amount and relative change in red blood cell transfusions and hematologic improvement.

In the original Phase 2 portion 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 reported at the European Hematology Association Annual Congress in June 2018, the initial cohort of 13 patients showed an increased durability and rate of transfusion independence compared to the overall trial population (≥8-week RBC-TI rate: 54% vs. 34%). Based on these data from the initial cohort, enrollment into the Phase 2 portion of IMerge was expanded to include an additional 25 patients (expansion cohort) who are non-del(5q) and naïve to HMA and lenalidomide treatment in order to increase the clinical experience and confirm the benefit-risk profile of imetelstat dosed at 7.5 mg/kg every four weeks in this target patient population.

To align with the completion of the IMbark primary analysis and their decision about the collaboration, Janssen conducted an initial data review of the expansion cohort, which they called a data snapshot. This data snapshot represented an early look at the expansion cohort since the median follow-up was less than half the time the 13-patient initial cohort had been followed when their data were first reported. The median baseline RBC transfusion burden for the expansion cohort (n=25) was 8.0 units/8 weeks, compared to 6.0 units for the initial 13-patient cohort.

In the data snapshot for the expansion cohort (n=25), the ≥8-week RBC-TI rate was 28%. Combining the expansion cohort with the 13-patient initial cohort for the target patient population (n=38), the ≥8-week RBC-TI rate was 37%. As of the data snapshot, sufficient time had not elapsed in the expansion cohort to assess the ≥24-week RBC-TI rate.

The safety profile from the additional enrolled patients was consistent with the safety profile from the original 32 patients, as well as with other clinical trials of imetelstat in hematologic myeloid malignancies. No new safety signals were identified. The most common adverse events were cytopenias.

Geron believes the combined data from the initial and expansion cohorts for the target patient population (n=38) support initiating the Phase 3 portion of IMerge to address an unmet medical need for patients who have failed ESAs and for whom currently available therapies show only modest efficacy.

Janssen submitted detailed results from the combined initial and expansion cohorts for the target patient population (n=38) in the Phase 2 portion of IMerge as an abstract for potential presentation at the 60th Annual Meeting of the American Society of Hematology (ASH). If the abstract is accepted for presentation at ASH, Geron expects more mature data from the target patient population in the Phase 2 portion of IMerge to be included in the ASH presentation. The Company also expects final data from the Phase 2 portion of IMerge to be available in 2019 and anticipates submitting such final data for presentation at a future medical conference in 2019.

Phase 3 Development Plan for Lower Risk MDS

Based on the combined data from the initial and expansion cohorts for the target patient population in the Phase 2 portion of IMerge, Geron plans to initiate the Phase 3 portion of IMerge after the sponsorship of the ongoing imetelstat clinical trials has been transferred from Janssen to Geron. Geron anticipates patient screening and enrollment for the Phase 3 portion of IMerge to begin by mid-year of 2019. In addition, Geron has engaged a global contract research organization (CRO) to support imetelstat clinical development.

IMbark Protocol-Specified Primary Analysis Highlights

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 approximately 200 patients with Intermediate-2 or High-risk myelofibrosis (MF) who have relapsed after or are refractory to prior treatment with a JAK inhibitor.

The co-primary efficacy endpoints for the trial are spleen response rate, defined as the proportion of patients who achieve a ≥35% reduction in spleen volume assessed by imaging; and symptom response rate, defined as the proportion of patients who achieve a ≥50% reduction in Total Symptom Score, at 24 weeks. Key secondary endpoints are safety and overall survival.

For the 9.4 mg/kg dosing arm (n=59), highlights from the primary analysis included a spleen response rate of 10% and a symptom response rate of 32%. No patients achieved complete remission, and one patient achieved partial remission. The safety profile 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. At the time of the primary analysis, median overall survival had not been reached after 23 months of median follow-up.

The extension phase of IMbark is ongoing to allow the long-term treatment and follow-up of patients. Data collection during this phase will consist of serious adverse events and survival.

Janssen submitted detailed results from the IMbark primary analysis as an abstract for potential presentation at the 60th Annual Meeting of the American Society of Hematology. If the abstract is accepted for presentation at ASH, Geron expects more mature data from the extension phase of IMbark to be included in the ASH presentation.

Geron intends to discuss the results of the IMbark primary analysis, including the assessment of overall survival as it compares to historical data, with experts in myelofibrosis, as well as regulatory authorities. The Company believes feedback from these discussions will provide important information on the scope and design of any potential future clinical trials for imetelstat in Intermediate-2 or High-risk MF patients who have relapsed after or are refractory to prior treatment with a JAK inhibitor.

Revised Financial Guidance

As a result of the termination of the CLA and Geron's decision to continue the development of imetelstat independently, the Company has revised its financial projections and now anticipates 2018 operating expenses to be approximately $37 million (previously $30 million). The Company expects its operating expenses to increase as it hires additional personnel and external service providers to support the development of imetelstat. As of August 31, 2018, the Company had approximately $183 million in cash and marketable securities which is expected to be sufficient to support its plans to initiate the Phase 3 portion of IMerge in 2019.

Conference Call

Geron will host a conference call to discuss its future development plans for imetelstat at 8:00 a.m. ET on Thursday, September 27, 2018.

Participants may access the conference call live via telephone by dialing domestically +1 (877) 303-9139 or internationally +1 (760) 536-5195. The passcode is 7987354. 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 to High risk myelofibrosis. Imetelstat received Fast Track designation from 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 clinical stage biopharmaceutical company focused on the 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 such statements regarding that Geron: (i) expects patient screening and enrollment of the Phase 3 portion of IMerge for lower risk MDS to begin by mid-2019; (ii) expects the transition of the imetelstat program from Janssen to Geron to take approximately 12 months; (iii) expects that Janssen will supply imetelstat to Geron for 24 months; (iv) believes that the combined data from the initial and expansion cohorts in the Phase 2 portion of IMerge support initiating the Phase 3 portion of IMerge; (v) expects more mature data from IMerge and IMbark to be presented at ASH in 2018; (vi) expects final data from IMerge to be available in 2019 and plans to submit such data for presentation at a medical conference in 2019; and (vii) expects that 2018 operating expenses will be approximately $37 million, and 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 transition from Janssen to Geron proceeds expeditiously and without delay; (ii) whether the United States Food and Drug Administration or other regulatory authorities permit the ongoing or future clinical trials of imetelstat, including without limitation, the Phase 3 portion of IMerge to proceed; (iii) whether Janssen provides the required supply of imetelstat on a timely basis, or at all; (iv) whether more mature data is collected and made available for presentation at ASH in 2018; (v) whether Geron is able to administer, operate and commence the Phase 3 portion of IMerge expeditiously; (vi) whether the final data from IMerge is available in 2019, or at all; and (vii) whether the operating expenses for the remainder of 2018 are greater than expected due to unforeseen events. 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 June 30, 2018. 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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