

GERON CORP
Form 8-K
June 15, 2015

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): **June 11, 2015**

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

0-20859
(Commission File Number)

75-2287752
(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)

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))

Item 7.01 Regulation FD Disclosure.

On June 11, 2015, the United States Food and Drug Administration (the "FDA") granted orphan-drug designation to imetelstat for the treatment of myelofibrosis. Imetelstat is a telomerase inhibitor discovered by Geron Corporation that has been exclusively licensed to Janssen Biotech, Inc. ("Janssen") on a worldwide basis for development and commercialization in oncology indications, including hematologic myeloid malignancies, and all other human therapeutic uses. Janssen sponsored the application to the FDA for orphan designation.

For a drug to qualify for orphan designation both the drug and the disease or condition must meet certain criteria specified in the Orphan Drug Act (the "ODA") and FDA's implementing regulations at 21 CFR Part 316. Orphan status is granted by the FDA's Office of Orphan Drug Products in order to support development of medicines for underserved or rare diseases and patient populations that affect fewer than 200,000 people in the United States. Orphan designation qualifies the sponsor of the drug for various development incentives of the ODA, including, if regulatory approval is received, market exclusivity, exemption from FDA application fees, and certain tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated. The granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a drug must be established through adequate and well-controlled studies.

The information contained in this Item 7.01 to this Current Report shall be deemed to be furnished and shall not be deemed to be filed for 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 7.01 to this Current Report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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: June 15, 2015

By:

/s/ Stephen N. Rosenfield
Stephen N. Rosenfield
Executive Vice President, General
Counsel and Corporate Secretary