GERON CORP
Form 8-K
November 13, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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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): **November 13, 2014**

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)

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On November 13, 2014 (the Execution Date), Geron Corporation (Geron or the Company) and Janssen Biotech, Inc., a Pennsylvania corporation (Janssen), entered into an exclusive collaboration and license agreement (the Collaboration Agreement) to develop and commercialize imetelstat worldwide for oncology, including hematologic myeloid malignancies, and all other human therapeutic uses. The effectiveness of the Collaboration Agreement is subject to the expiration or earlier termination of all applicable waiting periods under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976, as amended.

Under the Collaboration Agreement, Geron has granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all indications, and Janssen is responsible for the development of, seeking regulatory approval for, and commercializing imetelstat worldwide. Following a transition period, Janssen would also be responsible for the manufacture of imetelstat on a global basis. Under the Collaboration Agreement, development of imetelstat will initially proceed under a mutually agreed joint clinical development plan (CDP), which includes two agreed upon Phase 2 studies, one in myelofibrosis (the Initial Phase 2 MF Study) and one in myelodysplastic syndrome (the Initial Phase 2 MDS Study), to be pursued initially, as well as additional, possible registration studies in myelofibrosis (MF) and myelodysplastic syndrome (MDS), and possible exploratory Phase 2 and potential follow-on Phase 3 studies in acute myelogenous leukemia (AML). Development costs for the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study will be shared between the parties on a 50/50 basis. The Company expects the Initial Phase 2 MF Study to be initiated in mid-2015 followed later by the Initial Phase 2 MDS Study.

Upon the effectiveness of the Collaboration Agreement, Janssen will owe to Geron $35 million as an upfront payment. Following the protocol-specified primary analysis of the Initial Phase 2 MF Study or after a certain time period after the initiation of the first Phase 3 MF study, Janssen must notify Geron whether it elects to maintain its license rights and continue to advance the development of imetelstat in any indication. In the event that the Initial Phase 2 MF Study has been terminated early or suspended, Janssen must instead notify Geron of its election by the date that is the later of 24 months from the initiation of the planned Initial Phase 2 MDS Study or 24 months from the termination of the Initial Phase 2 MF Study or commencement of the suspension period, as applicable.

In the event that Janssen elects to continue to maintain its license rights and advance the development of imetelstat in any indication within the applicable timeframe set forth in the Collaboration Agreement (such election, the Continuation Election), Geron then would have an option (the U.S. Opt-In Rights) to share further U.S. development and promotion costs in exchange for higher tiered royalty rates and higher future milestone payments if imetelstat is successfully developed and approved. If Geron exercises the U.S. Opt-In Rights, then the parties would share U.S. development and promotion costs on a 20/80 basis (Geron 20%, Janssen 80%), Geron would receive a $65 million milestone payment at the time of the Continuation Election, and would be eligible to receive additional potential payments of up to $470 million in development and regulatory milestones, up to $350 million in sales milestones, and tiered royalties ranging from a mid-teens up to low twenties percentage rate on worldwide net sales of imetelstat in any countries where regulatory exclusivity exists or there are valid claims under the patent rights exclusively licensed to Janssen. In addition, if Geron exercises the U.S. Opt-In Rights, then Geron would also have a separate co-promotion option to provide 20% of the U.S. selling effort with sales force personnel, in lieu of funding 20% of U.S. promotion costs, upon regulatory approval and commercial launch of imetelstat in the United States. Such co-promotion would be conducted under a Janssen prepared promotion plan, and in accordance with a co-promotion agreement to be agreed by the parties at the time of Geron s exercise of its co-promotion option. Geron would be responsible for all costs associated with the fielding of its sales force in the conduct of such co-promotion. All product sales would be booked by Janssen. If Geron does not exercise the U.S. Opt-In Rights, then all further development and promotion costs beyond the Initial Phase 2 MF Study or Initial Phase 2 MDS Study would be borne by Janssen, Geron would receive a $65 million milestone payment at the time of the Continuation Election plus a $70 million payment for Janssen s retention of full U.S. rights, and would be eligible to receive additional potential payments of up to $415 million in development and regulatory milestones, up to $350 million in sales milestones, and tiered royalties ranging from a double-digit up to mid-teens percentage rate on worldwide net sales in any countries where regulatory exclusivity exists or there are valid claims under the patent rights exclusively licensed to Janssen. After a Continuation Election by Janssen, the Collaboration Agreement would remain in effect until the expiration of the last-to-expire patent or the royalty obligations on sales of imetelstat cease, unless terminated earlier. If Janssen does not effect a Continuation Election, then the Collaboration Agreement would terminate and all rights would revert to Geron.

Under the terms of the Collaboration Agreement, Geron and Janssen will create a joint governance structure, including joint development and steering committees and working groups, to oversee and manage worldwide regulatory, development and manufacturing work under the joint CDP and promotional activities (assuming Geron exercises the U.S. Opt-In Rights) for imetelstat, with Janssen responsible for the operational implementation of those activities. In addition, each of Geron and Janssen may propose to the joint development committee imetelstat development for any new indications not then provided for in the joint CDP and if the parties agree such development should be conducted outside of the joint CDP, each of Geron and Janssen would be entitled to independently undertake such development at its own cost, subject to the other party s obligation to provide reimbursement for its specified portion of the costs for such independent development following marketing approval of imetelstat in such newly proposed indication as a result of such independent development. In the event that Geron does not exercise the U.S. Opt-In Rights following Janssen s Continuation Election, the joint governance structure under the Collaboration Agreement would be dissolved, a joint oversight committee would monitor Janssen diligence obligations, and Geron would have no further rights to conduct any independent imetelstat development.

Under the terms of the Collaboration Agreement, Geron would remain responsible for prosecuting, at Janssen s direction, its patents licensed to Janssen on the Execution Date, with costs shared between Geron and Janssen on a 50/50 basis. For intellectual property developed under the Collaboration Agreement (Development IP), the party having sole ownership interest in such Development IP would be responsible for prosecuting the patents, with Janssen bearing all of the costs for Development IP solely owned by Janssen and costs shared between the parties on a 50/50 basis for Development IP either jointly owned or solely owned by Geron.

The Collaboration Agreement contains customary and other representations, warranties and covenants by Geron and Janssen. Each of Geron and Janssen is required to indemnify the other party against all losses and expenses relating to third party claims arising from its development and, where applicable, commercialization of imetelstat, and breaches of its representations, warranties and covenants.

Janssen may terminate the Collaboration Agreement at any time for convenience (which includes Janssen s failure to effect the Continuation Election), and due to a safety-related concern. Depending on when the notice of termination from Janssen occurs, Geron would be entitled to certain continued operational support and cost-sharing under various circumstances. Upon a termination by Janssen for safety reasons or for convenience (which includes the failure by Janssen to effect the Continuation Election) or upon a termination by Geron as a result of an uncured material breach of the Collaboration Agreement by Janssen, the following would occur:

- Geron would receive all rights to regulatory filings, and the clinical data contained in such filings, related to imetelstat;
- all licenses to Janssen would terminate;
- Janssen would provide Geron with a worldwide, exclusive, perpetual license to, with a right to sublicense, intellectual property developed under the collaboration and necessary to develop, manufacture and commercialize imetelstat;
- Janssen would support the transition of relationships with third party subcontractors or sublicensees to Geron; and
- Janssen would supply imetelstat for a period of up to 12 to 24 months from the effective date of termination to enable Geron to procure an alternative manufacturing source.

In addition to the above, in the case of a termination by Janssen for convenience (which includes the failure by Janssen to effect the Continuation Election), the following additional provisions would apply:

- Janssen would provide operational support to Geron for up to 12 months from the date of notice of termination; and
- Janssen would continue funding the development costs allocable to Janssen for certain periods, depending on the timing of termination.

In addition, either Geron or Janssen may terminate the Collaboration Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the Collaboration Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances.

The foregoing description of the Collaboration Agreement and the transactions contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by reference to, the complete text of the Collaboration Agreement, which will be filed with the Securities and Exchange Commission (the SEC) as an exhibit to the Company s Annual Report on Form 10-K for the year ending December 31, 2014.

Use of Forward-Looking Statements

Except for the historical information contained herein, this Current Report on Form 8-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that statements in this Current Report on Form 8-K regarding (i) the anticipated effectiveness of the Collaboration Agreement, (ii) the Company s receipt of an initial payment and potential receipt of development, regulatory, and sales milestones, as well as royalties on potential future sales of imetelstat commercialized under the Collaboration Agreement, (iii) planned and potential clinical trials of imetelstat to be conducted under the Collaboration Agreement, including the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study, and other potential activities under the Collaboration Agreement, and (iv) 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) the ability of the parties to satisfy all of the conditions for the effectiveness of the Collaboration Agreement, including the expiration or termination of waiting periods under HSR; (ii) the uncertain and time consuming product development and regulatory process, including whether the parties will succeed in overcoming all of the clinical safety and efficacy, technical, scientific, manufacturing and regulatory challenges in the development and commercialization of imetelstat; (iii) the fact that Geron may not receive any milestone, royalty or other payments from Janssen because Janssen may terminate the Collaboration Agreement for any reason; (iv) the ability of Geron and Janssen to protect and maintain intellectual property rights for imetelstat; (v) the Company s dependence on Janssen, including the risks that if Janssen were to breach or terminate the Collaboration Agreement or otherwise fail to successfully develop and commercialize imetelstat and in a timely manner, the Company would not obtain the anticipated financial and other benefits of the Collaboration Agreement and the clinical development or commercialization of imetelstat could be delayed or terminated; and (vi) other risks described in Geron s SEC filings, including under the heading Risk Factors Exhibit 99.1 hereto which is incorporated herein by reference. Additional information and factors that could cause actual results to differ materially from those in the forward-looking statements are contained under the heading Risk Factors in Exhibit 99.1 hereto which is incorporated herein by reference. 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.

Item 8.01. Other Events.

The Company is filing information for the purpose of updating and superseding the risk factor disclosure contained in its prior public filings, including those discussed under the heading Item 1A. Risk Factors in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 5, 2014. The updated risk factors are filed as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Updated Risk Factors

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: November 13, 2014

By: /s/ Stephen N. Rosenfield
Name: Stephen N. Rosenfield
Title: Executive Vice President, General Counsel and Corporate Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Updated Risk Factors