Geron Corporation Reports Third Quarter 2020 Financial Results and Current Events

11/5/2020

FOSTER CITY, Calif., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Geron Corporation (Nasdaq: GERN), a late-stage clinical biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2020. The Company will host a conference call today at 4:30 p.m. ET to discuss third quarter financial results and current events. As of September 30, 2020, Geron had approximately $274 million in cash and investments. Based on current planning assumptions, the Company estimates its current financial resources to be sufficient for its operations until the end of 2022.

“In the third quarter, we executed on our clinical, regulatory and publication plans for the imetelstat program,” said John A. Scarlett, M.D., Chairman and Chief Executive Officer. “We continued to advance both the enrollment of the ongoing IMerge Phase 3 clinical trial and start-up activities for the upcoming Phase 3 clinical trial in refractory myelofibrosis, which we have named IMpactMF. We also secured European orphan drug designation in lower risk MDS; received acceptance for presentation of all ten abstracts submitted to the ASH Annual Meeting; and had the IMerge Phase 2 data published in the well-respected Journal of Clinical Oncology. In addition, we strengthened our balance sheet with a loan facility that provides additional financial flexibility to support our plans for imetelstat development going forward.”

Dr. Scarlett added, “We continue to work toward completing enrollment in IMerge in the first quarter of 2021. However, the recent resurgence of the COVID-19 pandemic is causing an uncertain and unpredictable impact on clinical trial activities. Due to these challenges, we now believe the trial will most likely be fully enrolled in the second quarter of 2021. As long as enrollment is complete by the end of the first half of 2021, we continue to expect top-line results from IMerge to be available in the second half of 2022, as previously guided. Based on current feedback from clinical sites planned to participate in IMpactMF, we continue to expect that trial to be open for screening and enrollment in the first quarter of 2021.”

Current Events – Clinical Development

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

Enrollment for the IMerge Phase 3 clinical trial continued to progress in the third quarter. In August 2020, all 92 of the originally planned clinical sites were open for enrollment.

To address enrollment delays related to the COVID-19 pandemic experienced earlier this year, Geron implemented certain enrollment boosting activities, including engaging clinical science liaisons to interface directly with clinical sites and expanding the number of clinical sites to diversify the participating countries. The Company currently expects to add approximately 30 new clinical sites in several countries, including new sites in four additional countries that had not previously participated in IMerge. The Company expects almost all of the new sites to be open for screening and enrollment by the end of 2020.

Under current planning assumptions, the Company expects enrollment in the IMerge Phase 3 trial to be complete in the second quarter of 2021 and continues to expect top-line results to be available in the second half of 2022. This anticipated timing is subject to potential delays or interruptions associated with the evolving effects of the ongoing COVID-19 pandemic, which causes unpredictability when projecting future enrollment trends.

Upcoming IMpactMF Phase 3 Clinical Trial in Myelofibrosis (MF)

The Phase 3 clinical trial in refractory MF with overall survival (OS) as its primary endpoint, named IMpactMF, is expected to be open for screening and enrollment in the first quarter of 2021. Geron expects to engage over 150 sites across North America, South America, Europe and Asia. The clinical trial protocol has been finalized and is available on **clinicaltrials.gov**. Trial start-up activities are ongoing and include site selection, engagement of vendors, and building of the clinical trial database.

The final analysis for OS is event-driven and is planned to be conducted after more than 50% of the patients enrolled in the trial have died. An interim analysis of OS is planned to be conducted after approximately 70% of the total projected number of events for the final analysis have occurred. If the pre-specified, statistically significant difference in OS between the two treatment arms is met at the interim analysis, it is possible that data from the interim analysis could support a registration filing. Both the planned interim and final analyses are event-driven and could occur on different timelines than currently expected.

Under current planning assumptions, Geron plans 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.

Financial Resources to Reach Clinical Milestones

The Company's current cash position reflects net proceeds of approximately $140 million from a public offering in May 2020 and approximately $24 million in initial net proceeds from a $75 million loan facility that closed at the

end of the third quarter. The loan facility is available through year-end 2022 in three tranches subject to the achievement of certain clinical, financial and regulatory milestones. The loan facility provides access to non-dilutive financial resources to support the imetelstat development program, as well as working capital and general corporate purposes.

Third Quarter and Year - to - Date 2020 Results

For the third quarter of 2020, the Company reported a net loss of $19.7 million, or $0.06 per share, compared to $15.2 million, or $0.08 per share, for the comparable 2019 period. Net loss for the first nine months of 2020 was $51.8 million, or $0.20 per share, compared to $39.5 million, or $0.21 per share, for the comparable 2019 period.

Revenues for the three and nine months ended September 30, 2020 were $108,000 and $203,000, respectively, compared to $131,000 and $289,000 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 nine months ended September 30, 2020 were $20.1 million and $53.9 million, respectively, compared to $16.1 million and $42.8 million for the comparable 2019 periods.

Research and development expenses for the three and nine months ended September 30, 2020 were $13.6 million and $35.3 million, respectively, compared to $11.1 million and $27.1 million for the comparable 2019 periods. The increase in research and development expenses for the three and nine months ended September 30, 2020, compared to the same periods in 2019, primarily reflects increased costs to support the ongoing IMerge Phase 3 and start-up activities for the upcoming IMpactMF Phase 3 clinical trial. The increase also includes higher costs in connection with validating the imetelstat manufacturing process at contract manufacturers and additional personnel-related costs for expansion of the development team in 2019.

General and administrative expenses for the three and nine months ended September 30, 2020 were $6.5 million and $18.6 million, respectively, compared to $5.0 million and $15.6 million for the comparable 2019 periods. The increase in general and administrative expenses for the three and nine months ended September 30, 2020, compared to same periods in 2019, primarily reflects higher personnel-related expenses for additional general and administrative headcount to support growing operational activities and increased legal costs.

Interest and other income for the three and nine months ended September 30, 2020 was $504,000 and $1.7 million, respectively, compared to $1.0 million and $3.3 million for the comparable 2019 periods. The decrease in interest

and other income for the three and nine months ended September 30, 2020, compared to same periods in 2019, primarily reflects lower yields on the Company's marketable securities portfolio due to declining interest rates.

2020 Financial Guidance Reaffirmed

The Company continues to expect its 2020 operating expense burn to range from $70 to $75 million. This guidance includes new costs for start-up activities associated with the IMpactMF Phase 3 clinical trial 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, November 5, 2020 to discuss third 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 pre-registering online using the following link, **http://www.directeventreg.com/registration/event/7879966**. Upon registration, a phone number, Direct Event Passcode and unique Registrant ID will be sent via email. This information 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 IMpactMF, an upcoming 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) that imetelstat may have disease-modifying activity; (ii) that Geron's current financial resources are sufficient for its operations until the end of 2022; (iii) that IMpactMF will be open for screening and enrollment in the first quarter of 2021; (iv) that the loan facility is available through the end of 2022 subject to the achievement of certain clinical, financial and regulatory milestones; (v) that IMerge will likely be fully enrolled by the end of the second quarter of 2021; (vi) that top-line results for IMerge will be available in the second half of 2022; (vii) that almost all of the new IMerge sites will be open for screening and enrollment by the end of 2020; (viii) the possibility that data from the IMpactMF interim analysis could support a registrational filing; (ix) that under current planning assumptions, for IMpactMF Geron expects to 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; (x) that Geron's 2020 expense burn will range from $70 to $75 million; and (xi) 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 (iii), (v), (vi), (vii) and (ix) 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) that Geron will 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 (iii), (v), (vi), (vii) and (ix) above; (h) whether Geron is able to achieve the required milestones to be eligible for the additional tranches of the loan facility; (i) 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; (j) whether imetelstat is able

to maintain patent protection and have freedom to operate; (k) whether there are cost overruns in 2020 due to the current or evolving effects of the COVID-19 pandemic or otherwise; and (l) whether Geron can accurately project the timing of, or attain complete enrollment in IMerge or IMpactMF, 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 September 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 September 30, 2020	2019	Nine Months Ended September 30, 2020	2019
Revenues:				
License fees and royalties	$ 108	$ 131	$ 203	$ 289
Operating expenses:				
Research and development	13,613	11,109	35,260	27,149
General and administrative	6,510	4,994	18,590	15,637
Total operating expenses	20,123	16,103	53,850	42,786
Loss from operations	(20,015)	(15,972)	(53,647)	(42,497)
Interest and other income	504	1,021	1,733	3,296
Change in fair value of equity investment	(118)	(195)	109	(195)
Interest and other expense	(22)	(34)	(25)	(82)
Net loss	$ (19,651)	$ (15,180)	$ (51,830)	$ (39,478)
Basic and diluted net loss per share :				
Net loss per share	$ (0.06)	$ (0.08)	$ (0.20)	$ (0.21)
Shares used in computing net loss per share	318,799,174	189,123,647	255,560,779	187,367,621

CONDENSED BALANCE SHEETS

(In thousands)	September 30, 2020 (Unaudited)	December 31, 2019 (Note 1)
Current assets:		
Cash, cash equivalents and restricted cash	$ 45,319	$ 13,914
Current marketable securities	182,667	125,681
Other current assets	3,875	2,013
Total current assets	231,861	141,608
Noncurrent marketable securities	45,768	19,651
Property and equipment, net	689	408
Deposits and other assets	7,475	3,850
	$ 285,793	$ 165,517
Current liabilities	$ 24,154	$ 28,162
Noncurrent liabilities	28,807	2,200
Stockholders' equity	232,832	135,155
	$ 285,793	$ 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.

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Source: Geron Corporation