

Geron Announces Removal of Full Clinical Hold on Imetelstat IND

November 3, 2014 7:30 AM ET

2014 Third Quarter and Year-to-Date Financial Results Also Reported

Menlo Park, Calif., November 3, 2014 - Geron Corporation (Nasdaq: GERN) announced today that the U.S. Food and Drug Administration (FDA) has removed the full clinical hold on Geron's investigational new drug (IND) application for imetelstat. In addition, the FDA stated that Geron's proposed clinical development plan for imetelstat that is focused on high-risk myeloid malignancies, such as myelofibrosis (MF), is acceptable. The FDA acknowledged that the company does not intend to conduct further studies in, or develop imetelstat for, the treatment of essential thrombocythemia (ET) or polycythemia vera, which is consistent with the company's plans as originally disclosed in April 2013.

To address the full clinical hold, the FDA required Geron to provide follow-up information from imetelstat-treated patients who experienced liver function test (LFT) abnormalities until such abnormalities resolved to normal or baseline. Geron obtained clinical follow-up information from patients in the previously ongoing company-sponsored Phase 2 trials in ET and multiple myeloma (MM). These data were submitted to the FDA as part of the company's complete response. The company's analysis of these data concluded that in the ET trial LFT abnormalities resolved to normal or baseline in 14 of 18 follow-up patients. For the remaining four ET patients, at the time of the data cut-off, three patients showed improvement in LFT abnormalities and one patient had unresolved LFT abnormalities. Currently, two of the remaining four ET patients continue in follow-up. In the MM trial, LFT abnormalities resolved to normal or baseline in all nine follow-up patients. In addition, no emergent hepatic adverse events were reported during follow-up for either study.

The FDA also requested information regarding the reversibility of liver toxicity after chronic imetelstat administration in animals. The company submitted data from its previously conducted non-clinical toxicology studies, which included a six-month study in mice and a nine-month study in cynomolgus monkeys. In these studies, no clinical pathology changes indicative of hepatocellular injury were observed, and no clear signal of LFT abnormalities were identified.

With the lift of the full clinical hold, a multi-center Phase 2 clinical trial in MF is projected to begin in the first half of 2015.

Upcoming Investor Conference

Geron's management plans to provide an update on the company and development plans for imetelstat at the Stifel Healthcare Conference. The audio and slide presentation will be webcast and is scheduled to occur at 1:50 p.m. Eastern Time on Wednesday, November 19, 2014.

Third Quarter 2014 Financial Results

For the third quarter of 2014, the company reported a net loss of \$9.5 million, or \$0.06 per share, compared to \$8.3 million, or \$0.06 per share, for the comparable 2013 period. Revenues for the third quarter of 2014 were \$160,000 compared to \$181,000 for the comparable 2013 period. The company ended the third quarter of 2014 with \$142.5 million in cash and investments.

Total operating expenses for the third quarter of 2014 were \$10.1 million compared to \$8.9 million for the comparable 2013 period. Research and development expenses for the third quarter of 2014 were \$6.0 million compared to \$5.3 million for the comparable 2013 period. General and administrative expenses for the third quarter of 2014 were \$4.1 million compared to \$3.5 million for the comparable 2013 period. Operating expenses for the 2013 third quarter also included restructuring charges of \$116,000 in connection with the company's decisions to discontinue its discovery research programs and close its research laboratory facility in the second quarter of 2013.

The increase in research and development expenses for the third quarter of 2014, compared to the same period in 2013,

primarily reflected higher costs for the manufacturing of imetelstat. The increase in general and administrative expenses for the third quarter of 2014, compared to the same period in 2013, was primarily the net result of higher non-cash stock-based compensation expense and increased legal costs associated with the purported securities lawsuits and derivative lawsuit filed against the company, partially offset by reduced patent costs and transaction fees associated with the stem cell divestiture which closed in October 2013.

Interest and other income for the third quarter of 2014 amounted to \$91,000 compared to \$699,000 for the comparable 2013 period. The decrease in interest and other income for the third quarter of 2014, compared to the same period in 2013, was primarily the net result of a gain on the sale of excess laboratory equipment in connection with the closure of the company's research laboratory facility in 2013, partially offset by higher interest income due to increased cash and investment balances with the receipt of net cash proceeds from the underwritten public offering the company completed in February 2014.

Nine Months Ended 2014 Financial Results

Net loss for the first nine months of 2014 was \$26.7 million, or \$0.18 per share, compared to \$29.1 million, or \$0.23 per share, for the comparable 2013 period. Revenues for the first nine months of 2014 were \$1.0 million compared to \$1.1 million for the comparable 2013 period.

Total operating expenses for the first nine months of 2014 were \$28.3 million compared to \$30.7 million for the comparable 2013 period. Research and development expenses for the first nine months of 2014 were \$16.4 million compared to \$18.1 million for the comparable 2013 period. General and administrative expenses for the first nine months of 2014 were \$11.9 million compared to \$11.6 million for the comparable 2013 period. Year-to-date operating expenses for 2013 also included restructuring charges of \$1.0 million.

The decrease in research and development expenses for the first nine months of 2014, compared to the same period in 2013, was primarily the net result of lower clinical trial expenses with the wind-down of the imetelstat trials in solid tumors and GRN1005 trials in patients with brain metastases and reduced personnel-related and other research costs resulting from previous restructurings and the discontinuation of the company's discovery research programs, partially offset by higher costs for the manufacturing of imetelstat. The increase in general and administrative expenses for first nine months of 2014, compared to the same period in 2013, was primarily the net result of higher non-cash stock-based compensation expense and increased legal costs associated with the purported lawsuits, partially offset by reduced patent costs and transaction fees associated with the stem cell divestiture.

Interest and other income for the first nine months of 2014 was \$273,000 compared to \$836,000 for the comparable 2013 period. The decrease in interest and other income for the first nine months of 2014, compared to the same period in 2013, was primarily the net result of a gain in 2013 for the sale of excess laboratory equipment, partially offset by an increase in interest income in 2014.

About Geron

Geron is a clinical stage biopharmaceutical company developing 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 statements of historical fact, this press release contains forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding: (i) the company's development program being focused on high-risk myeloid malignancies such as MF; (ii) the projection that the Phase 2 clinical trial in MF will begin in the first half of 2015 and (iii) other statements that are not historical fact. 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

regarding: whether the FDA permits Geron to proceed with a Phase 2 clinical trial in MF; success of clinical operational activities; availability of drug supply; participation of clinical trial investigators; successful third-party contracts; being placed on another clinical hold; and technical, scientific and regulatory challenges. Additional detailed information and factors that could cause actual results to differ materially from those in the forward-looking statements is contained in Geron's periodic reports filed with the Securities and Exchange Commission primarily under the heading "Risk Factors," including in Geron's quarterly report on Form 10-Q for the quarter ended June 30, 2014. Undue reliance should not be placed on Geron's forward-looking statements, and Geron disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

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Financial table follows.

GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended		Nine Months Ended	
	<u>September 30,</u>		<u>September 30,</u>	
<i>(In thousands, except share and per share data)</i>	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
License fees and royalties	\$ 160	\$ 181	\$ 975	\$ 1,058
Operating expenses:				
Research and development	5,994	5,338	16,356	18,066
Restructuring charges	-	116	-	1,032
General and administrative	<u>4,073</u>	<u>3,460</u>	<u>11,920</u>	<u>11,643</u>
Total operating expenses	<u>10,067</u>	<u>8,914</u>	<u>28,276</u>	<u>30,741</u>
Loss from operations	(9,907)	(8,733)	(27,301)	(29,683)
Unrealized gain (loss) on derivatives	289	(208)	366	(207)
Interest and other income	91	699	273	836
Interest and other expense	<u>(22)</u>	<u>(12)</u>	<u>(61)</u>	<u>(44)</u>
Net loss	\$ <u>(9,549)</u>	\$ <u>(8,254)</u>	\$ <u>(26,723)</u>	\$ <u>(29,098)</u>

Basic and diluted net loss per share:

Net loss per share	\$ <u>(0.06)</u>	\$ <u>(0.06)</u>	\$ <u>(0.18)</u>	\$ <u>(0.23)</u>
Shares used in computing net loss per share	<u>156,843,989</u>	<u>128,293,074</u>	<u>152,338,668</u>	<u>128,146,333</u>

CONDENSED BALANCE SHEETS

	September 30, December 31,	
<i>(In thousands)</i>	<u>2014</u>	<u>2013</u>
	(Unaudited)	(Note 1)

Current assets:

Cash, cash equivalents and restricted cash \$	7,865	\$ 13,785
Current marketable securities	118,801	52,234
Other current assets	<u>1,526</u>	<u>1,038</u>
Total current assets	128,192	67,057

Noncurrent marketable securities	15,801	-
Property and equipment, net	63	92
Deposits and other assets	<u>191</u>	<u>195</u>
\$	<u>144,247</u>	\$ <u>67,344</u>

Current liabilities	\$ 7,069	\$ 7,587
Stockholders' equity	<u>137,178</u>	<u>59,757</u>
\$	<u>144,247</u>	\$ <u>67,344</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, 2013.

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