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): **August 6, 2020**

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.)

919 E. HILLSDALE BLVD., SUITE 250
FOSTER CITY, CALIFORNIA 94404

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	GERN	The Nasdaq Stock Market LLC

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 August 6, 2020, the Company issued a press release announcing its financial results for the three and six months ended June 30, 2020. 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 August 6, 2020.

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 6, 2020

By: /s/ Stephen N. Rosenfield

Name: Stephen N. Rosenfield

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

Press Release Dated August 6, 2020

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Geron Corporation Reports Second Quarter 2020 Financial Results and Current Events

FOSTER CITY, Calif., August 6, 2020 -- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2020. The Company will host a conference call today at 4:30 p.m. ET to discuss second quarter financial results and current events.

“In the second quarter, we achieved a number of key milestones that have changed the trajectory of the Company,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “After a successful meeting with the FDA, we announced plans to move forward with a Phase 3 clinical trial in refractory MF with overall survival as the primary endpoint. This decision was based on overall survival data from the IMbark Phase 2 trial that suggest imetelstat treatment could potentially double the remaining life expectancy for patients who have become refractory to JAK inhibitors.”

Dr. Scarlett added, “We reported clinically meaningful transfusion independence with longer durability from more mature data in the IMerge Phase 2 trial in lower risk MDS, which included 29% of patients being transfusion-free for more than one year. We also raised additional capital in the second quarter that we expect will sufficiently fund our development plans for the ongoing Phase 3 IMerge trial in lower risk MDS and the upcoming Phase 3 trial in refractory MF into the second half of 2022. These achievements, along with our experienced development team, position Geron to become a leader in the treatment of hematologic myeloid malignancies over the next several years.”

Current Events – Clinical Development and Regulatory

Ongoing IMerge Phase 3 Clinical Trial in Myelodysplastic Syndromes (MDS)

As of the end of July 2020, approximately 93% of the 90 clinical sites originally planned for the trial were open for screening and enrollment, compared to 68% in May.

The momentum of patient enrollment has begun to improve as the effects of the COVID-19 pandemic begin to wane in a majority of the countries where IMerge clinical sites are located. The Company continues to expect patient enrollment to be completed by the end of the first quarter of 2021, subject to potential future delays or interruptions associated with COVID-19. To help ensure achievement of this goal, the trial is being expanded from 90 to approximately 130 clinical sites. Geron expects a majority of these 40 new sites to be open for enrollment by the end of the year. Under current enrollment assumptions, the Company continues to expect top-line results in the second half of 2022.

Start-Up Activities for Planned Phase 3 Clinical Trial in Myelofibrosis (MF)

Geron expects to engage over 150 sites across North America, South America, Europe and Asia to participate in the planned global Phase 3 clinical trial in refractory MF. Trial start-up activities underway include identifying potential clinical sites for participation, as well as finalizing the clinical trial protocol. Geron plans to open the trial for screening and enrollment in the first quarter of 2021. Under current planning assumptions, Geron expects to complete patient enrollment in the second half of 2022, to conduct an interim analysis in the first half of 2023 and to conduct a final analysis in the first half of 2024.

European Commission Grants Orphan Drug Designation to Imetelstat for MDS

At the end of July, the European Commission granted orphan drug designation to imetelstat as a potential treatment for MDS based on a positive opinion from the European Medicines Agency Committee for Orphan Medicinal Products. Imetelstat has already been granted orphan drug designation by the United States Food and Drug Administration as a potential treatment for MDS.

Recent Data Presentations in June

KOL Event Highlighted Compelling Phase 2 Data from the European Hematology Association (EHA) Annual Congress

Key opinion leaders within hematologic myeloid malignancies reprised four presentations containing new clinical data and analyses related to imetelstat from the Virtual Edition of the EHA Annual Congress.

The recent EHA presentation of more mature data from 38 patients in the IMerge Phase 2 clinical trial in lower risk MDS reported notable continued durability, including a median duration of 8-week transfusion independence of 20 months, which is the longest duration reported to date in this trial. Also reported for the first time, 29% of the 38 patients were transfusion free for more than one year.

In addition, new analyses from the IMbark Phase 2 clinical trial in relapsed/refractory MF correlated the median overall survival observed in the trial with other clinical endpoints, such as improvement in fibrosis. These analyses provide further support for the planned Phase 3 clinical trial in refractory MF.

Overall, the EHA data and analyses continue to support the potential disease-modifying activity with imetelstat treatment as evidenced by the clinically meaningful durable transfusion independence in the Phase 2 IMerge trial and the improvement in overall survival in the Phase 2 IMbark trial.

Strengthened Balance Sheet to Achieve Development Plans

As of June 30, 2020, Geron had approximately $265 million in cash, cash equivalents, and current and non-current marketable securities. The Company's cash position reflects net proceeds of approximately $140 million from a public offering of securities in the second quarter. Based on current planning assumptions, the Company expects such funds to be sufficient for its operations into the second half of 2022 when top-line results for the IMerge Phase 3 clinical trial in lower risk MDS and completion of patient enrollment for the planned Phase 3 clinical trial in refractory MF are expected.

Second Quarter and Year-to-Date 2020 Results

For the second quarter of 2020, the Company reported a net loss of $15.8 million, or $0.06 per share, compared to $14.2 million, or $0.08 per share, for the comparable 2019 period. Net loss for the first six months of 2020 was $32.2 million, or $0.14 per share, compared to $24.3 million, or $0.13 per share, for the comparable 2019 period.

Revenues for the three and six months ended June 30, 2020 were $43,000 and $95,000, respectively, compared to $101,000 and $158,000 for the comparable 2019 periods. Revenues in 2020 and 2019 primarily reflect estimated royalties from sales of cell-based research products from the Company's divested stem cell assets. In connection with the divestiture of Geron's human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc., which acquired Asterias Biotherapeutics, Inc.) in 2013, Geron is entitled to receive royalties on future product sales.

Total operating expenses for the three and six months ended June 30, 2020 were $16.8 million and $33.7 million, respectively, compared to $15.3 million and $26.7 million for the comparable 2019 periods.

Research and development expenses for the three and six months ended June 30, 2020 were $10.8 million and $21.6 million, respectively, compared to $10.1 million and $16.0 million for the comparable 2019 periods. The increase in research and development expenses for the three and six months ended June 30, 2020, compared to the same periods in 2019, primarily reflects higher clinical development costs associated with the IMerge Phase 3 clinical trial, increased costs in connection with validating the imetelstat manufacturing process at contract manufacturers and higher personnel-related costs for additions to the development team in 2019.

General and administrative expenses for the three and six months ended June 30, 2020 were $6.0 million and $12.1 million, respectively, compared to $5.2 million and $10.6 million for the comparable 2019 periods. The increase in general and administrative expenses for the three and six months ended June 30, 2020, compared to same periods in 2019, primarily reflects increased personnel-related expenses for additional general and administrative headcount to support growing operational activities.

Interest and other income for the three and six months ended June 30, 2020 was $475,000 and $1.2 million, respectively, compared to $1.1 million and $2.3 million for the comparable 2019 periods. The decrease in interest and other income for the three and six months ended June 30, 2020, compared to same periods in 2019, primarily reflects lower yields on the Company's reduced marketable securities portfolio.

2020 Financial Guidance Reaffirmed

The Company expects its 2020 operating expense burn to range from $70 to $75 million. This guidance reflects cash conservation measures implemented in April due to the COVID-19 pandemic, such as suspending travel and postponing a planned imetelstat proof of concept study. It also reflects new costs for start-up activities associated with the planned Phase 3 clinical trial in refractory MF and additional costs for the expansion of clinical sites for the IMerge Phase 3 clinical trial.

Conference Call

Geron will host a conference call at 4:30 p.m. ET on Thursday, August 6, 2020 to discuss second quarter financial results and recent events.

A live, listen-only webcast will 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.

Participants may access the conference call live via telephone by dialing domestically +1 (888) 869-1189 or internationally +1 (706) 643-5902. The conference ID is 8496138. To minimize potential registration and access delays, Geron has implemented Direct Event, which allows participants to pre-register online using the following link, http://www.directeventreg.com/registration/event/8496138. Upon registration, a Direct Event Passcode and unique Registrant ID will be sent via email and will be needed in order to enter the conference call. Participants are advised to pre-register at least 10 minutes prior to joining the call.

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 apoptosis of malignant stem and progenitor cells, which allows potential recovery of normal hematopoiesis. Geron's imetelstat development program includes two registration-enabling studies, IMerge, an ongoing Phase 2/3 clinical trial in lower risk myelodysplastic syndromes (MDS), and a planned Phase 3 clinical trial in refractory myelofibrosis (MF) expected to be open for patient screening and enrollment in the first quarter of 2021. Imetelstat has been granted Fast Track designation by the United States Food and Drug Administration for both the treatment of patients with non-del(5q) lower risk MDS who are refractory or resistant to an erythropoiesis-stimulating agent and for patients with Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to janus kinase (JAK) inhibitor treatment.

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 therapeutic potential of imetelstat, including imetelstat’s potential survival benefit for refractory MF patients; (ii) that for the planned Phase 3 clinical trial in refractory MF, Geron expects to begin patient screening and enrollment in the first quarter of 2021, complete patient enrollment in the second half of 2022, conduct an interim analysis in the first half of 2023 and conduct a final analysis in the first half of 2024; (iii) that imetelstat may have disease-modifying activity; (iv) that the Company has sufficient finances to fund IMerge and the planned refractory MF clinical trial into the second half of 2022; (v) that for IMerge, Geron expects to complete enrollment in the first quarter of 2021 and have top-line results in the second half of 2022; (vi) that Geron’s 2020 operating expense range will be $70-75 million; and (vii) other statements that are not historical facts, constitute forward-looking statements. These forward-looking 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: (a) whether the current or evolving effects of the COVID-19 pandemic and resulting global economic and financial disruptions will materially and adversely impact Geron’s business and business prospects, its financial condition and the future of imetelstat; (b) whether Geron overcomes all of the potential delays and other adverse impacts caused by the current or evolving effects of the COVID-19 pandemic, and overcomes all the clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to meet the expected timelines and planned milestones in (ii), (iv) and (v) above; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether imetelstat is demonstrated to be safe and efficacious in clinical trials; (e) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (f) whether imetelstat actually demonstrates disease-modifying activity in patients; (g) whether imetelstat is able to maintain patent protection and have freedom to operate; (h) Geron’s need to raise substantial capital in order to complete the development and commercialization of imetelstat, including to meet all of the expected timelines and planned milestones in (ii), (iv) and (v) above; (i) whether there are cost overruns in 2020 due to the current or evolving effects of the COVID-19 pandemic or otherwise; (j) whether Geron can accurately project the timing of, or attain complete enrollment in IMerge, the planned Phase 3 refractory MF trial or of any potential future clinical trials of imetelstat, whether due to the current or evolving effects of the COVID-19 pandemic or otherwise; and (k) whether there are failures or delays in manufacturing sufficient quantities of imetelstat or other clinical trial materials in a timely manner, whether due to the current or evolving effects of the COVID-19 pandemic or otherwise. 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 filings and periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors” and elsewhere in such filings and reports, including Geron’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 and future filings and reports by Geron. 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)

(In thousands, except share and per share data)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Revenues:				
License fees and royalties	$ 43	$ 101	$ 95	$ 158
Operating expenses:				
Research and development	10,845	10,134	21,647	16,040
General and administrative	5,960	5,191	12,080	10,643
Total operating expenses	16,805	15,325	33,727	26,683
Loss from operations	(16,762)	(15,224)	(33,632)	(26,525)
Interest and other income	475	1,113	1,229	2,275
Change in fair value of equity investment	422	(98)	227	—
Other expense	41	(30)	(3)	(48)
Net loss	$ (15,824)	$ (14,239)	$ (32,179)	$ (24,298)
Basic and diluted net loss per share:				
Net loss per share	$ (0.06)	$ (0.08)	$ (0.14)	$ (0.13)
Shares used in computing net loss per share	246,966,143	186,556,082	223,594,118	186,475,055

CONDENSED BALANCE SHEETS

(In thousands)	June 30, 2020 (Unaudited)	December 31, 2019 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	$ 23,228	$ 13,914
Current marketable securities	195,881	125,681
Other current assets	1,634	2,013
Total current assets	220,743	141,608
Noncurrent marketable securities	46,223	19,651
Property and equipment, net	734	408
Other assets	7,114	3,850
	$ 274,814	$ 165,517
Current liabilities	$ 19,142	$ 28,162
Noncurrent liabilities	4,991	2,200
Stockholders' equity	250,681	135,155
	$ 274,814	$ 165,517

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2019.

CONTACT:
Suzanne Messere
Investor and Media Relations
investor@geron.com
media@geron.com

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