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): **March 7, 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 2.02 Results of Operations and Financial Condition

Geron Corporation (the "Company") is furnishing this information under Item 2.02 of Form 8-K.

The information in this Current Report, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the 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. The information in this Current Report, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, as amended, or the Exchange Act.

On March 7, 2019, the Company issued a press release announcing its financial results for the three and twelve months ended December 31, 2018. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 7, 2019.

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: March 7, 2019

By: /s/ Stephen N. Rosenfield
Name: Stephen N. Rosenfield
Title: Executive Vice President, Chief Legal Officer and Corporate Secretary

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Geron Corporation Reports Fourth Quarter and Full Year 2018 Financial Results and Recent Events

Conference Call Scheduled for 4:30 p.m. ET today

MENLO PARK, Calif., March 7, 2019 -- Geron Corporation (Nasdaq: GERN) today reported financial results for the fourth quarter and full year ended December 31, 2018 and recent events. As of year-end 2018, the Company had approximately $182 million in cash and marketable securities, which is sufficient to commence the planned Phase 3 clinical trial of imetelstat in lower risk myelodysplastic syndromes (MDS) by mid-year 2019.

"We expect 2019 to be a pivotal year," said John A. Scarlett, M.D., Chairman and Chief Executive Officer. "We are making good progress in the transition of the imetelstat program and expect to assume sponsorship of the imetelstat clinical trials by the end of the second quarter. We continue planning to open the Phase 3 clinical trial of imetelstat in lower risk MDS for enrollment by mid-year, as well as evaluating the potential for late-stage development in MF. In addition, we expect to further expand our team with individuals who have strong development expertise that will enable us to build a robust hematology-oncology franchise."

Recent Events

Building a Development Team with Hematology-Oncology Expertise

The Company recently announced the hiring of two key development executives. Aleksandra Rizo, M.D., Ph.D., the former clinical lead for the imetelstat program at Janssen, joined Geron as Chief Medical Officer. Israel Gutierrez, M.D., who has more than 20 years of oncology clinical development experience, joined Geron as Vice President, Pharmacovigilance and Drug Safety. In addition, Geron plans to open an office in northern New Jersey to access experienced personnel with late-stage hematology-oncology clinical drug development expertise, as well as to enable efficient support for global clinical trials, including the Phase 3 clinical trial of imetelstat in lower risk MDS.

Fourth Quarter 2018 Highlights

IMerge Phase 2 Data Presented Support Initiation of Phase 3 Trial in Lower Risk MDS

Data for the Phase 2 portion of IMerge were presented in an oral presentation at the American Society of Hematology (ASH) annual meeting on December 2, 2018. Geron believes these data support initiating the Phase 3 portion of IMerge to address an unmet medical need for patients for whom erythropoiesis stimulating agents (ESAs) are not effective and for whom currently available therapies show only modest efficacy, especially in patients with high baseline transfusion burdens who are difficult-to-treat. Lower risk MDS patients in the U.S. represent a large unmet need as there has not been a new drug approved by the Food and Drug Administration (FDA) since 2006.

In the Phase 2 portion of IMerge, 38 patients were enrolled who were transfusion dependent with Low or Intermediate-1 risk non-del(5q) MDS who have relapsed after or are refractory to prior treatment with an ESA and naïve to treatment with a hypomethylating agent (HMA) or lenalidomide. In the trial, transfusion dependence is defined as a patient requiring a minimum of four units of red blood cells (RBC) over a consecutive 8-week time period to treat anemia. The median baseline RBC transfusion burden in the Phase 2 portion of IMerge was eight units per eight weeks, ranging from four to 14 units. The primary efficacy endpoint of the trial is the rate of RBC transfusion-independence (RBC TI) lasting at least eight weeks (8-week RBC TI rate), which is defined as the proportion of patients who are transfusion free for at least eight consecutive weeks since entry into the trial. Key secondary endpoints include durability of response as evidenced through 24-week RBC TI rate and breadth of response through reduction in RBC transfusion burden and rate of RBC transfusions, as well as responses across MDS sub-types.

Primary Efficacy Endpoint:
- 37% (14/38) of patients achieved an 8-week RBC TI rate

Secondary Efficacy Endpoints:

Durability
- 26% (10/38) of patients achieved a 24-week RBC TI rate

Transfusion Reduction
- The rate of hematologic improvement-erythroid (HI-E) was 71% (27/38), as measured by a reduction of at least four RBC units over eight weeks compared with prior transfusion burden
- Mean relative reduction of RBC transfusion burden from baseline was 68%

Broad Clinical Activity Observed
- Similar 8-week RBC TI rates were observed in patients with baseline serum erythropoietin (sEPO) levels less than or greater than 500mU/mL
- 8-week RBC TI rates were also consistent between ringed-sideroblast (RS) positive patients and other patients

The ASH presentation reported data based on a data cut-off date of October 26, 2018. As of the data cut-off date, the median duration of RBC TI had not been reached. Geron expects more mature data from patients continuing on treatment in the Phase 2 portion of IMerge to be available in 2019 and anticipates submitting such data for presentation at a future medical conference.

IMbark Phase 2 Data Presented Suggest Meaningful Survival Outcome in Relapsed/Refractory MF Patients

Data from the Phase 2 IMbark clinical trial, including new overall survival data, were presented in an oral presentation at ASH on December 3, 2018.

The IMbark trial evaluated two starting dose levels of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in more than 100 patients with Intermediate-2 or High-risk myelofibrosis (MF) who were relapsed or refractory to janus kinase inhibitor (JAKi) therapy. To be eligible for enrollment in the IMbark trial, patients had to meet rigorous criteria for having failed or not responded to JAKi treatment, including documented progressive disease during or after JAKi therapy. The ASH presentation highlighted efficacy and safety data from the trial's primary analysis, as well as overall survival (OS) data with a clinical cutoff of October 22, 2018 and a median follow up of 27 months.

The ASH presentation reported that the median OS for the 9.4 mg/kg dosing arm was 29.9 months, which suggests a meaningful survival outcome with imetelstat treatment in this poor-prognosis, relapsed/refractory patient population where there are currently no approved treatments today. Other observational studies of similar patient populations at academic medical centers published recently in medical literature have reported median OS ranges of approximately 12 to 14 months after failure of or discontinuation of ruxolitinib, a JAKi.

Geron plans to discuss the potential for late-stage development of imetelstat in MF with current IMbark investigators, other key opinion leaders (KOLs) and regulatory authorities. The Company expects to facilitate KOL discussions over the coming months. Discussions with regulatory authorities are expected to begin after the investigational new drug (IND) sponsorship has been transferred back to Geron.

The Company plans to outline a decision regarding the potential for future late-stage development in MF by the end of the third quarter of 2019. In making this decision, Geron will conduct an assessment of what would be required to achieve clinical and regulatory success, including the cost and duration of any potential clinical trials.

Imetelstat Safety Results

The safety profile reported in both ASH presentations for imetelstat-treated patients was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. Cytopenias, particularly neutropenia and thrombocytopenia, were the most frequently reported adverse events, which were predictable, manageable and reversible.

Fourth Quarter and Year-End 2018 Results

For the fourth quarter of 2018, the company reported a net loss of $7.3 million, or $0.04 per share, compared to $7.4 million, or $0.05 per share, for the comparable 2017 period. For 2018, the company reported a net loss of $27.0 million, or $0.15 per share, compared to $27.9 million, or $0.18 per share, for 2017.

Revenues for the fourth quarter of 2018 were $375,000 compared to $191,000 for the comparable 2017 period. Revenues for 2018 and 2017 were each $1.1 million and included royalty and license fee revenues under various non-imetelstat license agreements. The Company adopted a new revenue recognition accounting standard as of January 1, 2018 using the modified retrospective transition method. Revenue for 2018 is presented under the new accounting standard, but revenue for 2017 has not been adjusted and continues to be reported under accounting standards used historically. Therefore, there is a lack of comparability between the periods presented. However, the Company does not expect the adoption of the new revenue recognition accounting standard to have a material impact to its financial statements on an ongoing basis.

Total operating expenses for the fourth quarter of 2018 were $10.0 million compared to $8.0 million for the comparable 2017 period. Total operating expenses for 2018 were $32.1 million compared to $30.3 million for 2017.

Research and development expenses for the fourth quarter of 2018 were $5.1 million compared to $2.5 million for the comparable 2017 period. Research and development expenses for 2018 were $13.4 million compared to $11.0 million for 2017. The increase in research and development expenses for the fourth quarter and year-to-date 2018 periods compared to comparable 2017 periods primarily reflects increases in Geron's share of imetelstat development costs under the former collaboration agreement with Janssen Biotech, Inc. (Janssen) where Geron's share increased from 50% to 100% as of the termination date of the collaboration agreement and additional costs for the contract research organization (CRO) and other consultants for the transition of the imetelstat program from Janssen to Geron.

General and administrative expenses for the fourth quarter of 2018 were $4.9 million compared to $5.5 million for the comparable 2017 period. General and administrative expenses for 2018 were $18.7 million compared to $19.3 million for 2017. The decrease in general and administrative expenses in 2018 compared to 2017 primarily reflects the net result of reduced personnel related expenses, including lower stock-based compensation expense, partially offset by higher consulting expenses and higher patent legal expenses with the termination of the imetelstat collaboration with Janssen, as imetelstat patent costs previously were being shared by the two companies on a 50/50 basis.

Interest and other income for the fourth quarter of 2018 was $1.1 million compared to $375,000 for the comparable 2017 period. Interest and other income for 2018 was $3.3 million compared to $1.4 million for 2017. The increase in interest and other income for 2018 compared to 2017 primarily reflects higher yields on the Company's marketable securities portfolio.

Planned 2019 Activities and Milestones

Geron's plans for 2019 primarily focus on advancing imetelstat development. The Company believes building a development team with hematology-oncology expertise is essential to executing the Phase 3 clinical trial in lower risk MDS and evaluating the potential for late-stage development in MF, as well as in the future, exploring additional indications for imetelstat and being able to pursue other innovative therapeutics in hematology-oncology. Geron expects the following activities and milestones to occur in 2019:

Transition of Imetelstat Development Program
- Complete the transfer of the IND back to Geron by the end of the second quarter.

- Complete the transfer of the imetelstat clinical development program back to Geron by the end of the third quarter.

- Actively recruit highly-experienced personnel with drug development expertise in myeloid malignancies.

MDS Development
- Commence screening and enrollment for the Phase 3 portion of IMerge by mid-year.

- Present more mature data from patients in the Phase 2 portion of IMerge at a medical conference.

MF Development
- Conduct discussions with IMbark investigators, other MF KOLs and regulatory authorities to identify and consider potential late-stage clinical development plans for relapsed/refractory MF patients.

- Outline decision regarding the potential for late-stage development of imetelstat in MF by the end of the third quarter.

Projected 2019 Financial Guidance

The Company expects its operating expenses to increase as it assumes full responsibility for the development and potential commercialization of imetelstat. For fiscal year 2019, the Company expects its operating expense burn to range from $65 to $70 million, of which approximately $10 to $15 million represents one-time costs, such as imetelstat program transition activities from Janssen to Geron, including the transfer of the IND sponsorship, and purchase of raw materials and other supplies in preparation for new drug manufacturing. In addition to the one-time costs, projected 2019 operating expense guidance includes costs for the expansion of the internal development team, the global Phase 3 clinical trial in MDS and the opening of the New Jersey office. The Company plans to grow to a total of approximately 30 to 40 employees by year-end 2019, of which half will be research and development personnel.

Conference Call

Geron will host a conference call to discuss fourth quarter and full year financial results and recent events at 4:30 p.m. ET on Thursday, March 7, 2019.

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 6771719. 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) the prospects for imetelstat; (ii) that patient screening and enrollment for the Phase 3 portion of IMerge will begin by mid-year 2019; (iii) that IMbark and IMerge will continue; (iv) that imetelstat may have disease-modifying activity; (v) that the IND will transfer to Geron by the end of the second quarter of 2019; (vi) that the imetelstat clinical development program will transfer to Geron by the end of the third quarter of 2019; (vii) that more mature data will be available from the Phase 2 portion of IMerge and will be presented at a medical conference in 2019; (viii) that Geron will discuss with IMbark investigators, other MF KOLs and regulatory authorities the potential for late-stage clinical development of imetelstat for relapsed/refractory MF patients and will outline its decision on this matter by the end of the third quarter of 2019; (ix) that the Company does not expect the adoption of the new revenue recognition accounting standard to have a material impact to its financial statements on an ongoing basis; (x) that the Company's operating expenses will be $65 to $70 million in 2019, and other financial projections and expectations; (xi) that the Company will grow to a total of 30 to 40 employees by year-end 2019; and (xii) 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 the transfer of the IND and imetelstat clinical development 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 begin 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 transfer of the IND and the imetelstat clinical development program to the Company occur in the second and third quarter of 2019, respectively; (v) whether experts in MF and regulatory authorities support a potential path for late-stage clinical development of imetelstat in relapsed/refractory MF; (vi) whether Geron's assessment of the prospects for clinical and regulatory success, including the cost and duration of any potential clinical trials, warrant pursuing late-stage development of imetelstat in MF; (vii) whether Geron has come to a decision regarding late-stage development in MF by the end of the third quarter of 2019; (viii) whether the new revenue recognition accounting standard has a material impact on Geron's financial statements on an ongoing basis; and (ix) 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 annual report on Form 10-K for the year ended December 31, 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.

Financial table follows.

GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS

	UNAUDITED Three Months Ended December 31,		Year Ended December 31,	
(In thousands, except share and per share data)	**2018**	**2017**	**2018**	**2017**
Revenues:				
License fees and royalties	$ 375	$ 191	$ 1,066	$ 1,065
Operating expenses:				
Research and development	5,081	2,523	13,432	11,033
General and administrative	4,883	5,454	18,707	19,287
Total operating expenses	9,964	7,977	32,139	30,320
Loss from operations	(9,589)	(7,786)	(31,073)	(29,255)
Interest and other income	1,120	375	3,291	1,416
Gain on settlement	1,460	—	1,460	—
Change in fair value of equity investment	(271)	—	(541)	—
Other expense	(20)	(18)	(154)	(77)
Net loss	$ (7,300)	$ (7,429)	$ (27,017)	$ (27,916)
Basic and diluted net loss per share:				
Net loss per share	$ (0.04)	$ (0.05)	$ (0.15)	$ (0.18)
Shares used in computing net loss per share	186,348,551	159,339,385	176,504,996	159,224,986

CONDENSED BALANCE SHEETS

(In thousands)	December 31, 2018	December 31, 2017
Current assets:		
Cash, cash equivalents and restricted cash	$ 10,844	$ 16,603
Current marketable securities	152,714	78,351
Other current assets	2,500	1,016
Total current assets	166,058	95,970
Noncurrent marketable securities	18,582	14,241
Property and equipment, net	59	102
Other assets	585	—
	$ 185,284	$ 110,313
Current liabilities	$ 7,551	$ 6,516
Stockholders' equity	177,733	103,797
	$ 185,284	$ 110,313

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