GERON CORP
Form 10-K
March 11, 2015

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2014

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .
Commission File Number: 0-20859

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**75-2287752**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
149 Commonwealth Drive, Suite 2070, Menlo Park, CA	**94025**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 473-7700**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**

Common Stock, $0.001 par value	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ý

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $501,005,000 based upon the closing price of the registrant's common stock on June 30, 2014 on the Nasdaq Global Select Market. The calculation of the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant excludes shares of common stock held by each officer, director and stockholder that the registrant concluded were affiliates on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 6, 2015, there were 157,700,375 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Document	**Form 10-K Parts**
Portions of the Registrant's definitive proxy statement for the 2015 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2014	III

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In this report, unless otherwise indicated or the context otherwise requires, "Geron," "the registrant," "we," "us," and "our" refer to Geron Corporation, a Delaware corporation.

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Forward-Looking Statements

This annual report on Form 10-K, including "Business" in Part I, Item 1 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7, contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause the results of Geron Corporation, or Geron or the Company, to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "expects," "plans," "intends," "will," "should," "projects," "believes," "predicts," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. The risks and uncertainties referred to above include, without limitation, risks related to our research and development efforts, our dependence on Janssen Biotech, Inc. for the development, regulatory approval, manufacture and commercialization of our sole product candidate, imetelstat, need for future capital, uncertainty of clinical trial results or regulatory approvals or clearances, the future development of imetelstat, including any future efficacy or safety results that cause the benefit-risk profile of imetelstat to become unacceptable, enforcement of our patent and proprietary rights, reliance upon investigators, potential competition and other risks that are described herein and that are otherwise described from time to time in our Securities and Exchange Commission reports including, but not limited to, the factors described in Part I, Item 1A, "Risk Factors," of this annual report on Form 10-K. Geron assumes no obligation for and except as required by law, disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

Calculation of Aggregate Market Value of Non-Affiliate Shares

For purposes of calculating the aggregate market value of shares of our common stock held by non-affiliates as set forth on the cover page of this annual report on Form 10-K, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company. These assumptions should not be deemed to constitute an admission that all executive officers, directors and 5% or greater stockholders are, in fact, affiliates of our company, or that there are no other persons who may be deemed to be affiliates of our company. Further information concerning shareholdings of our executive officers, directors and principal stockholders is incorporated by reference in Part III, Item 12 of this annual report on Form 10-K.

PART I

ITEM 1. BUSINESS

Company Overview

We are a clinical stage biopharmaceutical company focused on the development of a telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. The discovery and early development of imetelstat, our sole product candidate, was based on our core expertise in telomerase and telomere biology. Telomerase is an enzyme that enables cancer cells, including malignant progenitor cells, to maintain telomere length, which provides them with the capacity for limitless, uncontrolled proliferation. Using our proprietary nucleic acid chemistry, we designed imetelstat to be an oligonucleotide that targets and binds with high affinity to the active site of telomerase, thereby directly inhibiting telomerase activity and impeding malignant cell proliferation. Molecular responses in essential thrombocythemia, or ET, and remission responses, including reversal of bone marrow fibrosis,

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in myelofibrosis, or MF, suggest imetelstat has disease-modifying activity by inhibiting the progenitor cells of the malignant clone for the underlying disease in a relatively selective manner.

On November 13, 2014, we entered into an exclusive collaboration and license agreement, or the Collaboration Agreement, with Janssen Biotech, Inc., or Janssen, to develop and commercialize imetelstat worldwide for all indications in oncology, including hematologic myeloid malignancies, and all other human therapeutic uses. The Collaboration Agreement became effective on December 15, 2014 and we received $35 million from Janssen as an upfront payment. Additional consideration under the Collaboration Agreement includes payments up to a potential total of $900 million for the achievement of development, regulatory and commercial milestones, as well as royalties on worldwide net sales.

Under the Collaboration Agreement, Janssen is responsible for the development, manufacturing and commercialization of, and seeking regulatory approval for imetelstat worldwide. Development of imetelstat will proceed under a mutually agreed clinical development plan, which includes two Phase 2 studies to be pursued initially, one in myelofibrosis, referred to as the Initial Phase 2 MF Study, and one in myelodysplastic syndrome, referred to as the Initial Phase 2 MDS Study. We expect Janssen to initiate the Initial Phase 2 MF Study in mid-2015, followed by the Initial Phase 2 MDS Study to be initiated at the end of 2015. In addition, the clinical development plan may also include additional, possible registration studies in MF and myelodysplastic syndrome, or MDS, and possible exploratory Phase 2 and potential follow-on Phase 3 studies in acute myelogenous leukemia, or AML.

We believe our current operational and financial resources, including the upfront payment received from Janssen under the Collaboration Agreement, may enable us to acquire one or more oncology products, programs or companies to diversify our business.

Telomeres and Telomerase in Normal Development

In the human body, normal growth and maintenance of tissues occurs by cell division. However, most cells are only able to divide a limited number of times, and this number of divisions is regulated by telomere length. Telomeres are repetitions of a deoxyribonucleic acid, or DNA, sequence located at the ends of chromosomes. They act as protective caps to maintain stability and integrity of the chromosomes, which contain the cell's genetic material. Normally, every time a cell divides, the telomeres shorten. Eventually, they shrink to a critically short length, and as a result, the cell either dies by apoptosis or stops dividing and senesces.

Telomerase is a naturally occurring enzyme that maintains telomeres and prevents them from shortening during cell division in cells, such as stem cells, that must remain immortalized to support normal health. Telomerase consists of at least two essential components: a ribonucleic acid, or RNA, template (hTR), which binds to the telomere, and a catalytic subunit (hTERT) with reverse transcriptase activity, which adds a specific DNA sequence to the chromosome ends. The 2009 Nobel Prize for Physiology and Medicine was awarded to Drs. Elizabeth H. Blackburn and Carol W. Greider, together with Dr. Jack Szostak, who were former Geron collaborators, for the discovery of how chromosomes are protected by telomeres and the enzyme telomerase.

Telomerase is active during embryonic development, enabling the rapid cell division that supports normal growth. During the latter stages of human fetal development and in adulthood, telomerase is repressed in most cells, and telomere length gradually decreases during a lifetime. In tissues that have a high turnover throughout life, such as blood and gut, telomerase can be transiently upregulated in progenitor cells to enable controlled, self-limited proliferation to replace cells lost through natural cell aging processes. In proliferating progenitor cells, relatively long telomeres are maintained by upregulated telomerase. As the progeny of progenitor cells mature, telomerase is downregulated and telomeres shorten with cell division, preventing uncontrolled proliferation.

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Telomeres and Telomerase in Cancer

Telomerase is upregulated in many tumor progenitor cells, which enables the continued and uncontrolled proliferation of the malignant cells that drive tumor growth and progression. Telomerase expression has been found to be present in approximately 90% of biopsies taken from a broad range of human cancers. Our nonclinical studies, in which the telomerase gene was artificially introduced and expressed in normal cells grown in culture, have suggested that telomerase does not itself cause a normal cell to become malignant. However, the sustained upregulation of telomerase enables tumor cells to maintain telomere length, providing them with the capacity for limitless proliferation. We believe that the sustained upregulation of telomerase is critical for tumor progression as it enables malignant progenitor cells to acquire cellular immortality and avoid apoptosis, or cell death.

Telomerase Inhibition: Inducing Cancer Cell Death

We believe that inhibiting telomerase may be an attractive approach to treating cancer because it may limit the proliferative capacity of malignant cells. We and others have observed in various in vitro and rodent tumor models that inhibiting telomerase results in telomere shortening and arrests uncontrolled malignant cell proliferation and tumor growth. In vitro studies have suggested that tumor cells with short telomeres may be especially sensitive to the anti-proliferative effects of inhibiting telomerase. Our nonclinical data also suggest that inhibiting telomerase is particularly effective at limiting the proliferation of malignant progenitor cells, which have high levels of telomerase and are believed to be important drivers of tumor growth and progression.

Many hematologic malignancies, such as ET, MF, and polycythemia vera, or PV, are known to arise from malignant progenitor cells in the bone marrow that express higher telomerase activity and have shorter telomeres when compared to normal healthy cells. Recent nonclinical data reported in the journal *Cell Stem Cell* in December 2014 by Steven Lane, M.D., Ph.D., Queensland Institute of Medical Research, one of our nonclinical collaborators, provided proof-of-concept of the role of telomerase in disease initiation and progression in AML. Leukemic stem cells, or LSCs, are functionally described as cells within AML that are capable of initiating and maintaining the disease. Through their high expression of telomerase, LSCs are believed to be responsible for chemotherapy resistance and relapse in AML which make them an important therapeutic target as a durable treatment for AML. Data from the nonclinical study conducted by Dr. Lane suggest that imetelstat has the potential for disease-modifying activity in AML by targeting LSCs.

Imetelstat: The First Telomerase Inhibitor to Advance to Clinical Development

Imetelstat is a lipid conjugated 13-mer oligonucleotide that is designed to be complementary to and bind with high affinity to the RNA template of telomerase, thereby directly inhibiting telomerase activity. The compound has a proprietary thio-phosphoramidate backbone, which is designed to provide resistance to the effect of cellular nucleases, thus conferring improved stability in plasma and tissues, as well as improved binding affinity to its target. To improve the ability of imetelstat to permeate through cellular membranes, we conjugated the oligonucleotide to a lipid group. Imetelstat's IC50, or half maximal inhibitory concentration, is 0.5-10 nM in cell free assays. The tissue half-life of imetelstat, or the time it takes for the concentration or amount of imetelstat to be reduced by half, in bone marrow, spleen, liver and tumor has been estimated to be 41 hours in humans, based on data from animal studies and clinical trial data. The tissue half-life indicates how long a drug will remain present in the tissues, and a longer tissue half-life may enable a drug to remain at effective doses for a longer period of time.

Imetelstat has been shown in nonclinical studies to exhibit relatively preferential inhibition of the clonal proliferation of malignant progenitor cells compared to normal progenitors. For this reason, imetelstat has been studied as a treatment for malignant diseases.

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Imetelstat is the first telomerase inhibitor to advance to clinical development. The Phase 1 trials that we completed evaluated the safety, tolerability, pharmacokinetics and pharmacodynamic effects of imetelstat. Doses and dosing schedules were established that were tolerable and achieved target exposures in patients that were consistent with those required for efficacy in animal models. We believe adverse events were generally manageable and reversible. The dose-limiting toxicities were thrombocytopenia, or reduced platelet count, and neutropenia, or reduced neutrophil count. Following intravenous administration of imetelstat using tolerable dosing regimens, clinically relevant and significant inhibition of telomerase activity was observed in various types of tissue in which telomerase activity is measurable, including normal bone marrow hematopoietic cells, malignant plasma cells, hair follicle cells, and peripheral blood mononuclear cells.

Developing Imetelstat to Treat Hematologic Myeloid Malignancies

Proof-of-Concept in Essential Thrombocythemia

Myeloproliferative neoplasms, or MPNs, are hematologic myeloid malignancies that arise from malignant hematopoietic myeloid progenitor cells in the bone marrow, such as the precursor cells of red blood cells, platelets and granulocytes. Proliferation of malignant progenitor cells leads to an overproduction of any combination of myeloid white cells, red blood cells and/or platelets, depending on the disease. These overproduced cells may also be abnormal, leading to additional clinical complications. MPN diseases include PV, ET and MF. ET is an MPN characterized by a high platelet count, often accompanied by a high white cell count, and an increased risk of thrombosis, or bleeding, in higher risk patients.

In January 2011, we initiated a Phase 2 clinical trial of imetelstat in patients with ET. The Phase 2 ET trial was a multi-center, single arm, and open label trial that we designed to provide proof-of-concept for the potential use of imetelstat as a treatment for hematologic myeloid malignancies, such as MF, MDS or AML. The trial leveraged clinical observations from Phase 1 trials suggesting that imetelstat reduces platelet counts, as well as nonclinical observations that imetelstat distributes well to bone marrow in rodent models and selectively inhibits the proliferation of malignant progenitors ex vivo from patients with ET. Hematologic responses were measured by reductions in platelet counts, and molecular responses were measured by reductions in the JAK2 V617F mutant allele burden in circulating granulocytes as assessed by a reduction in the proportion of the abnormal Janus kinase 2, or JAK2, gene compared to the normal, or wild type JAK2 gene. We believe a decrease in the proportion of the JAK2 V617F mutant relative to the wild type JAK2 is consistent with selective inhibition of the malignant progenitor cells responsible for the disease.

Data from the primary efficacy analysis of the Phase 2 ET trial in October 2013 showed that imetelstat induced platelet count reductions in all 18 patients in the trial (a 100% hematologic response rate) and normalizations in 16 out of 18 patients (an 89% complete response rate). The median time on therapy was 17.1 months (range 6.9 months to 2.7 years). The JAK2 V617F gene mutation was detected in eight patients at baseline. Seven out of the eight (88%) patients achieved 72% to 96% reductions in JAK2 V617F allele burden that qualified as partial molecular responses with a median duration of 15.5 months. These data suggest that imetelstat inhibits the progenitor cells of the malignant clone believed to be responsible for the underlying disease in a relatively selective manner.

Adverse events reported in the Phase 2 ET trial have been similar to the adverse events reported in other imetelstat clinical trials, with fatigue, gastrointestinal symptoms (specifically nausea, diarrhea, constipation, and vomiting) and cytopenias being the most frequently observed adverse events. One patient experienced Grade 3 hepatic cirrhosis and encephalopathy which was assessed by the investigator to be possibly attributable to imetelstat, and later died of bleeding esophageal varices. Two patients experienced reversible Grade 3 alanine transaminase, which was assessed by the investigator to be possibly attributable to imetelstat. At least one abnormal liver function test, or LFT, was observed in

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laboratory findings in all patients in the trial, with some patients experiencing persistent low-grade LFT abnormalities with longer dosing. With longer dosing, Grade 1 increases in alkaline phosphatase were observed, associated with mostly Grade 1 to some Grade 2 unconjugated hyperbilirubinemia. The clinical significance and long-term consequences of such persistent low-grade LFT abnormalities is currently undetermined.

In March 2014, we received written notice from the United States Food and Drug Administration, or FDA, that our Investigational New Drug application, or IND, for imetelstat had been placed on full clinical hold following the FDA's review of safety data in our then ongoing clinical studies. A full clinical hold is an order that the FDA issues to a trial sponsor to suspend all ongoing clinical trials and delay all proposed trials under a given IND. With this clinical hold, any patients in an ongoing Geron-sponsored clinical trial could not receive any further treatment with imetelstat. Therefore, we stopped imetelstat treatment in our Phase 2 Geron-sponsored clinical trials in ET and multiple myeloma, or MM. In our Phase 2 ET trial, imetelstat treatment was stopped in eight patients and in our Phase 2 MM trial, imetelstat treatment was stopped in two patients. See below for discussion of removal of the full clinical hold.

In their notice to us, the FDA cited the following safety issues as the basis for the clinical hold: lack of evidence of reversibility of hepatotoxicity, risk for chronic liver injury and lack of adequate follow-up in patients who experienced hepatotoxicity. To address the clinical hold, we were required to provide clinical follow-up information on patients who experienced LFT abnormalities until LFT abnormalities resolved to normal or baseline and to provide information regarding the reversibility of the liver toxicity after chronic imetelstat administration in animals.

We submitted a complete response to the FDA to seek release of the full clinical hold. In the complete response, we provided clinical follow-up information from patients in the previously ongoing Geron-sponsored Phase 2 trials in ET and MM. Our analysis of these data concluded that in the Phase 2 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 showed improvement in LFT abnormalities and one had unresolved LFT abnormalities. In the Phase 2 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. In the complete response, we also provided data from our previously conducted nonclinical toxicology studies, which included a six-month study in mice and a nine-month study in cynomolgus monkeys. In those studies, no clinical pathology changes indicative of hepatocellular injury were observed, and no clear signal of LFT abnormalities were identified.

On October 31, 2014, the FDA removed the full clinical hold on our IND for imetelstat. In addition, the FDA stated that our proposed clinical development plan for imetelstat that is focused on high-risk myeloid malignancies, such as MF, is acceptable. The FDA acknowledged that we do not intend to conduct further studies in, or develop imetelstat for, the treatment of ET or PV, which is consistent with our plans as originally disclosed in April 2013.

Prior to initiation of the Initial Phase 2 MF Study, we plan to transfer our IND for imetelstat to Janssen as required by our Collaboration Agreement with them. For further discussion of the collaboration with Janssen, see the sub-section entitled, "Future Development of Imetelstat in Collaboration with Janssen".

Clinical Development in Myelofibrosis

MF is a myeloproliferative neoplasm among related diseases, such as ET, and is characterized by clonal proliferation of malignant hematopoietic progenitor cells in the bone marrow that causes bone marrow fibrosis, elevation in bone density, known as osteosclerosis, and abnormal rapid proliferation of blood vessels, known as pathological angiogenesis. MF patients may exhibit abnormally low red blood

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cells/hemoglobin, known as progressive anemia, abnormally low white blood cells, known as leukopenia, abnormally high white blood cells, known as leukocytosis, abnormally low platelets, known as thrombocytopenia, abnormally high platelets, known as thrombocytosis, immature blood cells, known as peripheral blood leukoerythroblastosis, and abnormally high precursor cells in the blood, known as excess circulating blasts. In addition, impaired blood production from the bone marrow causes blood production to shift to other organs such as the spleen and liver, known as extramedullary hematopoiesis, which leads to an enlarged spleen, known as splenomegaly, or an enlarged liver, known as hepatomegaly. MF patients can also suffer from debilitating constitutional symptoms, such as drenching night sweats, fatigue, severe itching, known as pruritus, fever and bone pain. The estimated prevalence of MF in the United States is approximately 13,000 patients, with an annual incidence of approximately 3,000 patients. Approximately 70% of MF patients have two to three risk factors (intermediate-2) or four or more risk factors (high risk), as defined by the Dynamic International Prognostic Scoring System Plus, or DIPSS Plus, described in a 2011 *Journal of Clinical Oncology* article. These patients have a median survival of approximately one to three years, representing a significant unmet medical need.

Allogeneic hematopoietic cell transplantation, or allo-HCT, is the only current treatment approach for MF that can lead to complete remission of the disease with normalization of peripheral blood counts, regression of bone marrow fibrosis, disappearance of cytogenetic abnormalities, normalization of spleen size and resolution of constitutional symptoms. However, use of allo-HCT is limited to a very small number of eligible patients due to the lack of suitable donors, older age and/or comorbid conditions. In addition, graft vs. host disease and life-threatening infections are other limitations of allo-HCT treatment.

Recent data presented in December 2014 at the American Society of Hematology, or ASH, Annual Meeting by Dr. Ron Hoffman of the Mount Sinai School of Medicine from in vitro translational studies have demonstrated that imetelstat inhibits malignant hematopoiesis and malignant megakaryopoiesis. In one study, hematopoietic stem cells were obtained from spleens of MF patients and normal cord blood. Imetelstat treatment on both in vitro cultures of stem cells showed selective inhibition of the proliferation of hematopoietic stem cells and myeloid progenitor cells and preferential depletion of malignant hematopoietic progenitor cells. In another study, peripheral blood mononuclear cells, or PBMCs, were taken from MF patients and normal patients. Imetelstat treatment on both in vitro cultures of cells showed selective inhibition of the proliferation of malignant megakaryocytic progenitor cells from myelofibrosis PBMCs; a reduction in the number of malignant megakaryocytes from myelofibrosis PBMCs; and inhibition of late-stage megakaryocytic maturation derived from both myelofibrosis and normal PBMCs. These in vitro data support the clinical remission responses observed to date in the investigator-initiated clinical trial of myelofibrosis being conducted at Mayo Clinic, or the MF Pilot Study, and the disease-modifying activity suggested by the MF Pilot Study results.

Pilot Study in Myelofibrosis (MF Pilot Study)

Based on the data from the Phase 2 ET trial, in November 2012, Dr. Ayalew Tefferi, or the investigator, initiated the MF Pilot Study to assess the effect of imetelstat in patients with MF. The MF Pilot Study is an open label trial in patients with primary MF, post-ET MF, or post-PV MF who have two to three risk factors (intermediate-2) or four or more risk factors (high risk) as defined by DIPSS Plus. In the MF Pilot Study, imetelstat is administered as a single agent over a two hour intravenous infusion to patients in multiple patient cohorts. In the first cohort, Cohort A, imetelstat is given once every three weeks. In the second cohort, Cohort B, imetelstat is given weekly for four weeks, followed by one dose every three weeks. Under the protocol, patients in Cohorts A and B may receive an intensified dosing regimen, up to once per week, after the initial six cycles of treatment. The starting dose of imetelstat in Cohorts A and B is 9.4 mg/kg, with dose reductions and dose holds allowed for toxicity. The primary endpoint in the MF Pilot Study is overall response rate, which is defined by the

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proportion of patients who are classified as responders, which means that they have achieved either a clinical improvement, or CI, partial remission, or PR, or complete remission, or CR, consistent with the criteria of the 2013 International Working Group for Myeloproliferative Neoplasms Research and Treatment, or IWG-MRT criteria, described in a 2013 *Blood* article. Secondary endpoints include reduction of spleen size by palpation, improvement in anemia or inducement of red blood cell transfusion independence, safety and tolerability.

In January 2014, Mayo Clinic closed the MF Pilot Study to new patient enrollment. Mayo Clinic's notification informing us of its decision to cease new patient enrollment did not indicate any concerns regarding efficacy or safety. In March 2014, we were informed by Mayo Clinic that the investigator's IND for the MF Pilot Study was placed on partial clinical hold by the FDA due to a safety signal of hepatotoxicity that was identified in Geron's Phase 2 clinical trials of imetelstat and that it was unknown if this hepatotoxicity was reversible. In order to resolve the partial clinical hold, the investigator was required to provide follow-up information regarding reversibility of hepatotoxicity for all patients who received imetelstat in the MF Pilot Study. The investigator submitted a complete response to the FDA to seek release of the partial clinical hold, and the partial hold was removed by the FDA in June 2014.

On July 31, 2014, we entered into an agreement with Mayo Clinic under which Mayo Clinic and the investigator agreed to transfer to us certain data and information from the MF Pilot Study, and agreed that we would assume full responsibility for the investigator's IND, as well as responsibility for the conduct of the MF Pilot Study as the trial sponsor. In September 2014, the investigator's IND, under which the MF Pilot Study has been conducted, was transferred to us and we assumed responsibility for the MF Pilot Study as the trial sponsor. Dr. Tefferi continues as the principal investigator for the trial. As of December 5, 2014, 23 patients out of the 80 patients enrolled in the MF Pilot Study continue to receive imetelstat treatment, which includes 17 out of 62 patients with MF, five out of nine patients with refractory anemia with ringed sideroblasts, or RARS, a subpopulation of MDS, and one out of nine patients with blast-phase MF.

Prior to initiation of the Initial Phase 2 MF Study, we plan to transfer the IND for the MF Pilot Study, as well as responsibility for the conduct of the MF Pilot Study as the trial sponsor, to Janssen, and they do not intend to enroll additional patients in the MF Pilot Study. The remaining patients in the MF Pilot Study will continue to receive imetelstat treatment and Janssen will continue to collect data and information from the MF Pilot Study. For further discussion of the collaboration with Janssen under the Collaboration Agreement, see the sub-section entitled, "Future Development of Imetelstat in Collaboration with Janssen".

Updated Preliminary Data from MF Pilot Study

In December 2014, the investigator presented updated preliminary efficacy and safety data (as of September 10, 2014) from Cohorts A and B of the MF Pilot Study (n=33) at the 2014 ASH Annual Meeting. The data presented in December 2014 updated the investigator's previous analysis from the preliminary data he had presented at ASH in December 2013. We believe that the updated preliminary data from the MF Pilot Study continue to suggest that imetelstat has disease-modifying activity in MF, with remissions that have been durable (median 11.1 months; range 6.9 months - 16.2 months as of September 10, 2014). The investigator reported that no new safety signals had been observed and myelosuppression continued to be the principal dose-limiting toxicity.

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Patient Demographics and Status

Below is a table setting forth the demographics of the first 33 patients enrolled in the MF Pilot Study, including certain disease characteristics and exposure to any prior treatments:

	Total (n=33)
Median Age (range; years)	67.0 (53.0 - 79.0)
Male	22 (66.7%)
Myelofibrosis Subtype	
Primary	18 (54.5%)
Post-ET	5 (15.2%)
Post-PV	10 (30.3%)
DIPSS-plus Risk Status	
Intermediate-2 Risk	16 (48.5%)
High Risk	17 (51.5%)
Previously Treated	26 (78.8%)
Median # of Prior Treatments (range)	2 (1 - 6)
Prior JAK inhibitors	19 (57.6%)
Abnormal Karyotype	16 (48.5%)
Unfavorable Karyotype per DIPSS-plus	6 (18.2%)
Transfusion Dependent	13 (39.4%)
Constitutional Symptoms±	21 (63.6%)
Palpable Splenomegaly	23 (69.7%)
Median (range; cm)	15.0 (5.0 - 33.0)

± DIPSS+ assessment of symptoms at baseline: Includes unexplained persistent fever greater than 38.3°C (or greater than 101°F) during the past six months, unexplained non-menopausal night sweats during past six months, unexplained weight loss greater than 10% body weight in the previous six months and unexplained, non-articular bone pain during past six months.

As of September 10, 2014, the median duration of treatment was 11 cycles (range two cycles - 21 cycles). Median time on treatment was 14.3 months (range 6.5 months - 18.9 months) for patients with a CR, PR or CI response. All other patients had a median time on treatment of 6.9 months (range 1.4 months - 16.4 months).

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Of these 33 patients, a total of nine patients remained on imetelstat treatment as of September 10, 2014. The following table describes patient status and reason for treatment discontinuation for each of the 33 patients, as reported by the investigator.

Patient Status and Reason for Treatment Discontinuation	**Total (n=33)**
On Treatment	9 (27.3%)
Discontinued Treatment:	24 (72.7%)
Stable Disease but Insufficient Response	15 (45.5%)
Disease Progression/Relapse	4 (12.1%)
Death[(1)]	2 (6.1%)
Adverse Event/Side Effects/Complications[(2)]	2 (6.1%)
Other Complicating Disease[(3)]	1 (3.0%)

(1) One death due to upper gastrointestinal hemorrhage (deemed unrelated to imetelstat per investigator assessment), the other due to intracranial hemorrhage with febrile neutropenia after prolonged myelosuppression (deemed possibly related to imetelstat per investigator assessment).

(2) One case of thrombocytopenia and the other persistent thrombocytopenia.

(3) Pre-existing problems with atrial fibrillation.

Updated Efficacy Data

The following table presents Geron's analysis of updated efficacy data as of September 10, 2014 for the first 33 eligible patients enrolled in the MF Pilot Study, using the IWG-MRT criteria:

Best Response by IWG-MRT	**Total (n=33)**
Overall Response (CR+PR+CI)	12 (36.4%)
Complete Remission (CR)	4 (12.1%)
Partial Remission (PR)	3 (9.1%)
Clinical Improvement (CI) by Anemia	1 (3.0%)
Clinical Improvement (CI) by Spleen	4 (12.1%)
Stable Disease (SD)	21 (63.6%)

Median onset of remission occurred at five cycles (range one cycle - nine cycles). As of September 10, 2014, six of seven CR/PR patients remained in remission with median duration of 11.1 months (range 6.9 months - 16.2 months). All four CR patients achieved reversal of bone marrow fibrosis including three with complete molecular response. Three CR/PR patients who were transfusion dependent at baseline became transfusion independent. Three CR/PR patients with splenomegaly at baseline achieved splenic response.

Additional efficacy results reported by the investigator included spleen response, transfusion independence and resolution of circulating blasts, leukoerythroblastosis, marked leukocytosis and thrombocytosis:

Eight of 23 (34.8%) patients with splenomegaly achieved spleen responses by palpation, which is defined as either greater than or equal to 50% decrease if the baseline is greater than or equal to 10 centimeters or becoming non palpable if baseline is five to less than 10 centimeters. The median spleen size at baseline was 15 centimeters below the left costal margin (range five centimeters - 33 centimeters).

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Four of 13 patients (30.8%) who were transfusion dependent at baseline became transfusion independent which is defined as absence of any packed red blood cells transfusions during any consecutive 12-week interval with a hemoglobin level of ≥8.5 grams per deciliter.

17 of 21 (81.0%) patients with circulating blasts, or immature cells, at baseline achieved complete (n=14, 66.7%) or partial (n=3, 14.3%) resolution.

22 of 27 (81.5%) patients with leukoerythroblastosis, a condition characterized by circulating immature granulocytes and nucleated red blood cells, achieved complete (n=13, 48.1%) or partial (n=9, 33.3%) resolution.

Eight of 10 (80.0%) patients with marked leukocytosis, a condition characterized by very elevated white blood cell counts, achieved complete (n=3, 30.0%) or partial (n=5, 50.0%) resolution.

11 of 11 (100.0%) patients with thrombocytosis, a condition characterized by high platelet counts in blood, achieved complete (n=10, 90.9%) or partial (n=1, 9.1%) resolution.

Updated Safety Data

The following table sets forth the non-hematologic adverse events as of September 10, 2014, which were generally mild to moderate and not dose-limiting, for the first 33 eligible patients enrolled in the MF Pilot Study:

	All (n=33)	**Related[1] (n=33)**
Fatigue	3 (9.1%)	
APTT	2 (6.1%)	
Atrial Fibrillation	2 (6.1%)	
Heart Failure	2 (6.1%)	
Hyperkalemia	2 (6.1%)	
Ejection Fraction Decreased	1 (3.0%)	
Intracranial Hemorrhage[2]	1 (3.0%)[3]	1 (3.0%)[3]
Febrile Neutropenia	1 (3.0%)[3]	1 (3.0%)[3]
Upper GI Hemorrhage[2]	1 (3.0%)	
Hyponatremia	1 (3.0%)	
Lipase Increased	1 (3.0%)	
Lung Infection	1 (3.0%)	
Pain	1 (3.0%)	
Pyoderma Gangrenosum[4]	1 (3.0%)	
Small Intestinal Obstruction	1 (3.0%)	

(1) Deemed possibly related to imetelstat per investigator assessment.

(2) Grade 5 event.

(3) Same patient.

(4) The pyoderma gangrenosum is associated with a post-operative complication of a splenectomy, or spleen removal.

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The following table sets forth all hematologic adverse events greater than or equal to Grade 3 as of September 10, 2014 for the first 33 patients enrolled in the MF Pilot Study.

	Worst Grade*	Cohort A (n=19)	Cohort B (n=14)	Total (n=33)
Thrombocytopenia	3	8 (42.1%)	1 (7.1%)	9 (27.3%)
	4	2 (10.5%)	5 (35.7%)	7 (21.2%)
Neutropenia	3	4 (21.1%)	2 (14.3%)	6 (18.2%)
	4	2 (10.5%)	4 (28.6%)	6 (18.2%)
Anemia	3	7 (36.8%)	9 (64.3%)	16 (48.5%)
	4			
Leukopenia	3	3 (15.8%)	6 (42.9%)	9 (27.3%)
	4	2 (10.5%)	1 (7.1%)	3 (9.1%)

* Hematologic toxicity is defined as worsening in grade after baseline.

The following table sets forth hematologic adverse events related to imetelstat as reported by the investigator lasting greater than or equal to four weeks as of September 10, 2014. These events mainly were observed in a small number of patients who received weekly dosing initially.

		Cohort A (n=19)	Cohort B (n=14)	Total (n=33)
Grade 3/4 Laboratory Finding Lasted ≥ 4 Weeks	Thrombocytopenia	5 (26.3%)	3 (21.4%)	8 (24.2%)
	Neutropenia	1 (5.3%)	2 (14.3%)	3 (9.1%)
	Either	5 (26.3%)	5 (35.7%)	10 (30.3%)
Grade 4 Laboratory Finding Lasted ≥ 4 Weeks	Thrombocytopenia	0	1 (7.1%)	1 (3.0%)
	Neutropenia	1 (5.3%)	1 (7.1%)	2 (6.1%)
	Either	1 (5.3%)	2 (14.3%)	3 (9.1%)

To mitigate the risk of severe, persistent cytopenias, the protocol for the MF Pilot Study was amended to raise the hematologic threshold for retreatment and include more stringent monitoring and dose adjustment criteria. Since then, no further episodes of significant bleeding events associated with thrombocytopenia, or infections associated with neutropenia, or additional episodes of febrile neutropenia have been reported to us by the investigator. As a result, we believe that the myelosuppressive effect of the drug may be manageable through dose hold rules and dose modifications.

Since the MF Pilot Study is ongoing, additional data from the remaining patients enrolled in the MF Pilot Study continues to be generated and is not reflected in the data discussed above. In this regard, additional and updated safety and efficacy data generated from the MF Pilot Study may be materially different from the data discussed above. Additional or updated data from the MF Pilot Study are also subject to any review or verification procedures that Janssen may conduct as the trial sponsor for the MF Pilot Study after it assumes responsibility for the conduct of the MF Pilot Study, and since this could result in material differences from the data reported by the investigator or us, additional or updated data that may be reported from the MF Pilot Study should be considered carefully and with caution. Analyses performed by Janssen after it becomes the sponsor of the MF Pilot Study may result in conclusions that are materially different from the investigator's analyses or ours, and therefore preliminary data should be considered carefully and with caution. As such, final data from the MF Pilot Study may be materially different from the data discussed above. Accordingly, the data discussed above should be considered carefully and with caution. Please refer to the risk factor

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entitled "Risks Related to Clinical and Commercialization Activities Success in early clinical trials may not be indicative of results in subsequent clinical trials. Likewise, preliminary data reported by investigators from time-to-time are subject to review and verification procedures that could result in material differences to final data and may change as more patient data become available" under Part I, Item 1A, "Risk Factors," of this annual report on Form 10-K.

Future Development of Imetelstat in Collaboration with Janssen

On November 13, 2014, we entered into the Collaboration Agreement with Janssen to develop and commercialize imetelstat worldwide for all indications in oncology, including hematologic myeloid malignancies, and all other human therapeutic uses. The Collaboration Agreement became effective on December 15, 2014, and we received $35 million from Janssen as an upfront payment.

Under the Collaboration Agreement, we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all indications, and Janssen is responsible for the development, manufacturing and commercialization of, and seeking regulatory approval for, imetelstat worldwide. Development of imetelstat will proceed under a mutually agreed clinical development plan, which includes the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study. We expect Janssen to initiate the Initial Phase 2 MF Study in mid-2015, followed later by the Initial Phase 2 MDS Study to be initiated at the end of 2015. In addition, the clinical development plan may also include possible registration studies in MF and MDS, and possible exploratory Phase 2 and potential follow-on Phase 3 studies in AML. Development costs for the planned Initial Phase 2 MF Study and the planned Initial Phase 2 MDS Study will be shared between the parties on a 50/50 basis.

Following the protocol-specified primary analysis of the Initial Phase 2 MF Study, which results are referred to in this annual report on Form 10-K as the Initial Phase 2 MF Results, or a certain time period after the initiation of the first Phase 3 MF study, Janssen must notify us of their decision, or a Continuation Decision, as to whether they elect to maintain the license rights granted to them under the Collaboration Agreement 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 us of their Continuation Decision by the date that is the later of 24 months after the initiation of the planned Initial Phase 2 MDS Study or 24 months after the termination of the Initial Phase 2 MF Study or commencement of the suspension period, as applicable.

In the event that Janssen notifies us of an affirmative Continuation Decision, we will then have an option to share further U.S. development and promotion costs, or the U.S. Opt-In Rights, in exchange for higher tiered royalty rates and higher future potential milestone payments if imetelstat is successfully developed and approved. If we exercise the U.S. Opt-In Rights, then we and Janssen will share U.S. development and promotion costs on a 20/80 basis (Geron 20%, Janssen 80%), we will receive a $65 million milestone payment at the time of the Continuation Decision, and will 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 a 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 we exercise the U.S. Opt-In Rights, we will also have a separate co-promotion option, or the U.S. 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 us and Janssen at the time of our exercise of the U.S. Co-Promotion Option. We would be responsible for all costs associated with establishing and maintaining our sales force in any conduct of such co-promotion. All product sales would be booked by Janssen. If we do not exercise the U.S. Opt-In Rights upon an affirmative Continuation Decision by Janssen, then all further development and promotion costs

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beyond the Initial Phase 2 MF Study or Initial Phase 2 MDS Study will be borne by Janssen, we will receive a $65 million milestone payment at the time of the Continuation Decision plus a $70 million payment for Janssen's retention of full U.S. rights, and will 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 a 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.

Under the terms of the Collaboration Agreement, we and Janssen have created 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 clinical development plan and promotional activities (assuming we exercise the U.S. Opt-In Rights) for imetelstat, with Janssen responsible for the operational implementation of those activities. In addition, both we and Janssen may propose to the joint development committee imetelstat development for any new indications not then provided for in the joint clinical development plan and if we and Janssen agree such development should be conducted outside of the joint clinical development plan, both we and Janssen would be entitled to independently undertake such development at the developing party's own cost, subject to the other party's obligation to provide reimbursement for its specified portion of the development costs plus a premium following marketing approval of imetelstat in such newly proposed indication as a result of such independent development. In the event that we do not exercise the U.S. Opt-In Rights following Janssen's Continuation Decision, the joint governance structure under the Collaboration Agreement would be dissolved, a joint oversight committee would monitor the progress of the collaboration, and we would have no further rights to conduct any independent imetelstat development.

Research and Development

Since our inception, we have devoted a significant amount of resources to develop our current and former product candidates. For information regarding research and development expenses incurred during 2014, 2013 and 2012, see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expenses".

In light of projected reduced operational demands as a result of the Collaboration Agreement with Janssen, on March 3, 2015, we announced an organizational resizing to reduce our workforce from 39 to 21 positions, representing a reduction of approximately 46% of our workforce. As a result of this action, we expect personnel related research and development expenses to decrease in the future. For a further discussion, see Note 15 on Subsequent Event in Notes to Consolidated Financial Statements of this annual report on Form 10-K.

Intellectual Property

Intellectual property, including patent protection, is very important to our business. We file patent applications in the United States and other jurisdictions, and we also rely on trade secret protection and contractual arrangements to protect aspects of our business. An enforceable patent with appropriate claim coverage can provide an advantage over competitors who may seek to employ similar approaches to develop therapeutics, and so our future commercial success will be in part dependent on our intellectual property strategy. The information provided in this section should be reviewed in the context of the section entitled "Risks Related to Protecting Our Intellectual Property" under Item 1A, "Risk Factors".

The development of biotechnology products, including ours, typically includes the early development of a technology, followed by rounds of increasingly focused innovation around a product opportunity, including identification and definition of a specific product candidate and uses thereof,

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manufacturing processes, product formulation and administration methods. The result of this process is that biotechnology products are often protected by several families of patent filings that are filed at different times during product development and cover different aspects of the product. Consequently, earlier filed, broad technology patents will usually expire ahead of patents covering later developments such as product formulations, so that patent expirations on a product may span several years. Patent coverage may also vary from country to country based on the scope of available patent protection. There are also opportunities to obtain extension of patent coverage for a product in certain countries, which add further complexity to the determination of patent life.

We endeavor to monitor worldwide patent filings by third parties that are relevant to our business. Based on this monitoring, we may determine that an action is appropriate to protect our business interests. Such actions may include negotiating patent licenses where appropriate, filing oppositions or reexaminations against a patent, or filing a request for the declaration of an interference with a United States patent application or issued patent.

Imetelstat

The following table shows the estimated latest expiration dates for the composition of matter patents for our sole product candidate, imetelstat. Composition of matter patents generally provide the most material coverage, and therefore may convey competitive advantages. Because imetelstat is still under development, subsequent innovation and associated patent filings may provide additional patent coverage with later expiration dates. Examination of overseas patent applications typically lags behind U.S. examination particularly where cases are filed first in the United States. The stated U.S. expiration date includes a patent term adjustment for delays in prosecution by the U.S. Patent and Trademark Office, but does not account for a potential patent term extension that may be available to compensate us for delays in FDA regulatory review of a new drug application.

Product Candidate	U.S. Patent Status / Expiration Date	Europe Patent Status / Expiration Date	Japan Patent Status / Expiration Date
Imetelstat	Issued / 2025	Issued / 2020*	Issued / 2024

*

An additional composition of matter patent application for imetelstat has been filed that, if issued, would provide European patent protection until 2024.

Our patent rights relating to imetelstat which have been exclusively licensed to Janssen for all disorders or medical conditions include those covering the nucleic acid sequence of hTR, the RNA component of telomerase, against which the oligonucleotide component of imetelstat is targeted; composition claims to the drug molecule and related telomerase inhibiting molecules; the amidate nucleic acid chemistry used in the oligonucleotide; as well as manufacturing processes for the drug, and method of treatment and kit claims, certain of which are co-owned by us. Our proprietary nucleic acid chemistry is covered by patent families that we acquired in 2002 from Lynx Therapeutics, Inc., as well as in patents that we filed for further developments of this chemistry. Certain of our patent rights for measuring the expression of telomerase activity or the length of telomeres in cells have been non-exclusively licensed to Janssen.

As noted previously, we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all disorders or disease conditions. Under the terms of the Collaboration Agreement with Janssen, we remain responsible for prosecuting, at Janssen's direction, the patents exclusively licensed to Janssen, with costs shared between us and Janssen on a 50/50 basis. For intellectual property developed under the Collaboration Agreement, the party having sole ownership interest in such intellectual property will be responsible for prosecuting any such patents, with Janssen bearing all of the patent costs for such intellectual property solely owned by Janssen and with patent costs for such intellectual property either jointly owned or solely owned by us shared between the parties on a 50/50 basis.

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Telomerase

Our patent rights relating to telomerase that cover the cloned genes that encode the catalytic protein component (hTERT) of human telomerase and cells that are immortalized by expression of recombinant hTERT are co-owned with and in-licensed exclusively from the University of Colorado. Certain patents for identifying telomerase modulators or diagnosing cancer by measuring the expression of telomerase activity are co-owned and in-licensed from the University of Texas Southwestern Medical Center and the University of California.

Licensing

In addition to the Collaboration Agreement with Janssen (see the section entitled "Future Development of Imetelstat in Collaboration with Janssen" above for further discussion of the Collaboration Agreement with Janssen), we have also granted licenses to a number of other organizations in the ordinary course of our business to utilize aspects of our technologies to develop and commercialize products outside of our imetelstat program. These include:

licenses to several biotechnology and pharmaceutical companies to use telomerase immortalized cells in drug discovery research;

licenses to several companies to commercialize telomerase immortalized cells for drug discovery applications;

licenses to several companies to sell antibodies specific to telomerase for research purposes;

licenses to several companies to develop and commercialize reagent kits, or to provide services, for the measurement of telomere length or telomerase activity for research purposes;

a license to a company to develop and commercialize a particular telomerase based technology for cancer detection; and

a license to a company for the development of cancer immunotherapies for veterinary applications.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in efforts related to the biological mechanisms related to imetelstat, including the study of telomeres, telomerase and our proprietary oligonucleotide chemistry, and the research and development of therapies for the treatment of hematologic myeloid malignancies. In addition, other products and therapies that could compete directly with imetelstat currently exist or are being developed by pharmaceutical and biopharmaceutical companies and by academic institutions, government agencies and other public and private research organizations.

Our sole product candidate, imetelstat, if approved for marketing, will face significant competition from approved drugs, drugs currently under development and any other drugs that may be subsequently approved. Imetelstat would have to compete successfully based on efficacy, safety, convenience, price, cost-effectiveness and other relevant factors. In addition, imetelstat would have to compete against other drugs with a variety of decision makers, including physicians, patients, government and private third-party payors, technology assessment groups and patient advocacy organizations. We cannot guarantee that we, in collaboration with Janssen, will be able to compete successfully on any of these factors. If we or Janssen cannot compete successfully on any of the factors described previously, Janssen may terminate the Collaboration Agreement and our business may fail.

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Imetelstat is likely to be in highly competitive markets. We are aware of products in research or development by our competitors that address the diseases we are targeting, and any of these products may compete with imetelstat. Our competitors may succeed in developing their products before we do, obtaining approvals from the FDA or other regulatory agencies for their products more rapidly than we do, or developing products that are more effective than imetelstat. These products or technologies might render our technology obsolete or noncompetitive. There may also be product candidates of which we are not aware at an earlier stage of development that may compete with imetelstat. In addition, imetelstat may need to compete or combine with existing therapies, many with long histories of use.

Many companies are developing alternative therapies to treat hematologic myeloid malignancies and, in this regard, are competitors of ours and Janssen. For example, if approved for commercial sale for the treatment of MF, imetelstat would compete against Incyte Corporation's ruxolitinib, or Jakafi®, which is orally administered. In clinical trials, Jakafi® reduced spleen size, abdominal discomfort, early satiety, bone pain, night sweats and itching in MF patients. Recently, there have also been reports of overall survival benefit as well as improvement in bone marrow fibrosis from Jakafi® treatment. Other treatment modalities for MF include:

- hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms;
- splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cell counts; and
- chemotherapy and pegylated interferon.

Drugs for the treatment of MF-associated anemia include erythropoiesis-stimulating agents, androgens, danazol, corticosteroids, thalidomide and lenalidomide. There are other investigational treatments further advanced in development than imetelstat, such as momelotinib by Gilead Sciences, Inc. and pacritinib by Cell Therapeutics, Inc., which are currently in Phase 3 clinical trials, and other inhibitors of the JAK-STAT pathway, as well as several investigational treatments in early phase testing such as histone deacetylase inhibitors, inhibitors of heat shock protein 90, hypomethylating agents, PI3 Kinase and mTOR inhibitors, hedgehog inhibitors, anti-LOX2 inhibitors, recombinant pentraxin 2 protein, KIP-1 activators, TGF-beta inhibitors, FLT inhibitors, and other tyrosine kinase inhibitors.

Independently, Janssen is developing therapies for hematologic malignancies, including AML, MDS, MM and ABC-subtype diffuse large B-cell lymphoma. Molecular and cellular pathways of interest include:

- cell surface targets for immune-directed therapy;
- immune checkpoint inhibition;
- leukemia stem cells;
- pathway addiction (genetic alterations, cell-type specific pathways);
- conditional sensitivity (stress, protein-producing tumors);
- targeting of T-cells and natural killer "NK" cells to tumors;
- identification of novel tumor-specific antigens; and
- progression from early MDS to AML and cancer interception.

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Success by Janssen in any of these approaches may compete with imetelstat or render imetelstat obsolete or noncompetitive. A decision by Janssen to discontinue the imetelstat program and terminate the Collaboration Agreement would materially and adversely affect our business and business prospects.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We anticipate increased competition in the future as new companies explore treatments for hematologic myeloid malignancies, which may significantly impact the commercial viability of imetelstat. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our imetelstat program.

In addition to the above factors, we and Janssen expect to face competition in the following areas:

product efficacy and safety;

convenience of product administration;

cost of manufacturing;

the timing and scope of regulatory consents;

status of reimbursement coverage;

price; and

patent position, including potentially dominant patent positions of others.

As a result of the foregoing, competitors may develop more commercially desirable or affordable products, or achieve earlier patent protection or product commercialization than us or Janssen. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, competitive to imetelstat. Some of these products may have an entirely different approach or means of accomplishing therapeutic effects similar to those that may be demonstrated by imetelstat. Competitors may develop products that are safer, more effective or less costly than imetelstat, or more convenient to administer to patients and, therefore, present a serious competitive threat to imetelstat. In addition, competitors may price their products below what Janssen may determine to be an acceptable price for imetelstat, may receive better third-party payor coverage and/or reimbursement, or may be more cost effective than imetelstat. Such competitive products or activities by competitors may render imetelstat obsolete, which may cause Janssen to terminate the Collaboration Agreement and which would severely and adversely affect our business prospects.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture and marketing of our sole product candidate, imetelstat, in collaboration with Janssen. We anticipate that imetelstat will require regulatory approval by governmental agencies prior to commercialization. In particular, potential human therapeutic products, such as imetelstat, are subject to rigorous preclinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in European and other countries. Various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and recordkeeping related to such products and their marketing. In collaboration with Janssen, the process of obtaining these approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

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United States Food and Drug Administration Regulatory Approval Process

Prior to commencement of clinical trials involving humans, preclinical testing of new pharmaceutical products is generally conducted on animals in the laboratory to evaluate the potential efficacy and safety of a product candidate. The results of these trials are submitted to the FDA as part of an IND application, which must be cleared by the FDA before clinical testing in humans can begin. Typically, clinical evaluation involves a time consuming and costly three phase trial process. In Phase 1, clinical trials are conducted with a small number of healthy volunteers or patients afflicted with a specific disease to assess safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. The Phase 2 trials can be conducted comparing the investigational treatment to a comparator arm, or not. If used, a comparator usually includes standard of care therapy. Safety and efficacy data from Phase 2 clinical trials, even if favorable, may not provide sufficient rationale for proceeding to a Phase 3 clinical trial. In Phase 3, large scale, multi center, comparative trials are conducted with patients afflicted with a target disease to provide sufficient data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend, or terminate the trials.

The results of the preclinical and clinical testing of small molecules and many biologic drugs are submitted to the FDA in the form of a New Drug Application, or NDA, for review and for approval prior to commencement of commercial sales. In the case of blood products, vaccines, or gene and cell therapies, the results of clinical trials are submitted to the FDA as a Biologics License Application, or BLA. In responding to an NDA/BLA submission, the FDA may grant a marketing authorization, impose limitations on a marketing authorization, request additional information, deny the application if it determines that the application does not provide an adequate basis for approval, or refuse to review an application that has been submitted if it determines that the application does not provide an adequate basis for filing and review.

European and Other Regulatory Approval Process

Prior to initiating clinical trials in a region outside of the United States, a clinical trial application must be submitted and reviewed by the appropriate regulatory authority regulating the country in which the trial will be conducted. Whether or not FDA clearance or approval has been obtained, approval of a product by comparable regulatory authorities in Europe and other countries is necessary prior to commencement of marketing the product in such countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant an approval, or may require additional data before granting it, even though the relevant product has been cleared or approved by the FDA or another authority. As with the FDA, the regulatory authorities in the European Union, or EU, and other developed countries have lengthy approval processes for pharmaceutical products. The process for gaining approval in particular countries varies, but generally follows a similar sequence to that described for FDA approval. In Europe, the European Medicine Agency, or EMA, and the European Committee for Proprietary Medicinal Products, or CPMP, provide a mechanism for EU member states to exchange information on all aspects of product licensing. The EU has established the EMA for the evaluation of medical products, with both a centralized procedure with which the marketing authorization is recognized in all EU member states and a decentralized procedure, the latter being based on the principle of licensing within one member country followed by mutual recognition by the other member countries.

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Other Regulations

We are also subject to various and often changing federal, state, local and international laws, rules, regulations, guidelines and recommendations relating to safe working conditions and manufacturing practices.

Manufacturing

A typical sequence of steps in the manufacture of imetelstat drug product includes the following key components:

- starting materials, which are well-defined raw materials that are used to make bulk drug substance;
- bulk drug substance, which is the active pharmaceutical ingredient in a drug product that provides pharmacological activity or other direct effect in the treatment of disease; and
- final drug product, which is the finished dosage form that contains the drug substance that is shipped to the clinic for patient treatment.

Under the Collaboration Agreement, after a transition period, Janssen will be responsible for the manufacture and/or supply of imetelstat on a global basis for clinical trials and, after any regulatory approval, all commercial activities. Consequently, we will be, and expect to remain, dependent on Janssen to appropriately supply imetelstat. Currently, third-party contractors perform certain process development and other technical and scientific work with respect to imetelstat, in addition to supplying starting materials and manufacturing drug substance and drug product. We or Janssen do not have direct control over their personnel or operations. These third-party contractors, and/or any other contractors that Janssen may rely upon for the manufacture and/or supply of imetelstat, typically complete their services on a proposal by proposal basis under master supply agreements and may need to make substantial investments to enable sufficient capacity increases and cost reductions, and to implement those regulatory and compliance standards necessary for successful Phase 3 clinical trials and commercial production. These third-party contractors, and/or any other contractors that Janssen may rely upon for the manufacture and/or supply of imetelstat, may not be able to achieve such capacity increases, cost reductions, or regulatory and compliance standards, and even if they do, such achievements may not be at a commercially reasonable cost. Neither we nor Janssen have any long-term commitments or commercial supply agreements with any of the third-party contractors for imetelstat.

We currently have a master service agreement with two third-party contractors for labeling and packaging of imetelstat final drug product and for distribution of imetelstat to clinical sites in North America. In addition, we have agreements with two third-party contractors for release and distribution of imetelstat drug product to clinical sites in Europe. These third-party contractors provide services on a proposal by proposal basis. If requested by Janssen, we may transfer or assign these agreements to Janssen to the extent permissible by the terms of the agreements or agreed with such third-party contractors.

We have also entered into quality agreements with our imetelstat bulk drug substance and final drug product manufacturers, and our labeling, packaging and distribution service providers. The master and quality agreements are designed to ensure product quality, compliance with current Good Manufacturing Practices, or cGMP, and oversight of third parties for all critical aspects of imetelstat production, testing, release, labeling and packaging, storage and distribution. If requested by Janssen, we may transfer or assign these agreements to Janssen to the extent permissible by the terms of the agreements or agreed with such third-party contractors.

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Concentration of Revenues

In 2014 and 2013, the majority of our revenues were from license fees and royalties under licenses granted to several biotechnology and pharmaceutical companies to use telomerase immortalized cells in drug discovery research and for drug discovery applications. Two customers accounted for approximately 31%, 42% and 59% of our 2014, 2013 and 2012 revenues, respectively. In 2012, the majority of our revenues were from license fees and royalties related to our license and collaboration agreement with GE Healthcare UK, Limited, or GE Healthcare, for the development and commercialization of cellular assay products and our license agreement with Asia Biotech Corporation related to our telomerase activation technology. Upon the closing of the stem cell divestiture under the Contribution Agreement on October 1, 2013, the license agreement with GE Healthcare, including any future revenue payments thereunder, was transferred to Asterias Biotherapeutics, Inc. In December 2012, we assigned our telomerase activation technology to Telomerase Activation Sciences, Inc. and terminated our license agreement with Asia Biotech Corporation. Future royalty obligations by Asia Biotech Corporation under the license agreement have been terminated. We operate in one operating segment and have operations solely in the United States. All of our long-lived assets are maintained in the United States. Information regarding total revenues, net loss and total assets is set forth in our financial statements included in Item 8 of this annual report on Form 10-K.

Stem Cell Divestiture; Asterias Series A Distribution

Background

On October 1, 2013, we closed the transaction to divest our human embryonic stem cell assets and our autologous cellular immunotherapy program pursuant to the terms of the previously disclosed asset contribution agreement, or the Contribution Agreement, that we entered into in January 2013 with BioTime, Inc., or BioTime, and BioTime's wholly owned subsidiary, Asterias Biotherapeutics, Inc., or Asterias (formerly known as BioTime Acquisition Corporation) and received 6,537,779 shares of Asterias Series A common stock. In accordance with our contractual obligations under the Contribution Agreement, we distributed all of the shares of Asterias Series A common stock to our stockholders on a pro rata basis, or distributed cash in lieu thereof, which we refer to as the Series A Distribution. We completed the Series A Distribution to eligible stockholders on August 15, 2014 and have no remaining obligations for the Series A Distribution. See further discussion in Note 7 on Divestiture of Stem Cell Assets in Notes to Consolidated Financial Statements of this annual report on Form 10-K.

In connection with the Contribution Agreement, BioTime made certain contributions to Asterias, including five-year warrants to purchase 8,000,000 shares of BioTime common stock at an exercise price of $5.00 per share, or the BioTime Warrants. Upon the completion of the Series A Distribution, Asterias distributed the BioTime Warrants on a pro rata basis to the holders of Asterias Series A common stock. The BioTime Warrant distribution was completed on October 1, 2014.

Consultants

We have consulting agreements with a number of leading academic scientists, clinicians and regulatory experts. These individuals serve as key consultants, expert witnesses, or as members of clinical advisory panels with respect to our imetelstat program or in legal proceedings. They also serve as important contacts for us throughout the broader scientific and clinical communities. They are distinguished individuals with expertise in numerous fields, including telomere and telomerase biology, cellular biology, molecular biology, oncology and drug regulations.

We retain each consultant according to the terms of a consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, some consultants hold options to purchase our common stock and restricted stock awards, subject to the vesting requirements contained in the consulting

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agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer, or may have other consulting or advisory agreements that may limit their availability to us.

Executive Officers of the Company

The following table sets forth certain information with respect to our executive officers as of January 31, 2015:

Name	Age	Position
John A. Scarlett, M.D.	63	President and Chief Executive Officer
Olivia K. Bloom	46	Executive Vice President, Finance, Chief Financial Officer and Treasurer
Melissa A. Kelly Behrs	51	Executive Vice President, Business Development and Portfolio and Alliance Management
Andrew J. Grethlein, Ph.D.	50	Executive Vice President, Development and Technical Operations
Stephen N. Rosenfield, J.D.	65	Executive Vice President, General Counsel and Corporate Secretary

John A. Scarlett, M.D., has served as our Chief Executive Officer and a director since September 2011 and President since January 2012. Prior to joining Geron, Dr. Scarlett served as President, Chief Executive Officer and a member of the board of directors of Proteolix, Inc., a privately held, oncology-oriented biopharmaceutical company, from February 2009 until its acquisition by Onyx Pharmaceuticals, Inc., an oncology-oriented biopharmaceutical company, in November 2009. From February 2002 until its acquisition by Ipsen, S.A. in October 2008, Dr. Scarlett served as the Chief Executive Officer and a member of the board of directors of Tercica, Inc., an endocrinology-oriented biopharmaceutical company, and also as its President from February 2002 through February 2007. From March 1993 to May 2001, Dr. Scarlett served as President and Chief Executive Officer of Sensus Drug Development Corporation. In 1995, he co-founded Covance Biotechnology Services, Inc., a contract biopharmaceutical manufacturing operation, and served as a member of its board of directors from inception to 2000. From 1991 to 1993, Dr. Scarlett headed the North American Clinical Development Center and served as Senior Vice President of Medical and Scientific Affairs at Novo Nordisk Pharmaceuticals, Inc., a wholly owned subsidiary of Novo Nordisk A/S. Dr. Scarlett received his B.A. degree in chemistry from Earlham College and his M.D. from the University of Chicago, Pritzker School of Medicine.

Olivia K. Bloom has served as our Executive Vice President, Finance since February 2014, Chief Financial Officer since December 2012 and Treasurer since February 2011. Ms. Bloom previously served as our Senior Vice President, Finance from December 2012 to February 2014, Chief Accounting Officer from September 2010 to December 2012 and Vice President, Finance from January 2007 to December 2012. Ms. Bloom joined the Company in 1994 as a Senior Financial Analyst and from 1996 to 2011 served as our Controller. Prior to Geron, Ms. Bloom started her career in public accounting at KPMG Peat Marwick and became a Certified Public Accountant in 1994. Ms. Bloom graduated Phi Beta Kappa with a B.S. in Business Administration from the University of California at Berkeley.

Melissa A. Kelly Behrs has served as our Executive Vice President, Business Development and Portfolio & Alliance Management, since July 2014. Prior to that she was our Executive Vice President, Portfolio and Alliance Management, since February 2014 and she was our Senior Vice President, Portfolio and Alliance Management, from September 2012 to February 2014. Ms. Behrs joined Geron in November 1998 as Director of Corporate Development. Since then, she has served in various managerial positions, including General Manager, R&D Technologies; Vice President, Corporate

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Development; Senior Vice President, Therapeutic Development, Oncology; and Senior Vice President, Strategic Portfolio Management. From 1990 to 1998, Ms. Behrs worked at Genetics Institute, Inc., a biotechnology research and development company, serving initially as Assistant Treasurer and then as Associate Director of Preclinical Operations where she was responsible for all business development, regulatory, and project management activities for the Preclinical Development function. Ms. Behrs received a B.S. from Boston College and an M.B.A. from Babson College.

Andrew J. Grethlein, Ph.D., has served as our Executive Vice President, Development and Technical Operations, since July 2014. Prior to that he served as our Executive Vice President, Technical Operations, since September 2012. Prior to joining Geron, Dr. Grethlein was Executive Vice President and Chief Operating Officer for Inspiration Biopharmaceuticals, a biopharmaceutical company, from January 2010 to September 2012. From October 2008 until January 2010, Dr. Grethlein was Senior Vice President of Biotechnology and Portfolio Management Team Leader for Hematology at Ipsen S.A., a global specialty pharmaceutical company. His responsibilities at Ipsen included planning and execution of worldwide strategy for product and portfolio development in the hematologic therapeutic area. From 2003 to 2008, Dr. Grethlein served as Senior Vice President of Pharmaceutical Operations at Tercica, Inc., an endocrinology-oriented biopharmaceutical company. In this role, he was a member of the senior executive team that governed corporate strategy, business planning and company operations, and had responsibility for all manufacturing and quality functions. Before joining Tercica, Dr. Grethlein served in various positions at Elan Corporation, a biotechnology company, from 1997 to 2003, including as Senior Director, South San Francisco Pharmaceutical Operations, where he had responsibility as site head for commercial manufacturing operations. From 1995 to 1997, Dr. Grethlein served as Manager, Biologics Development and Manufacturing, for Athena Neurosciences, Inc., a pharmaceutical company. Prior to this, he served in various engineering positions for the Michigan Biotechnology Institute, a nonprofit technology research and business development corporation. Dr. Grethlein received his A.A. degree in liberal arts from Simon's Rock Early College, his B.S. in biology from Bates College, and his M.S. and Ph.D. in chemical engineering from Michigan State University.

Stephen N. Rosenfield, J.D., has served as our Executive Vice President, General Counsel and Corporate Secretary since February 2012, General Counsel and Secretary since January 2012 and Secretary since October 2011. From July 2009 to February 2012, Mr. Rosenfield has been a consultant to private companies. From October 2008 until June 2009, Mr. Rosenfield was the General Counsel and Secretary of Tercica, Inc., a U.S. subsidiary of Ipsen, S.A., a global specialty pharmaceutical company. From June 2004 until October 2008, Mr. Rosenfield was the General Counsel and Secretary of Tercica, Inc., an endocrinology-oriented biopharmaceutical company, from January 2006 until October 2008, he was also the Executive Vice President of Legal Affairs, and from June 2004 until January 2006, Mr. Rosenfield was the Senior Vice President of Legal Affairs. Prior to joining Tercica, Mr. Rosenfield served as the Executive Vice President of Legal Affairs, General Counsel and Secretary of InterMune, Inc., a biotechnology company focused in pulmonology and fibrotic diseases. Prior to joining InterMune, Mr. Rosenfield was an attorney at Cooley LLP, an international law firm, where he served as outside counsel for biotechnology and technology clients. Mr. Rosenfield received a B.S. from Hofstra University and a J.D. from Northeastern University School of Law.

Employees

As of December 31, 2014, we had 42 employees, of whom 7 hold Ph.D. degrees and 13 hold other advanced degrees. Of this current total workforce, 22 employees were engaged in, or directly supported, our research and development activities, and 20 employees were engaged in business development, legal, finance and administration. None of our employees are covered by a collective bargaining agreement; nor have we experienced work stoppages. We consider relations with our employees to be good.

On March 3, 2015, we announced an organizational resizing to reduce our workforce from 39 to 21 positions, representing a reduction of approximately 46% of our workforce. For a further discussion, see Note 15 on Subsequent Event in Notes to Consolidated Financial Statements of this annual report on Form 10-K.

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Corporate Information

Geron Corporation was incorporated in the State of Delaware on November 28, 1990.

Available Information

Our internet address is www.geron.com. Information included on our website is not part of this annual report on Form 10-K. We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. In addition, copies of our annual reports are available free of charge upon written request. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is www.sec.gov.

ITEM 1A. RISK FACTORS

Our business is subject to various risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below, together with all of the other information included in this annual report on Form 10-K. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

RISKS RELATED TO OUR BUSINESS

We are dependent upon our collaborative relationship with Janssen to further develop, manufacture and commercialize imetelstat, our sole product candidate. If Janssen fails to perform as expected, the potential for us to generate future revenues from milestone payments and royalties from imetelstat would be significantly reduced, the development and/or commercialization of imetelstat may be terminated or substantially delayed, and our business would be severely harmed.

Under the terms of the Collaboration Agreement, we and Janssen have created a joint governance structure, including joint development and steering committees and working groups, to oversee and manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat; however, Janssen is solely responsible for the operational implementation of those activities. Accordingly, the timely and successful completion by Janssen of those activities will significantly affect the timing and amount of any revenues from milestone payments and royalties we may receive under the Collaboration Agreement, and these activities will be influenced by, among other things, the efforts and allocation of resources by Janssen, none of which we control. If Janssen does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval and/or commercialization efforts related to imetelstat could be delayed or terminated, and it could become necessary for us to assume the responsibilities for the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat at our own expense. Accordingly, there can be no assurance that any of the development, regulatory or sales milestones will be achieved or that we will receive any future milestone or royalty payments under the Collaboration Agreement.

In addition, because Janssen is solely responsible for the operational implementation of worldwide regulatory, development, manufacturing and commercialization activities related to imetelstat, we are solely dependent on Janssen to provide us with timely and accurate information concerning these

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activities. If we do not receive accurate information from Janssen in a timely manner, or at all, regarding these activities, including, for example, plans for, and enrollment, efficacy and safety results from, clinical trials, then the timeliness and accuracy of our public disclosures, as well as our governance-related decision-making regarding these activities, may be adversely affected.

Our collaboration with Janssen may be unsuccessful due to other factors, including the following:

- Janssen may choose to terminate the Collaboration Agreement for convenience;
- Janssen may provide a negative Continuation Decision and halt its development of imetelstat;
- the results of the Initial Phase 2 MF Study and/or the Initial Phase 2 MDS Study may be negative or inconclusive, or Janssen may observe safety issues in either of these studies, which may result in a negative Continuation Decision by Janssen, in which case we would receive no further payments from Janssen under the Collaboration Agreement;
- Janssen may choose not to develop and commercialize imetelstat in certain markets or for one or more indications, if at all;
- Janssen may take considerably more time advancing imetelstat through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from Janssen, and ultimately, any royalties on worldwide net sales;
- in the event of a dispute between us and Janssen regarding Janssen's performance under the Collaboration Agreement, it may be difficult for us to prove that Janssen breached its obligation to use "commercially reasonable efforts" with regard to the development, regulatory approval, manufacture and commercialization of imetelstat under the Collaboration Agreement;
- Janssen may not dedicate the resources necessary to carry imetelstat through clinical development or may not obtain the necessary regulatory approvals, and this would delay the achievement of development, regulatory or sales milestones;
- Janssen's ability to achieve development and manufacturing objectives or milestones may be delayed or substantially impacted if we fail to transfer technology and information related to imetelstat to Janssen in a timely manner or at all;
- subject to our election of the U.S. Co-Promotion Option, Janssen will be responsible for all aspects of the commercialization of imetelstat worldwide, including pricing decisions which would affect the royalties on worldwide net sales we could receive;
- Janssen may change the focus of its commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to imetelstat, which would have the direct effect of reducing our royalties or share of potential co-promotion activities since the extent of our U.S. Co-Promotion Option is limited to a percentage of overall promotion activities under the Collaboration Agreement;
- after assuming manufacturing responsibilities for imetelstat, Janssen may fail to manufacture or supply sufficient quantities of imetelstat for use in planned clinical trials, which could delay, suspend or stop any imetelstat clinical activities;
- Janssen may fail to develop a commercially viable formulation or manufacturing process for imetelstat, and may fail to manufacture or supply sufficient quantities of imetelstat for commercial use, if approved, which would result in lost sales revenue and reduced royalties for us;

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Janssen may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could delay, suspend or stop clinical activities being performed by Janssen or by us; and

if Janssen is acquired during the term of our collaboration, the acquirer may have different strategic priorities that could cause it to terminate the Collaboration Agreement or reduce its commitment to our collaboration.

If our collaboration with Janssen is unsuccessful as a result of any of the above factors, or any other factor, then Janssen may terminate the Collaboration Agreement, and we would not be eligible for any further payments from Janssen under the Collaboration Agreement, which would severely and adversely affect our business and business prospects.

Delays in the initiation of, or the inability to initiate, subsequent clinical trials of imetelstat, such as the Initial Phase 2 MF Study or the Initial Phase 2 MDS Study planned to be conducted under the Collaboration Agreement, could result in increased development costs and would delay our ability to earn revenues from milestone payments or royalties from the Collaboration Agreement with Janssen.

To date, we have not initiated any clinical trials evaluating imetelstat in any hematologic myeloid malignancies (other than essential thrombocythemia), including myelofibrosis, or MF. Advancing clinical development of imetelstat will be influenced by results from existing clinical trials, such as the MF Pilot Study, and potential future clinical trials of imetelstat in hematologic myeloid malignancies, such as the Initial Phase 2 MF Study or the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. The commencement of potential future clinical trials of imetelstat could be delayed or abandoned for a variety of reasons, including as a result of failures or delays by Janssen in:

obtaining regulatory clearance to commence subsequent clinical trials of imetelstat in a timely manner, or at all, in the United States or other countries;

properly designing, commencing, enrolling, conducting or completing potential future clinical trials, including the Initial Phase 2 MF Study or the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, and promptly or adequately reporting data from such trials;

demonstrating sufficient safety and efficacy in future Phase 2 clinical trials, including the Initial Phase 2 MF Study or the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, to obtain regulatory clearance to commence subsequent clinical trials in a timely manner, or at all, in the United States or other countries;

properly conducting and/or completing the MF Pilot Study;

manufacturing sufficient quantities of imetelstat and in a manner that meets the quality standards of the FDA and other regulatory agencies;

ensuring the ability to manufacture imetelstat at acceptable costs for Phase 3 clinical trials and commercialization;

obtaining clearance or approval of proposed trial designs or manufacturing specifications from the FDA and other regulatory authorities;

reaching agreement on acceptable terms and on a timely basis, if at all, with collaborators and vendors located in the United States or foreign jurisdictions, including contract research organizations, laboratory service providers and trial sites, on all aspects of clinical trials;

obtaining institutional review board or ethics committee approval to conduct clinical trials at prospective clinical trial sites; and

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identifying and successfully screening and enrolling appropriate subjects for participation in clinical trials and retaining those subjects in the clinical trials.

Failures or delays with respect to any of these events could adversely affect the ability to initiate, maintain or successfully complete any future clinical trials of imetelstat, which could increase development costs, impair our ability to earn revenues from milestone payments or royalties from the Collaboration Agreement with Janssen or cause Janssen to terminate the Collaboration Agreement, any of which could adversely impact our financial results and would have severe adverse effects on our business and business prospects.

If there are any safety or efficacy results that cause the benefit-risk profile of imetelstat to become unacceptable, the clinical development of imetelstat would be delayed or halted, and Janssen may terminate the Collaboration Agreement, which would severely and adversely affect our business prospects, and may cause us to cease operations.

Imetelstat may prove to have undesirable or unintended side effects or other characteristics adversely affecting its safety, efficacy, cost-effectiveness or marketability that could prevent or limit its approval for marketing and successful commercial use, or that could delay or prevent the commencement and/or completion of clinical trials for imetelstat. For example, although the FDA removed the full clinical hold on our IND for imetelstat, if patients in current or future clinical trials experience similar or more severe hepatotoxicity, including elevated LFTs or severe hepatic adverse events, such IND for imetelstat may again be placed on clinical hold, and we, in collaboration with Janssen, may be precluded from further developing imetelstat. In addition, if regulatory submissions requesting approval to market imetelstat are submitted, after reviewing the data in such submissions, the FDA and regulatory agencies in other countries may conclude that the overall benefit-risk profile of imetelstat treatment, including hepatotoxicity or severe hepatic adverse events, may preclude approval of imetelstat for marketing or further development for any indications, including hematologic malignancies. Any of these events would severely harm our business and prospects, and would likely cause us to cease operations.

Further, in our Phase 1 clinical trials of imetelstat, we observed dose-limiting toxicities, including thrombocytopenia when the drug was used as a single agent, and neutropenia when the drug was used in combination with paclitaxel, as well as a low incidence of severe infusion reactions. In our Phase 2 clinical trials of imetelstat in ET, MM, and solid tumors, we have observed hematologic toxicities as well as gastrointestinal events, infections, muscular and joint pain, fatigue and infusion reactions. In addition, in our Phase 2 clinical trials of imetelstat, we have observed LFT abnormalities, the clinical significance and long-term consequences of which are currently undetermined. In our Phase 2 trial in ET, one patient died of bleeding esophageal varices, a complication of chronic liver disease, for which imetelstat could not be excluded as a causative agent. In the MF Pilot Study, myelosuppression has been the primary dose-limiting toxicity reported to date, consistent with our observations in previous Geron-sponsored imetelstat studies. However, during the MF Pilot Study, more persistent and profound myelosuppression, particularly thrombocytopenia, was observed with imetelstat administered on a weekly basis. This included one case of febrile neutropenia after prolonged myelosuppression with intracranial hemorrhage resulting in patient death, which was assessed as possibly related to imetelstat by the investigator. Since the MF Pilot Study is an ongoing study with additional data being generated, the benefit-risk profile of imetelstat in MF will continue to be assessed, including the risk of hepatotoxicity and severe cytopenias that may be associated with life-threatening clinical outcomes.

Clinical trials by their nature examine the effect of a potential therapy in a sample of the potential future patient population. As such, clinical trials conducted with imetelstat, to date and in the future, may not uncover all possible adverse events that patients treated with imetelstat may experience. In collaboration with Janssen, we may observe or report dose-limiting toxicities or other safety issues in potential future clinical trials of imetelstat, including the Initial Phase 2 MF Study and the Initial

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Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. Likewise, because previously enrolled patients continue to receive imetelstat in the MF Pilot Study, additional or more severe toxicities or safety issues in the MF Pilot Study, including additional serious adverse events and clinically significant LFT abnormalities, may be observed or reported as patient treatment continues and more data become available. If such toxicities or other safety issues in any clinical trial of imetelstat result in an unacceptable benefit-risk profile, then:

- the commencement and/or completion of any current or future clinical trials, including the MF Pilot Study and the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, would likely be delayed or prevented;

- the MF Pilot Study or any potential future clinical trials, including the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, may be placed on clinical hold or halted by regulatory authorities, such as the previous clinical holds placed by the FDA on our IND for imetelstat and the IND for the MF Pilot Study; or

- additional, unforeseen trials or preclinical studies may be required to be conducted.

The occurrence of any of these events would likely cause Janssen to abandon their development of imetelstat entirely and terminate the Collaboration Agreement. Any termination of the Collaboration Agreement by Janssen would have a material adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which may cause us to cease operations.

If Janssen does not elect to continue the development of imetelstat in a timely manner, or at all, our business and business prospects would be severely harmed.

Under the terms of the Collaboration Agreement, Janssen is not obligated to make any additional payments to us until it makes an affirmative Continuation Decision following the results of the Initial Phase 2 MF Study, or, if the Initial Phase 2 MF Study is terminated early or suspended for an extended period of time, within a certain time period thereafter as set forth in the Collaboration Agreement. The timing of Janssen's Continuation Decision also affects the timing and availability of our decision regarding U.S. Opt-In Rights, as well as our election of the U.S. Co-Promotion Option. If the Initial Phase 2 MF Study is terminated early, suspended for an extended period of time, or is otherwise unsuccessful, Janssen may provide a negative Continuation Decision, in which case, the Collaboration Agreement would terminate, we would not be eligible for any further payments from Janssen under that agreement and our business and business prospects would be severely and adversely affected.

In addition, Janssen may terminate the Collaboration Agreement at any time for convenience. If Janssen terminates the Collaboration Agreement, then, depending on the timing of such event:

- we would no longer have the right to receive any milestone payments or royalties under the Collaboration Agreement;

- the development of imetelstat would likely be terminated or significantly delayed;

- we would bear all of the risks and costs related to the further clinical development, manufacturing, regulatory approval and commercialization of imetelstat;

- we would need to raise additional capital if we were to choose to pursue imetelstat development on our own, or we would need to establish alternative collaborations with third-party collaboration partners, which may not be possible in a timely manner or at all, or may not be possible on terms acceptable to us, in which case it would likely be necessary for us to limit the

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size or scope of the imetelstat development program or seek additional funding by other means to accommodate the increased expenditures; and

we would need to hire additional employees to support the development and commercialization of imetelstat, which would increase our need for additional funding.

Any termination of the Collaboration Agreement by Janssen at any time would have a material adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which would have severe adverse effects on our business and business prospects, and may cause us to cease operations.

Our decision to exercise our U.S. Opt-In Rights under the Collaboration Agreement with Janssen for imetelstat must be made within a limited time after Janssen makes an affirmative Continuation Decision and, as a result, we may be required to make a substantial capital investment based on limited clinical data.

We must elect to exercise our U.S. Opt-In Rights within a short timeframe following Janssen's Continuation Decision. Although we expect to receive information from Janssen regarding data from the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study, proposed future clinical development plans and costs, estimates in timing for commercializing imetelstat and related promotional activities, and calculation of our share of development costs incurred to date by Janssen that we will be required to reimburse if we exercise our U.S. Opt-In Rights, we will be required to rapidly decide whether to make a substantial capital investment in imetelstat prior to the conclusion of any Phase 3 registration-enabling clinical trial. Accordingly, if imetelstat were to become unsuccessful in any Phase 3 registration-enabling clinical trial or fails to receive regulatory approval, we would not receive any financial return on this substantial capital investment. Such an occurrence would negatively impact our financial condition and results of operations.

Our Collaboration Agreement with Janssen prohibits us from developing or commercializing any product that operates through the same mechanism of action as imetelstat, and our U.S. co-promotion rights may be terminated if we market or promote any such products for any oncology indication. As a result of this, or for any other reason, we may not be able to successfully acquire or in-license promising product opportunities for development, which would limit our growth and revenue potential.

We plan to seek to diversify our sole product candidate development risk by identifying promising product opportunities for development, which we may seek to acquire or in-license. However, the Collaboration Agreement with Janssen prohibits us from commercializing, under the intellectual property we have licensed exclusively to Janssen, any substance whose identified or known mechanism of action is telomerase inhibition. Further, if we exercise our U.S. Co-Promotion Option under the Collaboration Agreement, we will be required to certify at the time of exercising our U.S. Co-Promotion Option that we are not marketing or promoting, and have no right to market or promote, any such products for any oncology indication. Our right to co-promote in the U.S. may be terminated by Janssen if we develop or commercialize a product for treating an oncology indication that acts through the same mechanism of action as imetelstat or that is substitutable for imetelstat. Accordingly, our Collaboration Agreement with Janssen could adversely affect our ability to acquire or in-license, or to research, develop or market, promising product candidates.

In addition, we may not be able to identify promising product candidates. The competition to acquire or in-license rights to promising product candidates is fierce, and many of our competitors are large, multinational pharmaceutical and biotechnology companies with considerably more financial, development and commercialization resources and experience than we have. Thus, even if we succeed in identifying promising product candidates, we may not be able to acquire rights to them on acceptable terms, or at all. In any event, any growth through acquisition or in-licensing will depend upon our identifying and obtaining promising product candidates, our ability to develop those product

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candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize these product candidates. If we are unable to identify and acquire promising product candidates, we will be unable to diversify our sole product candidate development risk, and our growth and revenue potential could be limited.

We may not be able to successfully retain key personnel to support our collaboration with Janssen or to manage any future growth.

Under the terms of the Collaboration Agreement, we and Janssen have created a joint governance structure, including committees and working groups, to manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat, and we will have ongoing responsibilities to oversee and participate in the collaboration with Janssen. In addition, we will remain responsible for prosecuting, at Janssen's direction, the patents we licensed to Janssen, and have sole responsibility for those patents that were not licensed to Janssen. If we are unable to successfully retain, motivate and incentivize our personnel, our ability to support the Collaboration Agreement with Janssen could be impaired, and our business and the price of our common stock would be adversely impacted.

In addition, our future growth and success depend to a significant extent on the skills, experience and efforts of our executive officers and key members of our clinical and scientific staff. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. The previous restructurings we implemented and the recently announced organizational resizing, as well as our collaboration with Janssen and uncertainties regarding our ability to diversify our sole product candidate development risk, could have an adverse impact on our ability to retain and recruit qualified personnel or we may incur unanticipated inefficiencies caused by our reduced personnel resources. We may be unable to retain our current personnel or attract or assimilate other highly qualified management and development personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and could impair our ability to support our collaboration with Janssen or to support future growth.

We and certain of our officers have been named as defendants in three purported securities lawsuits, two of which are securities class action lawsuits, and certain of our officers and directors have been named as defendants in a derivative lawsuit. These, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits and any other lawsuits will be costly to defend or pursue and are uncertain in their outcome.

Securities-related class action lawsuits and derivative litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs.

On March 14, 2014, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, or the California District Court, naming as defendants us and certain of our officers. The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff alleges, among other things, that we failed to disclose facts related to the occurrence of persistent low-grade LFT abnormalities observed in our Phase 2 trial of imetelstat in ET or PV patients and the potential risk of chronic liver injury following long-term exposure to imetelstat. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees.

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On March 28, 2014, a second purported securities class action lawsuit was commenced in the California District Court, naming as defendants us and certain of our officers. This lawsuit, which is based on the same factual background as the purported securities class action lawsuit that commenced on March 14, 2014, also alleges violations of the Securities Exchange Act of 1934 and seeks damages and an award of reasonable costs and expenses, including attorneys' fees.

On June 30, 2014, both of the foregoing lawsuits, or the Class Action Lawsuits, were consolidated for all purposes, and a lead plaintiff and lead counsel were appointed by the California District Court. On July 21, 2014, the California District Court ordered the lead plaintiff to file its consolidated amended complaint in the Class Action Lawsuits, which was filed on September 19, 2014. We filed our motion to dismiss the consolidated amended complaint on November 18, 2014. The plaintiff's opposition to our motion to dismiss was filed on January 20, 2015, and we filed our reply on February 25, 2015. The court hearing for the motion to dismiss has been scheduled for April 10, 2015.

On June 6, 2014, a purported securities lawsuit, not styled as a class action, was commenced in the United States District Court for the Southern District of Mississippi, or the Mississippi District Court, naming as defendants us and certain of our officers. This lawsuit, which is based on the same factual background as the Class Action Lawsuits, also alleges violations of the Securities Exchange Act of 1934 and seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On August 11, 2014, we filed a motion to transfer the purported securities lawsuit filed in the Mississippi District Court to the California District Court so it could be consolidated with the purported Class Action Lawsuits. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, and the transferred case has been consolidated by the California District Court with the purported Class Action Lawsuits filed in the California District Court.

On April 21, 2014, a stockholder purporting to act on our behalf filed a derivative lawsuit in the Superior Court of California for the County of San Mateo against certain of our officers and directors. The lawsuit alleges breaches of fiduciary duties by the defendants and other violations of law. In general, the lawsuit alleges that the defendants caused or allowed the dissemination of allegedly false and misleading statements related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff is seeking unspecified monetary damages and other relief, including reforms and improvements to our corporate governance and internal procedures.

It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense against these lawsuits and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with these lawsuits. We currently are not able to estimate the possible cost to us from these matters, as these lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserve for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position.

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We may also be subject to litigation arising from our proposed or completed strategic transactions or if the results of our business and collaboration activities are not successful.

On October 1, 2013, we closed the transaction to divest our human embryonic stem cell assets and our autologous cellular immunotherapy program pursuant to the terms of the Contribution Agreement that we entered into in January 2013 with BioTime and Asterias. On November 13, 2014, we announced that we had entered into the Collaboration Agreement with Janssen to develop and commercialize imetelstat worldwide. We may face litigation arising from or related to the value received by our stockholders, if any, from our distribution of the Asterias Series A common stock and/or the BioTime Warrants distributed by Asterias under the Contribution Agreement, or our role as a named underwriter with respect to our distribution of the Asterias Series A common stock, including the delays we experienced with respect to completing our distribution of the Asterias Series A common stock, or we may face litigation based on other matters related to the Contribution Agreement and the Collaboration Agreement or the transactions contemplated thereby, including if we are unable to generate substantial value under the Collaboration Agreement with Janssen or such collaboration is not otherwise successful.

As a result of these and other factors, we may be exposed to a number of litigation risks related to the transactions contemplated by the Contribution Agreement and the Collaboration Agreement, including declines or fluctuations in our stock price, additional advisor and legal fees, distractions to our management caused by activities undertaken in connection with resolving any disputes related to the transactions, or the loss of important contractual rights. As another example, some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our human embryonic stem cell programs. Thus, certain stockholders may have attributed substantial financial value to our stem cell assets and may believe that the Asterias Series A common stock, BioTime Warrants and/or cash received in the distributions pursuant to the Contribution Agreement were inadequate consideration for such assets.

Similarly, the announcement and/or completion of these strategic transactions could result in litigation arising out of any claims that our stockholders suffered financial losses due to the transactions, the approval of our stockholders was required under applicable law or otherwise should have been obtained prior to the completion of either or both of these transactions, or that our officers and directors breached their fiduciary duties in connection with the approval and completion of these transactions. Although we believe that stockholder approval was not required under applicable law in order to complete either or both of these transactions and therefore we neither sought nor intend to seek such stockholder approval, it is possible that persons who were stockholders at the time of the applicable transaction may claim that their approval was required, in which case litigation could follow, which could result in substantial damages to us and/or could negatively affect our rights and obligations under either of these agreements or, in the case of the Collaboration Agreement, could result in the termination of that agreement.

Likewise, our stockholders may believe that the financial and other terms of the Collaboration Agreement are not favorable to either us or our stockholders, including any belief that the potential payments we may receive under the Collaboration Agreement are inadequate. Litigation brought by our stockholders challenging the validity of, or financial losses resulting from, these transactions could also result in claims against us by Asterias and/or Janssen, and each of the Contribution Agreement and the Collaboration Agreement provide for indemnification by us of BioTime and Janssen, respectively, against all losses and expenses relating to breaches of our representations, warranties and covenants in the applicable agreement, which could expose us to further financial obligations and damages. The occurrence of any one or more of the above could have a significant adverse impact on our business and financial condition.

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In addition, if the results of our business and collaboration activities are not successful, including without limitation, if:

- we or Janssen are otherwise unable to continue development of imetelstat due to actions by regulatory authorities, such as the previous full clinical hold that was placed by the FDA on our IND for imetelstat in March 2014;
- we, Janssen or any investigators ascertain that the use of imetelstat results in significant systemic or organ toxicities, including hepatotoxicity, or other safety issues resulting in an unacceptable benefit-risk profile;
- the conduct of previous clinical trials, such as the MF Pilot Study, and future clinical trials, such as the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, results in patient injury or death, or any failure to meet regulatory and compliance requirements;
- the final or any preliminary results from the MF Pilot Study, or any subsequent clinical trial of imetelstat, including the Initial Phase 2 MF Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, are not deemed to be successful;
- Janssen discontinues the further development of imetelstat and terminates the Collaboration Agreement; or
- Asterias is unable to develop our stem cell assets, and we are not able to receive any royalties from the sale of any potential stem cell products by Asterias,

our stock price would likely decline, and future litigation may result. A decision adverse to our interests in any such lawsuits could result in the payment of substantial damages by us, and could have a material adverse effect on our cash flow, results of operations and financial position or could otherwise severely harm our business.

Our business may also bring us into conflict with our licensees, licensors, or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. For example, we are subject to the risk of possible disagreements with Janssen, including those regarding the development and/or commercialization of imetelstat, interpretation of the Collaboration Agreement and ownership of proprietary rights. In addition, in certain circumstances we may believe that we have achieved a particular milestone and Janssen may disagree with our belief. In that case, receipt of that milestone payment may be delayed or may never be received, which would adversely affect our financial condition and may require us to adjust our operating plans. While the Collaboration Agreement provides for a joint governance structure to oversee and manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat, Janssen generally will, subject to limited exceptions, have the deciding vote in the event of any disagreement. In any event, the joint governance structure contemplated by the Collaboration Agreement will be dissolved in the event that we do not exercise our U.S. Opt-In Rights, which would preclude our ability to participate in any further decision-making for imetelstat. Reliance on a joint governance structure also subjects us to the risk that changes in key management personnel that are members of the various joint committees may materially and adversely affect the functioning of these committees, which could significantly delay or preclude imetelstat development and/or commercialization. As a result of possible disagreements with Janssen, we also may become involved in litigation or arbitration, which would be time-consuming and expensive.