

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 11, 2022**

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-20859
(Commission File Number)

75-2287752
(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 11, 2022, the Company issued a press release announcing its financial results for the three and six months ended June 30, 2022. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	<u>Press release dated August 11, 2022.</u>
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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 11, 2022

By: /s/ Stephen Rosenfield

Name: Stephen N. Rosenfield

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

Press Release Dated, August 11, 2022

**Geron Corporation Reports Second Quarter 2022 Financial Results***Top-Line Results from IMerge Phase 3 Trial in Lower Risk MDS Continue to be Expected in Early January 2023**Current and Projected Financial Resources Expected to Support Planned Milestones and Operations Through Middle of 2024**Conference Call Scheduled for 4:30 p.m. ET Today*

FOSTER CITY, Calif., August 11, 2022 -- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company developing a first-in-class telomerase inhibitor, imetelstat, to treat hematologic malignancies, today reported financial results for the second quarter of 2022 and key upcoming expected milestones.

“We continue to focus intently on our plans for a catalyst-rich next two years, during which we expect to transform Geron from a development stage to commercial company,” said John A. Scarlett, M.D., Geron’s Chairman and Chief Executive Officer. “Our plan to disclose Phase 3 top-line results in lower risk MDS remains on track for early January 2023. Assuming positive top-line results, U.S. and EU regulatory submissions are also planned in the first and second half of 2023, respectively. In addition, we expect to continue the stage-gated buildout of our commercial capabilities and key talent across our organization to support a potential commercial U.S. launch of imetelstat in the first half of 2024.”

“In order to maintain a strong balance sheet, we also recently amended our existing loan facility to secure up to \$50 million in additional non-dilutive capital, which we expect to be available in 2023,” Dr. Scarlett continued. “With these potential added debt proceeds, we believe our current and projected financial resources will be sufficient to fund our expected level of operations until the middle of 2024.”

Key Upcoming Expected Milestones*Lower Risk Myelodysplastic Syndromes (MDS)*

- Top-line results from IMerge Phase 3 in early January 2023
- New Drug Application submission in the U.S. in the first half of 2023
- Marketing Authorization Application submission in the EU in the second half of 2023
- U.S. approval and commercial launch in the first half of 2024

Myelofibrosis

- Open remaining selected IMpactMF Phase 3 clinical sites by year-end 2022
- IMpactMF interim analysis in 2024

Pipeline expansion in additional indications and treatment combinations

- Start IMpress investigator-led study of single-agent imetelstat in relapsed/refractory (R/R) acute myeloid leukemia (AML) and higher risk MDS in the second half of 2022
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- Start TELOMERE investigator-led Phase 1/2 study of imetelstat in combination with hypomethylating agents (HMAs) or venetoclax in R/R AML in the second half of 2022
- Initial preclinical lymphoid malignancies data by year-end 2022
- Preliminary data from IMproveMF Phase 1 study of imetelstat in combination with ruxolitinib in frontline myelofibrosis by year-end 2023

Additional Projected Financial Resources

In April 2022, the Company closed an underwritten public offering of common stock and warrants. The net cash proceeds from this offering were approximately \$70 million, after deducting the underwriting discount and other offering expenses. The Company could receive up to \$51.8 million in additional funding from the potential exercise of warrants from this offering, as well as up to \$72.5 million from the potential exercise of warrants from an underwritten public offering that closed in May 2020.

In June 2022, the Company expanded its existing loan facility with Hercules Capital, Inc. and Silicon Valley Bank, from up to \$75 million to up to \$125 million. This amendment of the debt facility provides up to \$50 million in additional non-dilutive capital, potentially available in 2023.

Of the aggregate \$125 million loan facility, \$50 million is currently outstanding. The remaining \$75 million is potentially available to Geron in four tranches. The first tranche of \$20 million is available until September 15, 2023, subject to the achievement of certain clinical and financial milestones. The second tranche of \$10 million is available to the Company through December 15, 2023, subject to the achievement of certain clinical and regulatory milestones, and satisfaction of certain capitalization requirements. The third tranche of \$20 million is available to the Company from September 15, 2023 until September 15, 2024, subject to the achievement of certain clinical and regulatory milestones, and satisfaction of certain capitalization requirements. The final tranche of \$25 million is available to the Company through year-end 2024, subject to approval from the lenders.

Current and Projected Financial Resources

As of June 30, 2022, the Company had approximately \$220 million in cash and marketable securities.

Under current planning assumptions, the Company projects its existing capital resources plus projected future proceeds of up to approximately \$124 million from the potential exercise of the currently outstanding warrants and up to \$50 million from the recently amended debt facility will be sufficient to fund Geron's estimated level of operations, which includes stage-gated activities for potential U.S. commercial launch of imetelstat in lower risk MDS, until the middle of 2024.

Second Quarter 2022 Results

For the second quarter of 2022, the Company reported a net loss of \$28.1 million, or \$0.07 per share, compared to \$29.6 million, or \$0.09 per share, for the comparable 2021 period. Net loss for the first six months of 2022 was \$58.2 million, or \$0.16 per share, compared to \$57.4 million, or \$0.18 per share, for the comparable 2021 period.

Revenues for the three and six months ended June 30, 2022, were \$73,000 and \$196,000, respectively, compared to \$107,000 and \$244,000 for the comparable 2021 periods. Revenues in both years primarily reflect estimated royalties from sales of cell-based research products from the Company's divested stem cell assets.

Total operating expenses for the three and six months ended June 30, 2022, were \$28.0 million and \$56.8 million, respectively, compared to \$29.0 million and \$57.6 million for the comparable 2021 periods.

Research and development expenses for the three and six months ended June 30, 2022, were \$20.6 million and \$42.7 million, respectively, compared to \$21.9 million and \$43.1 million for the comparable 2021 periods. The

decrease in research and development expenses for the three and six months ended June 30, 2022, compared to the same periods in 2021 primarily reflects the net result of decreased manufacturing costs due to the timing of imetelstat manufacturing batches; partially offset by increased personnel-related expenses for additional headcount and higher consulting costs related to preparation for top-line results and regulatory submissions in lower risk MDS.

General and administrative expenses for the three and six months ended June 30, 2022, were \$7.4 million and \$14.1 million, respectively, compared to \$7.1 million and \$14.5 million for the comparable 2021 periods. The increase in general and administrative expenses for the three months ended June 30, 2022, compared to the same period in 2021, primarily reflects the net result of increased costs for commercial preparatory activities and higher personnel-related expenses for additional headcount; partially offset by lower legal fees and reduced consulting costs related to modernizing the internal infrastructure to support potential commercial launch. The decrease in general and administrative expenses for the six months ended June 30, 2022, compared to the same period in 2021, primarily reflects the net result of reduced consulting costs and lower legal fees; partially offset by higher personnel-related expenses.

Interest income was \$330,000 and \$442,000 for the three and six months ended June 30, 2022, respectively, compared to \$136,000 and \$309,000 for the same periods in 2021. The increase in interest income for the three and six months ended June 30, 2022, compared to the same periods in 2021, primarily reflects a larger marketable securities portfolio with the receipt of net cash proceeds from the underwritten public offering completed in April 2022 and higher yields from recent marketable securities purchases.

Interest expense was \$1.6 million and \$3.1 million for the three and six months ended June 30, 2022, respectively, compared to \$804,000 and \$1.5 million for the same periods in 2021. The increase in interest expense for the three and six months ended June 30, 2022, compared to the same periods in 2021, primarily reflects rising interest rates and increased principal debt balance. Currently, the Company has \$50.0 million in principal debt outstanding.

Net other income was \$1.1 million for each of the three and six months ended June 30, 2022, respectively, compared to net other expense of \$17,000 and net other income of \$1.2 million for the same periods in 2021. In the second quarter of 2022, the Company recognized other income of approximately \$1.3 million related to the reimbursement of certain legal expenses under its insurance policies. During the first quarter of 2021, the Company sold all of its holdings in an equity investment resulting in a net realized gain of \$1.2 million, including foreign currency translation adjustments.

Projected 2022 Financial Guidance Reaffirmed

For fiscal year 2022, under generally accepted accounting principles (GAAP), the Company continues to expect total operating expenses in the range of approximately \$155 million to \$165 million, which includes non-cash items such as: stock-based compensation expense, amortization of debt discounts and issuance costs, as well as depreciation and amortization. The Company continues to expect non-GAAP total operating expenses for fiscal year 2022 in the range of approximately \$140 million to \$150 million, which excludes estimated non-cash items such as: stock-based compensation expense, amortization of debt discounts and issuance costs, as well as depreciation and amortization.

The fiscal year 2022 financial guidance reflects costs to support: (a) preparatory activities for top-line results from the IMerge Phase 3 clinical trial and readiness for potential regulatory submissions and commercialization of imetelstat in lower risk MDS; (b) continued conduct of IMerge and IMPactMF and commencement of new clinical studies associated with the imetelstat pipeline expansion strategy; (c) finalizing validation batches of imetelstat at contract manufacturers to enable future production of imetelstat for clinical and commercial purposes; (d) projected increases in headcount and (e) interest payments on outstanding debt.

As of June 30, 2022, the Company had 86 employees. The Company plans to grow to a total of approximately 90 to 100 employees by year-end 2022.

Conference Call

Geron will host a conference call at 4:30 p.m. ET on Thursday, August 11, 2022 to review recent events and second quarter 2022 financial results.

A live webcast of the conference call and related presentation will be available on the Company's website at www.geron.com/investors/events. An archive of the webcast will be available on the Company's website for 30 days.

Participants may access the webcast by registering online using the following link: <https://conferencingportals.com/event/SmvIMvWL>. Participants that are unable to register online can access the conference call via telephone by dialing domestically +1 (888) 330-2434 or internationally +1 (240) 789-2725. The conference ID is 67335.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic malignancies. Data from Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in myeloid hematologic malignancies resulting in malignant cell apoptosis and potential disease-modifying activity. 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 associated kinase (JAK) inhibitor treatment.

About IMerge Phase 3

IMerge Phase 3 is a double-blind, randomized, placebo-controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 170 transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes (MDS), also referred to as lower risk MDS, who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent (ESA). The primary endpoint is the rate of red blood cell (RBC) transfusion independence (TI) for any consecutive period of eight weeks or longer, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, duration of TI 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.

IMerge Phase 3 is fully enrolled and patient enrollment has been closed. For additional information about IMerge Phase 3, visit ClinicalTrials.gov/NCT02598661.

About IMPactMF Phase 3

IMPactMF is an open label, randomized, controlled Phase 3 clinical trial with registrational intent. The trial is designed to enroll approximately 320 patients with Intermediate-2 or High-risk myelofibrosis (MF) who are refractory to prior treatment with a JAK inhibitor, also referred to as refractory MF. Patients will be randomized to receive either imetelstat or best available therapy. The primary endpoint is overall survival (OS). Key secondary endpoints include symptom response, spleen response, progression free survival, complete remission, partial remission, clinical improvement, duration of response, safety, pharmacokinetics, and patient reported outcomes.

IMpactMF is currently enrolling patients. For further information about IMpactMF, including enrollment criteria, locations and current status, visit ClinicalTrials.gov/NCT04576156.

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 malignancies. The Company currently is conducting two Phase 3 clinical trials: IMerge in lower risk myelodysplastic syndromes and IMpactMF in refractory myelofibrosis.

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 for IMerge Phase 3, Geron expects top-line results to be available in early January 2023; (ii) that Geron believes current and projected financial resources are expected to support planned milestones and operations through the middle of 2024; (iii) that Geron expects to transform from a development stage to commercial company; (iv) that Geron expects a potential U.S. approval and commercial launch of imetelstat in the first half of 2024; (v) that Geron expects up to \$75 million in non-dilutive capital to be potentially available through the existing loan facility; (vi) that in lower risk MDS, Geron expects a New Drug Application submission in the U.S. in the first half of 2023 and a Marketing Authorization application submission in the EU in the second half of 2023; (vii) that in myelofibrosis, Geron expects to open the remaining selected IMpactMF Phase 3 clinical sites by year-end 2022 and an interim analysis in 2024; (viii) that Geron expects the IMpress study to start in the second half of 2022; (ix) that Geron expects the TELOMERE study to start in the second half of 2022; (x) that Geron expects initial preclinical lymphoid malignancies data by year-end 2022; (xi) that Geron expects preliminary data from IMproveMF by year-end 2023; (xii) that Geron expects proceeds of up to approximately \$124 million from the exercise of currently outstanding warrants; (xiii) that Geron expects total GAAP operating expenses in 2022 to be approximately \$155 to \$165 million and non-GAAP operating expenses in 2022 to be approximately \$140 to \$150 million; (xiv) that imetelstat has the potential to demonstrate disease-modifying activity and (xv) 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/or the Russia/Ukraine conflict cause global economic and financial disruptions that 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/or the Russia/Ukraine conflict, and overcomes all the enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to have the financial resources for, and to meet the expected timelines, planned milestones and events in (i) and (iii) to (xii) 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 IMerge Phase 3 and IMpactMF to enable regulatory approval; (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 and the ability to target the malignant stem and progenitor cells of the underlying disease; (g) that Geron may seek to raise substantial additional capital in order to complete the development and commercialization of imetelstat to meet all of the expected timelines, planned milestones and events in (i) and (iii) to (xii) above; (h) whether regulatory authorities require an additional clinical trial for approval even if IMerge Phase 3 or IMpactMF meet their respective primary endpoints; (i) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials in a timely manner, or at all; (j) whether the patient follow-up period of 12 months in IMerge Phase 3 results in not obtaining adequate data to demonstrate safety and efficacy, including transfusion independence, for achieving success in the primary analysis; (k) whether the FDA will approve imetelstat for lower risk MDS based on

IMerge Phase 3 safety and efficacy data that is similar to the data in IMerge Phase 2: (l) whether Geron can accurately project the timing of enrollment in its clinical trials, whether due to the current or evolving effects of the COVID-19 pandemic, the Russia/Ukraine conflict, or otherwise; (m) whether Geron is able to enroll its clinical trials at a pace that would enable the financial resources for, and to meet the expected timelines, planned milestones and events in (i) to (xii) above; (n) whether the outstanding warrants will be exercised and result in proceeds of up to approximately \$124 million and (o) whether the clinical, regulatory and financial milestones and capitalization requirements are achieved to enable availability of the \$75 million in debt tranches. 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, 2022 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.

Non-GAAP Financial Measure

To supplement Geron's financial results and guidance presented in accordance with GAAP, the Company is providing projected non-GAAP total operating expenses, which excludes stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization, from projected GAAP total operating expenses. The Company believes this non-GAAP financial measure, when considered together with other financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Geron's results from period to period and to projected forward-looking guidance, and to identify operating trends in Geron's business. The exclusion of non-cash items, such as stock-based compensation expense, amortization of debt discounts and issuance costs and depreciation and amortization, does not directly or immediately relate to the operational performance for the periods presented. This projected non-GAAP financial measure is in addition to, not a substitute for, or superior to, measures of financial performance projected in accordance with GAAP. Geron encourages investors to carefully consider the Company's results under GAAP, as well as the supplemental non-GAAP financial information, to more fully understand Geron's business.

Financial table follows.

GERON CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

<i>(In thousands, except share and per share data)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
License fees and royalties	\$ 73	\$ 107	\$ 196	\$ 244
Operating expenses:				
Research and development	20,606	21,937	42,705	43,050
General and administrative	7,443	7,059	14,142	14,537
Total operating expenses	<u>28,049</u>	<u>28,996</u>	<u>56,847</u>	<u>57,587</u>
Loss from operations	(27,976)	(28,889)	(56,651)	(57,343)
Interest income	330	136	442	309
Interest expense	(1,581)	(804)	(3,060)	(1,547)
Other income and expense, net	1,110	(17)	1,054	1,183
Net loss	<u>\$ (28,117)</u>	<u>\$ (29,574)</u>	<u>\$ (58,215)</u>	<u>\$ (57,398)</u>
Basic and diluted net loss per share:				
Net loss per share	<u>\$ (0.07)</u>	<u>\$ (0.09)</u>	<u>\$ (0.16)</u>	<u>\$ (0.18)</u>
Shares used in computing net loss per share	<u>403,868,713</u>	<u>327,026,907</u>	<u>368,166,148</u>	<u>325,342,161</u>

CONDENSED CONSOLIDATED BALANCE SHEETS

<i>(In thousands)</i>	June 30, 2022 (Unaudited)	December 31, 2021 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	\$ 76,421	\$ 35,235
Current marketable securities	143,230	148,851
Other current assets	7,724	3,120
Total current assets	<u>\$ 227,375</u>	<u>\$ 187,206</u>
Noncurrent marketable securities	—	28,651
Property and equipment, net	641	650
Deposits and other assets	10,145	9,527
	<u>\$ 238,161</u>	<u>\$ 226,034</u>
Current liabilities	\$ 46,879	\$ 45,521
Noncurrent liabilities	49,235	54,097
Stockholders' equity	142,047	126,416
	<u>\$ 238,161</u>	<u>\$ 226,034</u>

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2021.

CONTACT:

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