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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2023

or

☐ **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: 000-20859

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.)**
919 East Hillsdale Blvd., Suite 250, Foster City, CA	**94404**
(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:	**Trading symbol(s):**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value	GERN	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 ☒ No ☐

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 ☐ No ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $1,394,546,000 based upon the closing price of the registrant's common stock on June 30, 2023 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 February 23, 2024, there were 546,059,309 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Document	**Form 10-K Parts**
Portions of the Registrant's definitive proxy statement for the 2024 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2023.	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, and its wholly owned subsidiaries, Geron UK Limited, a United Kingdom company, and Geron Netherlands, B.V., a Dutch company.

Forward-Looking Statements

This annual report on Form 10-K, including "Business" in Part I, Item 1 of this annual report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this annual report on Form 10-K, 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 and uncertainties related to: (a) whether the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, may have issues with the New Drug Application, or NDA, or marketing authorization application, or MAA, for imetelstat for Low or Intermediate-1 risk myelodysplastic syndromes, or lower-risk MDS, that delay or prevent approval and a potential commercial launch; (b) whether we will be able to continue to develop imetelstat or advance imetelstat to subsequent clinical trials, or that we will be able to receive regulatory approval for or successfully commercialize imetelstat, on a timely basis or at all; (c) whether imetelstat may cause, or have attributed to it, adverse events that could further delay or prevent the commencement and/or completion of clinical trials, delay or prevent its regulatory approval, or limit its commercial potential; (d) whether the IMpactMF Phase 3 trial for R/R MF has a positive outcome and demonstrates safety and effectiveness to the satisfaction of the FDA and international regulatory authorities, and whether our projected rates for enrollment and death events differ from actual rates, which may cause the interim and final analyses to occur later than anticipated; (e) whether we overcome all of the enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to have the financial resources for, and to meet the expected timelines and planned milestones; (f) if imetelstat is approved for marketing and commercialization, whether we are able to establish and maintain effective sales, marketing and distribution capabilities, obtain adequate coverage and third-party payor reimbursement, and achieve adequate acceptance in the marketplace; (g) whether imetelstat actually demonstrates disease-modifying activity in patients; (h) whether there are failures in manufacturing or supplying sufficient quantities of imetelstat that would delay, or not permit, the anticipated commercial launch or not enable ongoing or planned clinical trials; (i) whether we are able to obtain and maintain the exclusivity terms and scopes provided by patent and patent term extensions, regulatory exclusivity, and have freedom to operate; (j) that we may be unable to successfully commercialize imetelstat due to competitive products, or otherwise; (k) that we may decide to partner and not to commercialize independently in the U.S. or in Europe and other international markets; (l) whether we have sufficient resources to satisfy our debt service obligations and to fund our planned operations; (m) that we may seek to raise substantial additional capital in order to complete the development and commercialization of imetelstat and to meet all of the expected timelines and planned milestones, and that we may have difficulty in or be unable to do so; and (n) the impact of general economic, industry or political climate in the U.S. or internationally and the effects of macroeconomic conditions on our business and business prospects, financial condition and results of operations; as well as 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 "Risk Factors," in Part I, Item 1A 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.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this summary to be a complete discussion of all potential risks or uncertainties that may substantially impact our business. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K. The summary below is qualified in its entirety by that more complete discussion of such risks and uncertainties. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. You should consider carefully the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K as part of your evaluation of an investment in our common stock.

Risks Related to the Development of Imetelstat

- Our future success depends solely on imetelstat, our only product candidate, and we cannot be certain that we will be able to continue to develop imetelstat or advance imetelstat to subsequent clinical trials, or that we will be able to receive regulatory approval for or to commercialize imetelstat, on a timely basis or at all.
- Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could further delay or prevent the commencement and/or completion of clinical trials for imetelstat, delay or prevent its regulatory approval, or limit its commercial potential.
- If IMpactMF fails to demonstrate safety and effectiveness to the satisfaction of the FDA or international regulatory authorities, we would incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of imetelstat in patients with relapsed/refractory MF, which would have a material adverse effect on our business, business prospects and the future of imetelstat.
- Our clinical trials of imetelstat could be interrupted, delayed, terminated or abandoned for a variety of reasons which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.
- We rely on third parties to conduct our current and potential future clinical trials of imetelstat. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to continue the development of, obtain regulatory approval for, or commercialize imetelstat.

Risks Related to Regulatory Approval and Commercialization of Imetelstat

- If we are unable to obtain regulatory approval for and successfully commercialize imetelstat, including obtaining and maintaining licenses where required for us to sell imetelstat, or experience significant delays in doing so, our business will be materially harmed.
- If imetelstat is approved for marketing and commercialization and we are unable to establish and maintain effective sales, marketing and distribution capabilities, or obtain coverage and adequate third-party payor reimbursement, we will be unable to successfully commercialize imetelstat.
- Any regulatory approval that we may potentially receive for imetelstat could be subject to restrictions, and we may be subject to penalties or product withdrawal if we fail to comply with regulatory requirements or if we experience unanticipated problems with imetelstat.

Risk Related to Compliance with Healthcare Laws

- If we fail to comply with federal, state and international healthcare laws, including fraud and abuse, transparency, and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Risks Related to Manufacturing Imetelstat

- We rely on third parties to manufacture and supply imetelstat, and we may be unable to ensure that we have adequate quantities of imetelstat that meet specifications that may be approved or required by regulatory authorities, and timelines necessary for current and potential future clinical trials and potential commercial uses, due to regulatory inspections of those third parties or otherwise.

Risks Related to Our Financial Position and Need for Additional Financing

- Our failure to obtain additional capital would force us to further delay, reduce or eliminate development and potential future commercialization of imetelstat, any of which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.
- We currently have no source of product revenue and may never become profitable.

Risks Related to Our Indebtedness

- Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

Risks Related to Protecting Our Intellectual Property

- If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat, our competitors could develop and commercialize products similar or identical to imetelstat, and our ability to successfully commercialize imetelstat may be adversely affected.

Risks Related to Competitive Factors

- If our competitors develop products, product candidates or technologies that are superior to or more cost-effective than imetelstat, this would significantly impact the development and commercial viability of imetelstat, which would severely and adversely affect our financial results, business and business prospects and the future of imetelstat, and might cause us to cease operations.

Risks Related to Information Technology Systems, Data Security and Data Privacy

- We are subject to legal and contractual obligations related to privacy, data protection and information security. Our actual or perceived failure, or that of third parties upon which we rely, to comply with such obligations or changes in such obligations may adversely affect our business, operations and financial performance.
- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences.

Risks Related to Our Common Stock and Financial Reporting

- Historically, our stock price has been extremely volatile, and your investment may suffer a decline in value.

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 and directors. In the case of 5% or greater stockholders, we have not deemed any such stockholders to be affiliates given the lack of facts and circumstances that would indicate that any such stockholders exercise, or have the ability to exercise, any control over Geron. These assumptions should not be deemed to constitute an admission that all executive officers and directors are, in fact, affiliates of Geron, or that there are no other persons who may be deemed to be affiliates of Geron. 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 late-stage biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our investigational first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize winning science in a treatment that may alter the underlying course of these diseases.

Our lead indication for imetelstat is in lower-risk MDS. In August 2023, our NDA for the treatment of transfusion-dependent anemia in adult patients with low-to-intermediate-1 risk MDS who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents, or ESAs, was accepted by the United States, or U.S., FDA, for review and assigned a Prescription Drug User Fee Act, or PDUFA, action date of June 16, 2024. In addition, the FDA has scheduled an advisory committee meeting as part of the NDA review on March 14, 2024. If imetelstat is approved for commercialization by the FDA, we anticipate commercial launch of imetelstat in lower-risk MDS in the U.S. could occur at the time of approval. In September 2023, we submitted an MAA in Europe that was validated for review by the EMA for imetelstat for the same proposed indication as in the U.S. We expect a review of the MAA could be completed in early 2025, and subject to approval by the European Commission, we believe EU commercial launch of imetelstat would occur in 2025.

Our NDA and EMA submissions are based on positive data from the IMerge Phase 3 clinical trial. The trial met its primary endpoint of ≥ 8-week transfusion independence rate and a key secondary endpoint of 24-week transfusion independence rate, demonstrating highly statistically significant (i.e., $p<0.001$ for both) and clinically meaningful benefits with imetelstat treatment versus placebo. Furthermore, statistically significant and clinically meaningful efficacy results were observed in the trial across key subtypes, including patients who were ringed sideroblast positive, or RS positive, and ringed sideroblast negative, or RS negative; patients with high and very high baseline transfusion burden; and patients classified as Low or Intermediate-1 risk according to the International Prognostic Scoring System, or IPSS. Consistent with prior imetelstat clinical experience, the most common serious adverse events were primarily short-lived, manageable thrombocytopenia and neutropenia.

In addition to lower-risk MDS, we are developing imetelstat for the treatment of several myeloid hematologic malignancies, including a Phase 3 clinical trial, named IMpactMF, in patients with Intermediate-2 or High-Risk myelofibrosis who have relapsed after or are refractory to treatment with a janus associate kinase inhibitor, or JAK inhibitor, or relapsed/refractory MF, with overall survival, or OS, as the primary endpoint, that currently is enrolling patients. In November 2023, the trial reached 50% enrollment. Based on our current planning assumptions for enrollment and event (death) rates in the trial, we expect the interim analysis for OS in IMpactMF may occur in the first half of 2025, and the final analysis may occur in the first half of 2026.

We are also conducting a Phase 1 combination therapy clinical trial, named IMproveMF, in first-line Intermediate-1, Intermediate-2 or High-Risk myelofibrosis, or frontline MF, that currently is enrolling patients and imetelstat is being studied in an investigator-led Phase 2 clinical trial, named IMpress, in Intermediate-2 or High-Risk myelodysplastic syndromes, or higher risk MDS, and acute myeloid leukemia, or AML, in which the first patient was dosed in June 2023.

We believe that the positive data from IMerge Phase 3 and IMerge Phase 2, as well as our prior Phase 2 clinical trial of imetelstat in patients with relapsed/refractory MF, provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells enabling recovery of bone marrow and normal blood cell production, which suggest potential disease-modifying activity. We believe this potential for disease modification could differentiate imetelstat from currently approved treatments in myeloid hematologic malignancies.

Commercial Plans for Imetelstat

If imetelstat is approved in lower-risk MDS for marketing by regulatory authorities, we plan to commercialize imetelstat ourselves in the U.S. Our U.S. launch strategy is designed to prepare imetelstat, the market and the company to ensure broad reimbursement and deliver a seamless customer experience to all stakeholders at launch. Several long-lead time activities have already been completed, such as securing a global trademark for the imetelstat brand name; finalizing third party logistics, our distribution network, and our patient support providers; and onboarding highly experienced commercial and medical affairs leadership teams. We continue to conduct pre-commercial preparations for the U.S., such as enhancing and/or establishing company processes and systems to support a potential commercial launch, refining our market research in lower-risk MDS, engaging in marketing and

commercial access/reimbursement preparatory efforts, and hiring our sales force, which we expect to occur in the first and second quarters of 2024. We continue to evaluate our strategy for the potential launch and commercialization of imetelstat in Europe. Based on our internal estimates of pricing and addressable patient populations in 2031 and if regulatory authorities approve imetelstat for marketing in lower-risk MDS and relapsed/refractory MF, we believe the potential combined total addressable market opportunity in the U.S. and Europe for imetelstat is approximately $7.0 billion, of which lower-risk MDS represents approximately $3.5 billion and relapsed/refractory MF represents approximately $3.5 billion.

Background of Telomerase Inhibition in Hematologic Malignancies and Imetelstat

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, 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, which binds to the telomere, and a catalytic subunit with reverse transcriptase activity, which adds a specific DNA sequence to the chromosome ends. The 2009 Nobel Prize for Physiology or Medicine was awarded to Drs. Elizabeth H. Blackburn, Carol W. Greider and Jack Szostak, former Geron collaborators, for the discovery of how chromosomes are protected by both telomeres and telomerase.

Telomerase is upregulated in many tumor cells and malignant stem and progenitor cells, enabling the continued and uncontrolled proliferation of the malignant cells that drive tumor growth and progression. We believe that inhibiting telomerase may be an attractive approach to treating cancer because it may limit the proliferative capacity of malignant stem and progenitor cells, which are believed to be important drivers of tumor growth and progression. We and others have observed in various in vitro, ex vivo and rodent tumor models that inhibiting telomerase: (a) results in telomere shortening and (b) arrests uncontrolled malignant cell proliferation and tumor growth.

Hematologic malignancies, or blood cancers, are classified according to the precursor cell type. A myeloid hematologic malignancy is a cancer that occurs in the myeloid hematopoietic progenitor cells, such as the precursor cells of red blood cells, platelets and certain myeloid white blood cells, such as granulocytes. Myeloid neoplasms include myeloproliferative neoplasms, MDS and AML. Examples of myeloproliferative neoplasms include chronic myeloid leukemia, essential thrombocythemia, or ET, polycythemia vera and MF. These myeloid neoplasms are different from lymphocytic malignancies which typically occur in the lymphoid cell progenitor lineage, such as precursor cells of T lymphocytes and B lymphocytes. Examples of lymphoid malignancies include acute lymphoblastic leukemia, chronic lymphocytic leukemia, lymphomas and multiple myeloma.

Many myeloid hematologic malignancies, such as ET, MF and MDS, have been shown to arise from malignant stem and progenitor cells that express higher telomerase activity and have shorter telomeres when compared to normal healthy cells. In vitro studies have suggested that tumor cells with short telomeres may be especially sensitive to the anti-proliferative effects of inhibiting telomerase.

Imetelstat: The First Telomerase Inhibitor to Advance to Clinical Development

Imetelstat, our proprietary telomerase inhibitor which was discovered and developed at Geron, was designed to inhibit telomerase in malignant cells with continuously upregulated telomerase.

Imetelstat is a lipid conjugated 13-mer oligonucleotide that we designed to be complementary to and bind with high affinity to the RNA template of telomerase, thereby directly inhibiting telomerase activity. Imetelstat does not act as an antisense inhibitor of protein translation. 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 penetrate cellular membranes, we conjugated the oligonucleotide to a lipid group. Imetelstat's IC50, or half maximal inhibitory concentration, is 3 – 9 nM in cell free assays. Single-dose pharmacokinetics in patients has shown dose-dependent increases in exposure to imetelstat, with a plasma half-life, which is the time it takes for the concentration or amount of imetelstat to be reduced by half, ranging from 4 – 5 hours. Data from animal studies and clinical trials have suggested that the residence time of imetelstat in bone marrow is long, with 0.19 – 0.51 μM

observed at 41 – 45 hours after a 7.5 mg/kg dose in patients. Imetelstat also has been shown in non-clinical studies to exhibit relatively preferential inhibition of the clonal proliferation of malignant progenitor cells compared to normal progenitor cells. For these reasons, imetelstat has been studied as a potential treatment for malignant diseases.

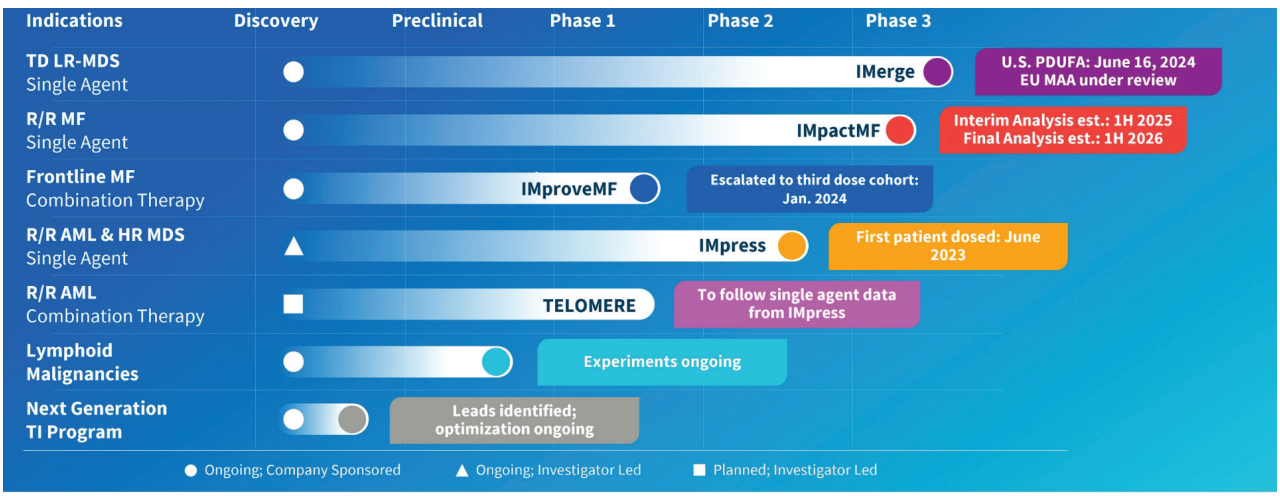
We believe imetelstat is the first telomerase inhibitor to advance to clinical development. The Phase 1 trials that we completed evaluated the safety, tolerability, pharmacokinetics and pharmacodynamic effects of imetelstat. We established doses and dosing schedules that were tolerable and achieved target exposures in patients that were consistent with those required for efficacy in animal models. 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. Dose-limiting toxicities included thrombocytopenia, or reduced platelet count, and neutropenia, or reduced neutrophil count.

Imetelstat's Potential Disease-Modifying Activity

We believe that imetelstat may have the potential to suppress the proliferation of malignant stem and progenitor cells while transiently affecting normal cells. Early clinical data from a Phase 2 trial of imetelstat in patients with ET, or the ET Trial, and a pilot study of imetelstat in patients with MF conducted at Mayo Clinic, or the Pilot Study, suggested that imetelstat inhibits the progenitor cells of the malignant clones believed to be responsible for the underlying diseases in a relatively select manner, indicating potential disease-modifying activity. These data were published in two separate articles in a September 2015 issue of *The New England Journal of Medicine*.

Clinical Development

Pipeline Chart



TD LR-MDS: transfusion-dependent lower-risk myelodysplastic syndromes; R/R MF: relapsed/refractory myelofibrosis; MF: myelofibrosis; R/R AML: relapsed/refractory acute myeloid leukemia; HR MDS: higher risk myelodysplastic syndromes; TI: telomerase inhibitor; PDUFA: Prescription Drug User Fee Act; MAA: marketing authorization application

Lower-Risk Myelodysplastic Syndromes (MDS)

MDS is a group of blood disorders in which the proliferation of malignant progenitor cells produces multiple malignant cell clones in the bone marrow resulting in disordered and ineffective production of the myeloid lineage, which includes red blood cells, white blood cells and platelets. In MDS, bone marrow and peripheral blood cells may have abnormal, or dysplastic, cell morphology. MDS is frequently characterized clinically by severe anemia, or low red blood cell counts, and low hemoglobin. In addition, other peripheral cytopenias, or low numbers of white blood cells and platelets, may cause life-threatening infections and bleeding. Transformation to AML occurs in up to 30% of MDS cases and results in poorer overall survival.

MDS is the most common of the myeloid malignancies. There are approximately 60,000 people in the U.S. living with the disease and approximately 16,000 reported new cases of MDS in the U.S. every year, according to

Decision Resources Group, MDS Syndicated Report 2020, 2021, 2022. MDS is primarily a disease of the elderly, with median age at diagnosis around 70 years. The majority of patients, approximately 70%, fall into what are considered to be the lower-risk groups at diagnosis, according to the International Prognostic Scoring System that assigns relative risk of progression to AML and overall survival by taking into account the presence of a number of disease factors, such as cytopenias and cytogenetics.

Chronic anemia is the predominant clinical problem in patients who have lower-risk MDS. Typically, these patients are treated with ESAs, such as erythropoietin, or EPO. Although ESAs provide an improvement in anemia in approximately 50% of patients, the effect is transient with a median duration of response of approximately two years. Once ESAs fail for patients, HMAs and lenalidomide have been used to improve anemia, but with limited success, such as reported ≥ 8-week red blood cell transfusion independence, or RBC-TI, rates of 17% for azacitidine, an HMA, and 27% for lenalidomide in non-del5q lower-risk MDS patients. In August 2023, Reblozyl, or luspatercept, was approved for the treatment of anemia in adult patients with very low-to-intermediate-risk MDS without previous erythropoiesis stimulating agent use, or ESA-naive, who may require regular RBC transfusions. In April 2020, luspatercept was approved for use in a subgroup of ESA-failed lower-risk MDS patients – those with ringed sideroblasts. Such patients comprise approximately 15% to 30% of all lower-risk MDS patients. The majority of patients who do not have ringed sideroblasts or who no longer respond to ESAs or other available drug therapies become dependent on red blood cell transfusions due to low hemoglobin. Serial red blood cell transfusions can lead to elevated levels of iron in the blood and other tissues, which the body has no normal way to eliminate. Iron overload is a potentially dangerous condition. Published studies in patients with MDS have shown that iron overload resulting from regular red blood cell transfusions is associated with a poorer overall survival and a higher risk of developing AML.

Phase 3 IMerge Trial in Lower-Risk MDS

IMerge is a two-part Phase 2/3 clinical trial evaluating imetelstat (7.5 mg/kg dose administered as a two-hour intravenous infusion every four weeks) in transfusion dependent lower-risk MDS patients who are relapsed after, refractory to, or ineligible for prior treatment with an ESA. To be eligible for IMerge, patients were required to be transfusion dependent, defined as requiring at least four units of packed red blood cells, or RBCs, over an eight-week period during the 16 weeks prior to entry into the trial.

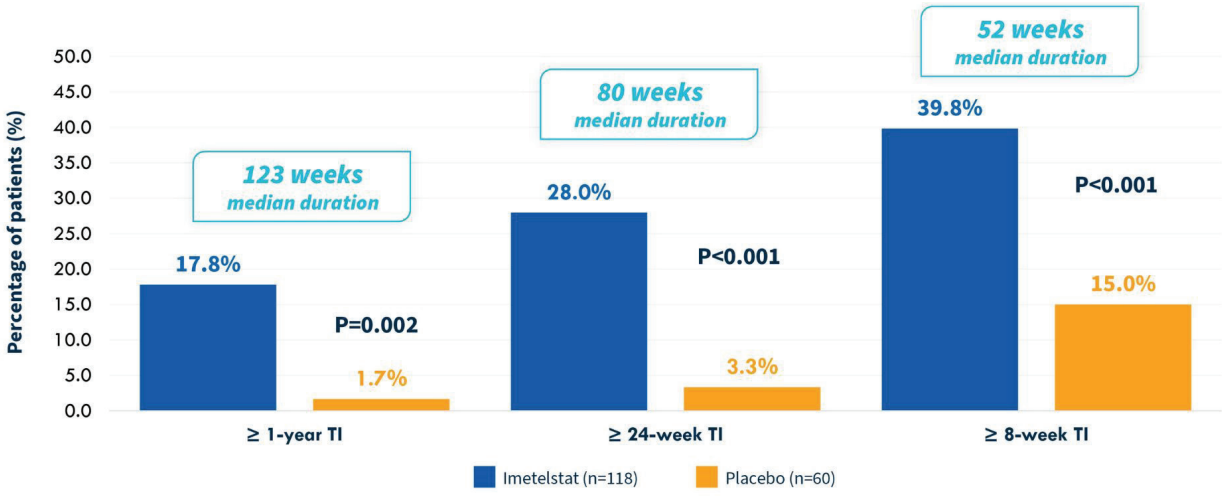
IMerge Phase 3 is a double-blind, 2:1 randomized, placebo-controlled clinical trial that, based on discussions with U.S. and European regulatory authorities, was designed to support, if successful, the registration of imetelstat in transfusion dependent lower-risk MDS. The trial enrolled patients with transfusion dependent lower-risk MDS who were relapsed, or refractory to, or ineligible for ESA, had not received prior treatment with either a hypomethylating agent, or HMA, or lenalidomide and were non-del(5q). IMerge Phase 3 was conducted at 118 medical centers globally in 17 countries in North America, Europe, Middle East and Asia.

The primary efficacy endpoint of IMerge Phase 3 was the rate of red blood cell transfusion independence, or RBC-TI, lasting at least eight weeks, defined as the proportion of patients without any RBC transfusions during any consecutive eight weeks since entry to the trial, or ≥ 8-week TI. Key secondary endpoints for IMerge Phase 3 included the rate of RBC-TI lasting at least 24 weeks, or 24-week TI, and the rate of hematologic improvement erythroid, or HI-E, which is a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. Other secondary endpoints included the time to and duration of RBC-TI; the proportion of patients achieving Complete Response, or CR, or Partial Response, or PR, according to the 2006 International Working Group, or IWG, criteria for MDS; the proportion of patients requiring RBC transfusions and the transfusion burden; the proportion of patients requiring the use of myeloid growth factors and the dose; assessments of the change in the patients' quality of life using several validated instruments; as well as an assessment of OS, and time to progression to AML.

In January 2023, we reported positive top-line results from IMerge Phase 3. Additional data were subsequently published at the European Hematology Association Annual Meeting in June 2023, the American Society of Hematology Annual Meeting in December 2023, and in *The Lancet* in December 2023, as summarized below.

A total of 178 patients were enrolled in IMerge Phase 3, with patients randomized on a 2:1 basis to imetelstat (n=118) or placebo (n=60), including patients with a broad range of lower-risk MDS subtypes and with high disease burden. The trial met its primary endpoint of ≥ 8-week TI rate and key secondary endpoint of 24-week TI rate, among others, demonstrating statistically significant and clinically meaningful results with imetelstat versus placebo with no new safety signals and safety results consistent with prior imetelstat clinical trials.

Durability of TI and response rates were significantly higher with imetelstat versus placebo, as summarized below:



8, 16, 24-week data cut off was October 2022; 1-year represents 3 additional months of data (cut off January 2023)
P-value is based on Cochran Mantel Haenszel test stratified for prior RBC transfusion burden (≤6 units or >6 units of RBCs/8 weeks) and baseline IPSS risk score (Low or Intermediate-1)
8-week TI = proportion of patients without any RBC transfusion for at least eight consecutive weeks since entry to the trial; 16-week TI = proportion of patients without any RBC transfusion for at least 16 consecutive weeks since entry to the trial; 24-week TI = proportion of patients without any RBC transfusion for at least 24 consecutive weeks since entry to the trial; 1-year TI = proportion of patients without any RBC transfusion for at least 52 consecutive weeks since entry to the trial

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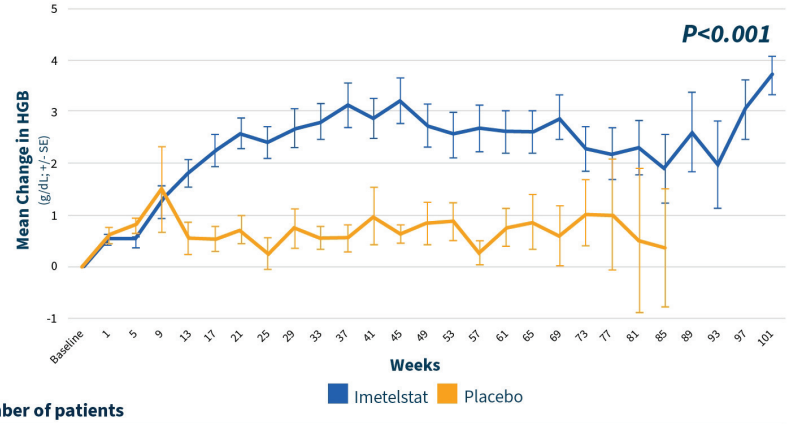
In addition, highly statistically significant (p<0.001) increase in hemoglobin levels over time were observed for imetelstat patients as shown in the graph below. For patients achieving ≥ 8-week TI, median increases in hemoglobin were 3.6 g/dL for imetelstat and 0.8 g/dL for placebo.



Number of patients

Imetelstat	118	59	53	54	47	42	48	48	43	43	31	37	31	35	32	25	26	24	23	21	19	18	11	11	9	9	5
Placebo	60	37	29	17	16	18	15	8	10	10	11	7	3	9	8	9	7	7	5	5	4	2	4				

The mean changes from the minimum Hgb of the values that were after 14 days of transfusions in the eight weeks prior to the first. Data points that have fewer than four patients are not shown.
P-value is based on a mixed model for repeated measures with Hgb change as the dependent variable, week, stratification factors, dose date, and treatment arm as the independent variables with autoregressive moving average (ARMA(1,1) covariance structure.

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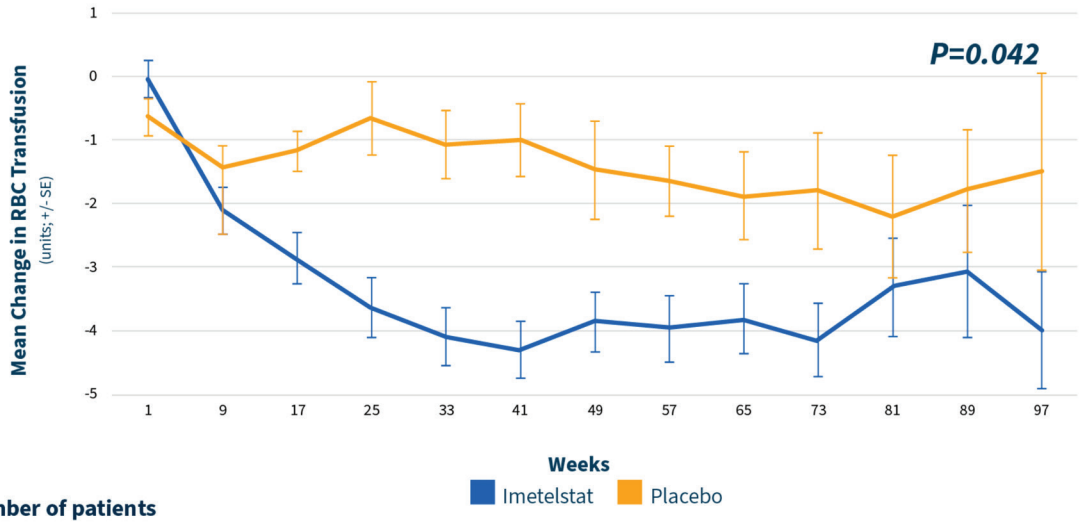
A statistically significant decrease in the number of RBC units transfused was achieved for imetelstat treated patients versus placebo, as shown in the graph below.



Number of patients

Imetelstat	115	104	95	76	60	55	45	43	33	26	22	14	10
Placebo	58	53	48	32	27	22	15	14	8	5	5	5	4

P-value is based on a mixed model for repeated measures with change in RBC transfusion as the dependent variable, week, stratification factors, prior transfusion burden, and treatment arm as the independent variables with autoregressive moving average (ARMA(1,1) covariance structure.

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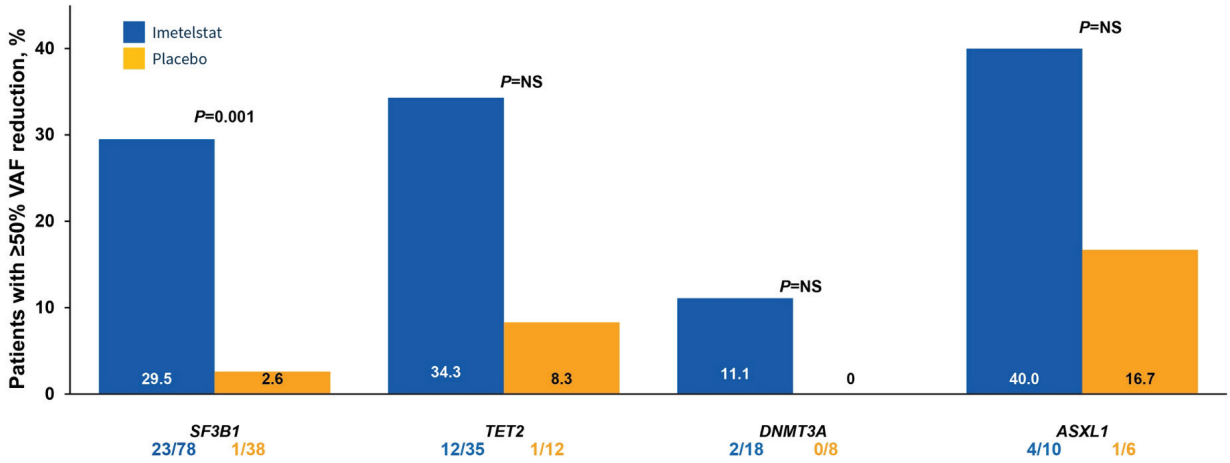
Furthermore, as shown in the table below, statistically significant ≥ 8-week RBC-TI rates were observed with imetelstat versus placebo across lower-risk MDS subtypes ($p<0.05$) and similar ≥ 8-week RBC-TI rates were observed for imetelstat within each subtype category in comparison to the overall population.

	Imetelstat, n (%)	**Placebo, n (%)**	**Difference (95% CI)**	**P-value***
Overall	47/118 (39.8)	9/60 (15.0)	24.8 (9.9, 36.9)	<0.001
WHO category				
RS+	33/73 (45.2)	7/37 (18.9)	26.3 (5.9, 42.2)	0.016
RS-	14/44 (31.8)	2/23 (8.7)	23.1 (-1.3, 40.6)	0.038
Transfusion burden				
4-6 units	28/62 (45.2)	7/33 (21.2)	23.9 (1.9, 41.4)	0.027
>6 units	19/56 (33.9)	2/27 (7.4)	26.5 (4.7, 41.8)	0.023
IPSS risk category				
Low	32/80 (40.0)	8/39 (20.5)	19.5 (-0.1, 35.2)	0.034
Intermediate-1	15/38 (39.5)	1/21 (4.8)	34.7 (8.8, 52.4)	0.004

* Cochran Mantel Haenszel test stratified for prior RBC transfusion burden (≤6 units or >6 units of RBCs/8 weeks) and baseline IPSS risk score (Low or Intermediate-1)

Clinical and molecular evidence supporting the potential for disease modification with imetelstat includes a one-year median TI duration for imetelstat ≥ 8-week TI responders, a median rise of 3.6 g/dL in hemoglobin levels in those same patients and ≥50% variant allele frequency decreases in SF3B1, TET2, DNMT3A and ASXL1 mutations, as shown in the graph below.



Presented at EHA 2023. Data cutoff: October 13, 2022.
Note: Analyses included patients in the intent-to-treat population with a detectable mutant allele for the indicated gene (≥5%) prior to treatment and ≥1 postbaseline mutation assessment. Ratios underneath the bars represent the number of patients with ≥50% VAF reduction as numerator and the total number of patients with detectable assessment (≥5% VAF) in specified mutation at baseline and any postbaseline mutation assessment as denominator. P value based on Cochran-Mantel-Haenszel test stratified for prior RBC transfusion burden (≤6 units or >6 units of RBC/8 weeks) and baseline IPSS risk score (low or intermediate-1).
ASXL1: additional sex combs like-1; DNMT3A: DNA (cytosine-5)-methyltransferase 3A; IPSS: International Prognostic Scoring System; NS: not significant; RBC: red blood cell; SF3B1: splicing factor 3b subunit 1; TET2: Tet methylcytosine dioxygenase 2; VAF: variant allele frequency.

The safety results in IMerge Phase 3 were consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. The most frequent non-hematologic toxicities occurring in ≥10% of patients on either imetelstat or placebo arms are listed in the table below. Grade 3 elevations in liver function tests, or LFTs, on imetelstat were short in duration (median < 2 weeks) and more than 80% resolved to Grade 2 or lower within 4 weeks, with no cases of liver test elevations consistent with Hy's Law or Drug Induced Liver Injury.

AE, n (%)	Imetelstat (n=118)		Placebo (n=59)	
	All Grades	Grade 3/4	All Grades	Grade 3/4
Asthenia	22 (18.6)	0	8 (13.6)	0
COVID-19*	21 (17.8)	2 (1.7)	9 (15.2)	3 (5.1)
Peripheral edema	13 (11.0)	0	8 (13.6)	0
Headache	15 (12.7)	1 (0.8)	3 (5.1)	0
Diarrhea	14 (11.9)	1 (0.8)	7 (11.9)	1 (1.7)
Alanine aminotransferase increased	14 (11.9)	3 (2.5)	4 (6.8)	2 (3.4)
Hyperbilirubinemia	11 (9.3)	1 (0.8)	6 (10.2)	1 (1.7)
Constipation	9 (7.6)	0	7 (11.9)	0
Pyrexia	9 (7.6)	2 (1.7)	7 (11.9)	0

* Includes COVID-19, asymptomatic COVID-19, COVID-19 pneumonia

The most frequent hematologic toxicities are listed in the table below.

AE, n (%)	Imetelstat (n=118)		Placebo (n=59)	
	All Grades	Grade 3/4	All Grades	Grade 3/4
Thrombocytopenia	89 (75.4)	73 (61.9)	6 (10.2)	5 (8.5)
Neutropenia	87 (73.7)	80 (67.8)	4 (6.8)	2 (3.4)
Anemia	24 (20.3)	23 (19.5)	6 (10.2)	4 (6.8)
Leukopenia	12 (10.2)	9 (7.6)	1 (1.7)	0

Clinical consequences from cytopenias were low and similar between imetelstat and placebo groups as shown in the table below.

Event, n (%)	Imetelstat (n=118)	Placebo (n=59)
Grade ≥3 bleeding events*	3 (2.5)	1 (1.7)
Grade ≥3 infections+	13 (11.0)	8 (13.6)
Grade febrile neutropenia**	1 (0.8)	0

* No ≥Grade 3 bleeding events in the setting of Grade 3/4 thrombocytopenia; on imetelstat: two patients with Grade 4 gastrointestinal bleeding, unrelated and resolved and one Grade 3 hematuria, unrelated and resolved

\+ On imetelstat: three patients with Grade 3/4 infections in setting of Grade 3/4 neutropenia; all three were sepsis and resolved with only one considered related

** Occurred at day 33, lasted 8 days; assessed by investigator as possibly related to imetelstat; patient subsequently achieved TI >40 weeks and remains on treatment at data cut-off

Furthermore, as shown in the table below, the median duration of cytopenias was shorter for imetelstat versus placebo and the percentage that resolved to ≤ Grade 2 within 4 weeks was higher for imetelstat versus placebo.

	Imetelstat+	Placebo
Thrombocytopenia events*		
Median duration, weeks, (range)	1.4 (0.1-12.6)	2.0 (0.3-11.6)
Resolved within <4 weeks, %	86.3	44.4
Neutropenia events*		
Median duration, weeks, (range)	1.9 (0-15.9)	2.2 (1.0-4.6)
Resolved within <4 weeks, %	81.0	50.0

\+ 18% of imetelstat treated patients received a median of 1 platelet transfusions; 35% of imetelstat treated patients received growth factor support

* Analysis performed for patients who experienced Grade 3/4 cytopenias. Resolution determined by return to Grade 2 or lower

Imetelstat AEs were manageable with dose modifications. Most AEs leading to dose modifications were grade 3–4 neutropenia or thrombocytopenia, and 74% of patients treated with imetelstat had dose modifications due to AEs. Only less than 15% of patients discontinued treatment due to treatment emergent AEs, or TEAEs. Imetelstat discontinuation due to TEAE generally occurred late in treatment (21.1 weeks median time to treatment discontinuation; range, 2.3 to 44.0 weeks).

Myelofibrosis (MF)

MF, a type of myeloproliferative neoplasm, is a chronic blood cancer in which abnormal or malignant precursor cells in the bone marrow proliferate rapidly, causing scar tissue, or fibrosis, to form. As a result, normal blood production in the bone marrow is impaired and may shift to other organs, such as the spleen and liver, which can cause them to enlarge substantially. People with MF may have abnormally low or high numbers of circulating RBCs, white blood cells or platelets, and abnormally high numbers of immature cells in the blood or bone marrow. MF patients can also suffer from debilitating constitutional symptoms, such as drenching night sweats, fatigue, severe itching, or pruritus, abdominal pain, fever and bone pain. There are approximately 13,000 patients living with MF in the U.S. and approximately 3,000 reported new cases each year, according to Decision Resources Group, Niche and Rare Disease Landscape & Forecast 2020.

Approximately 70% of MF patients are classified as having Intermediate-2 or High-risk disease, as defined by the Dynamic International Prognostic Scoring System Plus described in a 2011 *Journal of Clinical Oncology* article. Drug therapies currently approved by the FDA and other regulatory authorities for treating these MF patients include JAK inhibitors, ruxolitinib and fedratinib, as well as pacritinib, a kinase inhibitor. Currently, no drug therapy is approved for those patients who fail or no longer respond to JAK inhibitor treatment, and median survival for MF patients after discontinuation from ruxolitinib is only approximately 14–16 months, representing a significant unmet medical need.

IMpactMF: Ongoing Phase 3 Clinical Trial in Relapsed/Refractory MF

Trial Design

IMpactMF, our Phase 3 clinical trial in relapsed/refractory MF, is an open label, 2:1 randomized, controlled clinical trial designed to evaluate imetelstat (9.4 mg/kg administered by intravenous infusion over two hours every three weeks) in approximately 320 patients. Patients relapsed after or refractory to a JAK inhibitor are defined as having an inadequate spleen response or symptom response after treatment with a JAK inhibitor for at least six months, including an optimal dose of a JAK inhibitor for at least two months. The best available therapy, or BAT, control arm of IMpactMF excludes the use of JAK inhibitors. With respect to the trial design for IMpactMF, the FDA urged us to consider adding a third dosing arm to assess a lower dose and/or a more frequent dosing schedule that might improve the planned trial's chance of success by identifying a less toxic regimen and/or more effective spleen response, one of the trial's secondary endpoints. Based on data from IMbark, we believe that testing a lower dose regimen would likely result in a lower median OS, which is the trial's primary endpoint, in the imetelstat treatment arm. We believe existing data also suggest that lowering the dose would not result in a clinically meaningful reduction in toxicity. For these reasons, we therefore determined not to add a third dosing arm to the trial design, and the FDA did not object to our proposed imetelstat dose and schedule of 9.4 mg/kg every three weeks. Our belief may ultimately be incorrect. Therefore, our failure to add a third dosing arm could result in a failure to maintain regulatory clearance from the FDA and similar international regulatory authorities, could result in the trial's failure, or could otherwise delay, limit or prevent marketing approval of imetelstat for relapsed/refractory MF by the FDA or similar international regulatory authorities.

The primary efficacy endpoint for IMpactMF is OS. Key secondary endpoints include symptom response; spleen response; progression free survival; complete remission, partial remission or clinical improvement, as defined by the International Working Group for Myeloproliferative Neoplasms Research and Treatment criteria; duration of response; safety; pharmacokinetics; and patient reported outcomes. There are IMpactMF sites across North America, South America, Europe, Australia and Asia.

IMpactMF is designed with >85% power to detect a 40% reduction in the risk of death (hazard ratio=0.60; one-sided alpha=0.025). The final analysis for OS is planned to be conducted after more than 50% of the patients planned to be enrolled in the trial have died (referred to as an event). An interim analysis of OS, in which the alpha spend is expected to be approximately 0.01, is planned to be conducted after approximately 70% of the total projected number of events (deaths) for the final analysis have occurred.

Current Status of IMpactMF

IMpactMF opened for patient screening and enrollment in December 2020. As of December 31, 2023, we had all 180 selected sites open for patient enrollment, and we are continuing to evaluate potential additional sites. In November 2023, the trial reached 50% enrollment. Based on our planning assumptions for enrollment and event (death) rates in the trial, we expect the interim analysis for OS in IMpactMF may occur in the first half of 2025 and the final analysis may occur in the first half of 2026. Because these analyses are event-driven and it is uncertain whether actual rates for enrollment and events will reflect current planning assumptions, the results may be available

at different times than currently expected. At the interim analysis, if the pre-specified statistical OS criterion is met, then we expect such data may potentially support the registration of imetelstat in relapsed/refractory MF. Subject to protocol-specified stopping rules for futility, if the pre-specified OS criterion is not met at the interim analysis, the trial will continue to the final analysis, which is expected to occur approximately one year later.

The timing and achievement of either or both of the planned analyses depend on numerous factors. In addition, our ability to enroll, conduct and complete IMpactMF depends on whether we can obtain and maintain the relevant clearances from regulatory authorities and other institutions to enroll, conduct and complete the trial, and our ability to raise additional capital in order to complete the trial.

Improvement in Overall Survival and Potential Disease-Modifying Activity Observed in IMbark Phase 2

The IMbark Phase 2 clinical trial was designed to evaluate two dosing regimens of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in patients with relapsed/refractory MF. The co-primary efficacy endpoints for IMbark were spleen response rate, defined as the proportion of patients who achieve a reduction of at least 35% in spleen volume as assessed by imaging, and symptom response rate, defined as the proportion of patients who achieve a reduction of at least 50% in Total Symptom Score, at 24 weeks. Key secondary endpoints were OS and safety.

We previously reported efficacy and safety results from the IMbark Phase 2 clinical trial, including median OS of 28.1 months for patients on the high dose arm of the study, which is almost twice the reported median OS of 14–16 months in medical literature. To evaluate this potential benefit, we conducted a post-hoc analysis of OS for patients treated with imetelstat 9.4 mg/kg in IMbark compared to OS calculated from real world data, or RWD, collected at the Moffitt Cancer Center for patients who had discontinued treatment with ruxolitinib, a JAK inhibitor, and who were subsequently treated with BAT. To make a comparison between the IMbark data and RWD, a cohort from the real-world dataset was identified that closely matched the IMbark patients, using guidelines for inclusion and exclusion criteria as defined in the IMbark clinical protocol, such as platelet count and spleen size. Calculations from two propensity score analysis approaches resulted in a median OS of 30.7 months for the imetelstat-treated patients from IMbark, which is more than double the median OS of 12.0 months using RWD for patients treated with BAT. These analyses also showed a 65% – 67% lower risk of death for the imetelstat-treated patients vs. BAT-treated patients. We believe these analyses suggest potentially longer OS for imetelstat-treated relapsed/refractory MF patients in IMbark, compared to BAT in closely-matched patients from RWD. However, comparative analyses between RWD and our clinical trial data have several limitations. For instance, the analyses create a balance between treatment groups with respect to commonly available covariates, but do not take into account the unmeasured and unknown covariates that may affect the outcomes of the analyses. Potential biases are introduced by factors which include, for example, the selection of the patients included in the analyses, misclassification in the matching process, the small sample size, and estimates that may not represent the outcomes for the true treated patient population. For these and other reasons, such comparative analyses and any conclusions from such analyses should be considered carefully and with caution, and should not be relied upon as demonstrative or otherwise predictive or indicative of any current or potential future clinical trial results of imetelstat in relapsed/refractory MF, including IMpactMF.

In IMbark, patients also experienced other positive clinical outcomes, including symptom improvement, spleen reduction and bone marrow fibrosis improvement. In June 2020, we reported correlation analyses from IMbark that showed a trend of longer OS in patients who achieved symptom response, spleen volume reductions and improved bone marrow fibrosis, in a dose-dependent manner. Furthermore, the reductions in the variant allele frequency of key driver mutations in MF and the improvement in bone marrow fibrosis observed in IMbark have also been correlated to the improvement in OS. We believe the improvement in bone marrow fibrosis, potential survival benefit, molecular data and correlations from IMbark provide strong evidence of the potential for disease modification with imetelstat, which we believe differentiates imetelstat from currently approved treatments for MF.

The safety results observed in IMbark were consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. In the 9.4 mg/kg arm, reversible and manageable Grade 3/4 thrombocytopenia and neutropenia were reported in 24/59 patients (41%) and 19/59 patients (32%), respectively, without significant clinical consequences. 1/59 patients (2%) had Grade 3 febrile neutropenia. 3/59 patients (5%) had Grade 3/4 bleeding. 6/59 patients (10%) had Grade 3/4 infections. Furthermore, more than 70% of the observed Grade 3/4 cytopenias resolved to Grade 2 or lower by laboratory assessment within four weeks.

Additional Indications

IMproveMF: Phase 1 Combination Clinical Trial in Frontline Myelofibrosis (Frontline MF)

IMproveMF is a two-part Phase 1 clinical trial evaluating imetelstat in combination with ruxolitinib in patients with frontline MF. The trial is designed to use a Bayesian Optimal Interval design to test various doses of imetelstat in an escalating dose sequence with a defined number of patients per dosing arm. Escalation to the next higher dosing arm will only occur if the prior dose is tolerable to the patients. The primary objective of the first part of IMproveMF is to identify a recommended dosing regimen for further evaluation. Up to 20 patients are expected to be enrolled into the first part of IMproveMF, or IMproveMF Part 1. The first patient was dosed in IMproveMF in August 2022.

Upon identification of a tolerable dosing regimen for the combination treatment of imetelstat and ruxolitinib, the second part of IMproveMF, or IMproveMF Part 2, is planned to evaluate the efficacy and further evaluate the safety of that dosing regimen. Under IMproveMF Part 2, the primary endpoints are safety and symptom response rate, defined as the proportion of patients who achieve a $\geq$50% reduction in Total Symptom Score at 24 weeks. Secondary endpoints include change in fibrosis; spleen response rate, defined as the proportion of patients who achieve a $\geq$35% reduction in spleen volume from baseline as assessed by imaging; and the number of patients achieving complete remission, partial remission or clinical improvement, as defined by the International Working Group for Myeloproliferative Neoplasms Research and Treatment criteria. Up to 20 patients are expected to be enrolled into the IMproveMF Part 2.

In January 2024, the Safety Evaluation Team, or SET, for IMproveMF evaluated patient data from the second cohort of patients enrolled in IMproveMF. No dose-limiting toxicities were identified, and the SET made a decision to escalate to the third dose cohort, effective immediately.

IMpress: Investigator-Led Phase 2 Clinical Trial in Higher Risk Myelodysplastic Syndromes (Higher Risk MDS) and Acute Myeloid Leukemia (AML)

In collaboration with investigators in Germany, France and Australia, we are supporting IMpress, an investigator-led study of imetelstat in patients with higher risk MDS and relapsed/refractory AML, post-treatment with a hypomethylating agent, or HMA. The first patient in the IMpress study was dosed in June 2023.

IMpress is an open-label, single arm, Phase 2 clinical trial being conducted at three clinical sites. The primary endpoint is overall response rate per criteria from the 2018 International Working Group for MDS and the European LeukemiaNet for AML. Secondary endpoints include safety, duration of response, progression-free survival and overall survival. In addition, pending the results of IMpress, we plan to support a Phase 1/2 investigator-led study, called TELOMERE, in relapsed/refractory AML, using a combination approach of imetelstat and venetoclax or azacitidine.

Research Programs

Preclinical Lymphoid Hematologic Malignancies

Academic research data suggests that certain lymphoid hematologic malignancies have higher telomerase activity and shorter telomeres when compared to normal healthy cells. Thus, we believe a telomerase inhibition approach may have utility in this disease setting.

Based on this scientific hypothesis, we initiated a preclinical research project with MD Anderson Cancer Center to determine the potential application of imetelstat in lymphoid hematologic malignancies. Preliminary results from this research were published in *Blood* in November 2022. Based on early results, we plan to collaborate further with MD Anderson Cancer Center to conduct preclinical research to assess the potential therapeutic effect of imetelstat in lymphoid malignancies.

Next Generation Telomerase Inhibitor Discovery

We have initiated a discovery program to identify lead compounds as a potential next generation oral telomerase inhibitor. If the leads we have identified are optimized, we may conduct preclinical experiments that may serve as a basis for potential future clinical testing. Discovery research is an uncertain and unpredictable process. As such, the timing and nature of any results from this discovery effort are difficult to forecast. If we optimize lead compounds from this discovery program, we expect to provide an update on our efforts at that time.

Intellectual Property and Exclusivity

Intellectual property, including patent protection, is very important to our business. We file patent applications in the U.S. 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 the future commercial success of imetelstat, and therefore our future success, will be in part dependent on our intellectual property strategy.

Our intellectual property strategy includes the early development of a technology, such as imetelstat, followed by rounds of increasingly focused innovation around a product opportunity, including identification and definition of a specific product candidate and uses thereof, manufacturing processes, product formulation and methods of treatment and administration. The result of this process is that products in development are often protected by several families of patent filings that are filed at different times during the development process 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 and methods of treatment and administration, 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 an extension of patent coverage for a product in certain countries, which adds further complexity to the determination of patent life.

From time to time, we may 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 against a patent, filing a request for post grant review against a patent or filing a request for the declaration of an interference with a patent application or issued patent.

The information provided in this section should be reviewed in the context of the section entitled “Risks Related to Protecting Our Intellectual Property” described in “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Imetelstat

We have global rights to imetelstat. We own issued patents related to imetelstat in the U.S., Europe and other countries. 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 U.S. It may be possible to obtain patent term extensions of some patents in some countries for claims covering imetelstat, which could further extend the patent term.

We have issued patents in the U.S., Europe and other countries that provide patent coverage into 2033 pertaining to the treatment of MF and MDS with imetelstat. We also hold issued patents in the U.S., Europe and other countries covering imetelstat composition of matter.

In the U.S., our composition of matter patent coverage extends until December 2025, and our method of treatment patent rights for MDS and MF expire in March 2033. Under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (as amended), or the Hatch-Waxman Act, upon receipt of drug product approval, potential patent term extensions, if any, may be available to extend the patent term of either our composition of matter patent or our method of treatment patent for MDS in the U.S.

In Europe and other countries, our composition of matter patent coverage expires in September 2024, and our method of treatment patent rights for MDS and MF expire in November 2033. One of our patents in each member country of the European Patent Convention may be eligible for patent term extension under a Supplementary Protection Certificate, or SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation, upon receipt of drug product approval, such as, for example, our method of treatment patent for MDS. Our patent rights relating to imetelstat also include reagents useful in manufacturing processes for the drug, and method of treatment and kit claims, certain of which are co-owned with other entities.

If regulatory approval of imetelstat occurs after a patent has expired, we may be unable to obtain any patent term extension of that expired patent, and the scope of our patent rights will be limited. In addition, should we seek a patent term extension, we may not be granted any such patent term extension and/or the applicable time period of such patent term extension could be less than five years. Moreover, in some countries, including the U.S., the scope of protection for claims under such patent term extensions, if any, does not extend to the full scope of the claims but

is limited to the product composition as approved. Thus, if we receive drug product approval in the U.S. for imetelstat in lower-risk MDS in the first half of 2024, we may potentially extend the term of our product composition claims in the U.S. for a maximum of five years until December 2030, subject to U.S. Patent and Trademark Office, or USPTO, approval. If we do not receive a patent term extension for our U.S. composition of matter patent for imetelstat, our U.S. composition of matter patent will expire in December 2025.If we receive drug product approval in Europe for imetelstat in lower-risk MDS in the first half of 2025, we may potentially extend the term of our patents in the EEA for the method of treatment of MDS for a maximum of five years, from November 2033 until November 2038, subject to European Patent Office approval. Since we do not expect to receive marketing approval and submit a request for an SPC before September 2024, our European composition of matter patents will expire in countries of the European Economic Area, or EEA, and we must rely on regulatory exclusivity and our method of treatment patents. If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

Upon the effective date of termination of the license and collaboration agreement, or the Prior Collaboration Agreement, with Janssen Biotech, Inc., or Janssen, on September 28, 2018, we regained global rights to imetelstat and are continuing development of imetelstat on our own. In accordance with the termination provisions of the Prior Collaboration Agreement, we have an exclusive worldwide license for intellectual property developed under the Prior Collaboration Agreement for the further development of imetelstat, without any economic obligations to Janssen with respect to such license. Janssen has assigned to us certain intellectual property developed by it under the Prior Collaboration Agreement. We now are responsible for the costs of maintaining, prosecuting and litigating all imetelstat intellectual property that we own.

Market Exclusivity and Orphan Drug Designation

For a drug to qualify for orphan drug designation by the FDA, both the drug and the disease or condition must meet certain criteria specified in the Orphan Drug Act, or ODA, and FDA's implementing regulations. Orphan drug designation is granted by the FDA's Office of Orphan Drug Products in order to support development of medicines for underserved or rare diseases and patient populations that affect fewer than 200,000 people in the U.S. or, if the disease or condition affects more than 200,000 individuals annually in the U.S., if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the U.S. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including, if regulatory approval is received, the potential for seven years of market exclusivity with certain limited exceptions and certain tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication for a disease or condition other than the rare disease or condition for which the drug was granted orphan drug designation. The granting of orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval. The safety and effectiveness of a drug must be established through adequate and well-controlled studies. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

In June 2015 and December 2015, the FDA granted orphan drug designation to imetelstat for the treatment of MF and MDS, respectively.

In the U.S., under the Hatch-Waxman Act, upon drug product approval a new chemical entity is entitled to four years of data exclusivity and one year of market exclusivity, conferring a total of five years exclusivity, or NCE exclusivity, for the first-approved indication. Thus, if we receive drug product approval for imetelstat in lower-risk MDS in the first half of 2024, we expect that we will receive exclusivity in lower-risk MDS under the Hatch-Waxman Act until the first half of 2029. In addition, under the Orphan Drug Act of 1983, orphan drug designation confers market exclusivity in the designated indication for seven years after drug product approval. Thus, if we receive drug product approval for imetelstat in the U.S. for imetelstat in lower-risk MDS in the first half of 2024, we anticipate that we may receive market exclusivity under the Orphan Drug Act of 1982 in the U.S. until the first half of 2031.

In addition, a six-month pediatric extension may be available in the U.S. pursuant to the FDA Safety and Innovation Act of 2012, to the longest extension or exclusivity period available under any of the NCE exclusivity period, the orphan drug exclusivity period and a patent term extension.

In Europe, orphan drug designation by the European Commission provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union, or EU, and where no satisfactory treatment is available. In the EU, orphan drug designation also entitles a party to financial incentives such as reduction of fees or

fee waivers, as well as protocol assistance from the EMA during the product development phase, and direct access to the centralized authorization procedure. In addition, ten years of market exclusivity is granted following drug product approval, meaning that another application for marketing authorization of a later similar medicinal product for the same therapeutic indication will generally not be approved in the EU. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable to not justify maintenance of market exclusivity.

In December 2015 and July 2020, the EMA granted orphan drug designation to imetelstat for the treatment of MF and MDS, respectively.

In Europe, under the European Union Data Exclusivity Directive 2004/27/EC, upon drug product approval a new medicinal product is entitled to eight years of data exclusivity and two years of market exclusivity, conferring a total of ten years of exclusivity for the first-approved indication. Thus, if we receive drug product approval in Europe for imetelstat in lower-risk MDS in the first half of 2025, we anticipate receiving a total of ten years of exclusivity for lower-risk MDS, until the first half of 2035. Separately, orphan drug designation under the European Union Orphan drug regulation (EC) No. 141/2000 confers market exclusivity for ten years following drug product approval for each of the orphan disease indications. Thus, if we receive drug product approval in Europe for imetelstat in lower-risk MDS in the first half of 2025 and we maintain orphan drug designation, we anticipate that we may receive market exclusivity in Europe for imetelstat in lower-risk MDS until the first half of 2035. In addition, if we fulfill the pediatric investigation plan agreed upon with the European Medicines Agency, such market exclusivity may be extended for an additional two years under the European Pediatric Regulation, which may enable us to receive market exclusivity in Europe for imetelstat in lower-risk MDS for an additional two years, until the first half of 2037. Further, if we receive drug product approval in Europe for imetelstat for relapsed/refractory MF, and we maintain orphan drug designation, we anticipate that we may receive ten years exclusivity in Europe for relapsed/refractory MF following drug product approval.

Fast Track Designation

Fast Track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review. Fast Track designation is intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions. However, Fast Track designation does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that imetelstat will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data emerging from the imetelstat clinical development program.

In October 2017, the FDA granted Fast Track designation to imetelstat for the treatment of adult patients with transfusion-dependent anemia due to lower-risk MDS who do not have a deletion 5q chromosomal abnormality, also known as non-del(5q), and who are refractory or resistant to treatment with an erythropoiesis stimulating agent, or ESA (i.e., the treatment population in IMerge Phase 3).

In September 2019, the FDA granted Fast Track designation to imetelstat for the treatment of adult patients with Intermediate-2 or High-Risk MF whose disease has relapsed after or is refractory to JAK inhibitor treatment (i.e., the treatment population in IMpactMF).

Licensing

We have no material license agreements. We have global rights to imetelstat, which was discovered and developed at Geron.

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.

Since September 2018, we have engaged third-party contract manufacturers and have re-established our own manufacturing supply chain to manufacture and supply additional quantities of imetelstat that meet applicable regulatory standards for current and potential future clinical trials and potential commercial uses.

We do not have direct control over third-party personnel or operations. These third-party contract manufacturers, and/or any other third parties that we 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 contract manufacturers, and/or any other third parties that we 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. We are responsible for establishing any long-term commitments or commercial supply agreements with any of the third-party contract manufacturers for imetelstat. The information provided in this section should be reviewed in the context of the section entitled "Risks Related to Manufacturing Imetelstat" under Part I, Item 1A, "Risk Factors" of this annual report on Form 10-K.

Competition

The pharmaceutical and biotechnology industries are characterized by intense and dynamic competition with rapidly advancing technologies and a strong emphasis on proprietary products. While we believe our proprietary oligonucleotide chemistry; experience with the biological mechanisms related to imetelstat, telomeres and telomerase; clinical data to date indicating potential disease-modifying activity with imetelstat treatment; and knowledge and expertise around the development of potential treatments for myeloid hematologic malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Imetelstat will compete, if approved, with other products and therapies that currently exist, are being developed or will in the future be developed, some of which we may not currently be aware of.

Competition in Lower-Risk MDS

The current standard of care for the treatment of lower-risk MDS is the use of ESAs to address the patient's chronic anemia. Once ESAs are no longer effective, serial blood transfusions are often administered that can cause damaging effects to other organs due to iron overload, resulting in shorter survival. In addition, other best available therapies are used without durable effect for the patient.

In lower-risk MDS, positive top-line results from IMerge Phase 3 describe potentially meaningful and durable transfusion independence, activity across MDS patient subtypes, and potential disease-modifying activity achievable with imetelstat treatment. We believe that these key features are differentiators compared to currently approved products as well as investigational drugs currently in clinical development.

If approved for commercial sale for the treatment of lower-risk MDS, imetelstat would compete against a number of currently existing therapies, including ESAs and other hematopoietic growth factors that are indicated for anemia; immunomodulators, such as Revlimid (lenalidomide) by Celgene Corporation, or Celgene, a Bristol Myers Squibb Company, or BMS, company; hypomethylating agents, such as Vidaza (azacitidine) by Celgene and manufacturers of generic azacitidine; Dacogen (decitabine) by Otsuka America Pharmaceutical, Inc. and other manufacturers in the U.S. and Janssen in the EU; Inqovi (oral combination of decitabine and cedazuridine) by Astex Pharmaceuticals, Inc., or Astex; and Reblozyl (luspatercept), a TGF-beta inhibitor, by Acceleron Pharma, Inc., or Acceleron (acquired by Merck & Co., Inc., or Merck, in November 2021), in collaboration with Celgene. In August 2023, BMS announced that luspatercept was also approved for the treatment of anemia in ESA-naive adult patients with very low-to intermediate-risk MDS who may require regular RBC transfusions.

Other therapies currently in Phase 3 development in lower-risk MDS, some of which may obtain regulatory approval earlier than imetelstat include roxadustat, a hypoxia-inducible factor prolyl hydroxylase inhibitor, by FibroGen, Inc; Onureg (oral azacytidine) by BMS; and Hengqu (hetrombopag), an oral nonpeptide thrombopoietin receptor agonist, by Jiangsu Hengrui Pharmaceuticals Co., Ltd.

In addition, there are multiple Phase 1 and Phase 2 clinical trials of other agents being developed for lower-risk MDS, including but not limited to: LB - 100, a PP2A inhibitor, by Lixte Biotechnology Holdings, Inc.; bemcentinib, an AXL inhibitor, by BerGenBio ASA; H3B - 8800, a spliceosome inhibitor, by H3 Biomedicine, Inc.; KER-050, a TGF-beta inhibitor, by Keros Therapeutics, Inc., or Keros Therapeutics; TP-0184, an inhibitor of

ALK2 or ACVR1 kinase, by Sumitomo Dainippon Pharma Oncology, Inc; ilginatinib (NS-018), a JAK2 inhibitor, by NS Pharma, Inc., a U.S. subsidiary of Nippon Shinyaku Co., Ltd., or NS Pharma; a lower dose of ASTX727, an oral formulation of decitabine and cedazuridine, referred to as ASTX727 LD, by Astex; ASTX030, an oral formulation of azacitidine and cedazuridine, by Astex; R289, an oral inhibitor of interleukin receptor-associated kinases 1 and 4, or IRAK1/4, by Rigel Pharmaceuticals, Inc.; a combination treatment regimen of luspatercept and lenalidomide by BMS; roxadustat, a combination treatment of hypoxia-inducible factor prolyl hydroxylase inhibitor, by FibroGen, Inc. with luspatercept by BMS; and HuMax-IL8 (BMS-986253), an anti-IL-8 monoclonal antibody, by BMS and etavopivat, an oral, small molecule activator of erythrocyte pyruvate kinase (PKR) by Forma Therapeutics, Inc., a Novo Nordisk Company; canakinumab, an interleukin antagonist, by Novartis AG; and AG946, a next-generation pyruvate kinase-R (PKR) activator, by Agios Pharmaceuticals, Inc.

Competition in Relapsed/Refractory MF

The current standard of care for the treatment of Intermediate-2 or High-risk MF is the use of JAK inhibitors, to address the patient's symptoms. Once JAK inhibitors fail or are no longer effective, a variety of best available therapies are used since there are no approved treatments for this patient population and median OS is 14 to 16 months after discontinuation from the predominant JAK inhibitor being used today.

In Intermediate-2 or High-risk relapsed/refractory MF, data from IMbark suggest potential disease-modifying activity with imetelstat treatment and a potential meaningful improvement in OS, which is supported in a comparison to real-world data.

If approved for commercial sale for the treatment of MF, imetelstat would compete against currently approved JAK inhibitors: Jakafi (ruxolitinib) by Incyte Corporation, or Incyte, and Inrebic (fedratinib) by Celgene, as well as a kinase inhibitor, Vonjo (pacritinib), by CTI Biopharma Corp., which was approved in February 2022 for the treatment of adults with Intermediate or High-Risk primary or secondary myelofibrosis with a platelet count below 50 × 109/L and OJJAARA, or momelotinib, a kinase inhibitor which was approved in September 2023 for the treatment of intermediate or high-risk MF, including primary MF or secondary MF (postpolycythemia vera and post-essential thrombocytopenia), in adults with anemia, by GlaxoSmithKline plc, or GSK. 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; chemotherapy; and pegylated interferon. Drugs for the treatment of MF-associated anemia include ESAs, androgens, danazol, corticosteroids, thalidomide and lenalidomide.

Other therapies currently in Phase 3 development in MF, some of which may obtain regulatory approval earlier than imetelstat, include momelotinib, a JAK inhibitor, by GSK; or momelotinib plus AZD5153, a BET inhibitor by GSK; pelabresib (CPI-0610), a BET inhibitor, by MorphoSys AG; navitoclax, a BCLXL, BCL-2 and BCLW inhibitor, by AbbVie, Inc.; and parsaclisib, a PI3K delta inhibitor, by Incyte. Other approaches for MF currently under investigation that could compete with imetelstat in the future include luspatercept; zinpentraxin alfa (RG6354, formerly PRM-151), an anti-fibrosis antibody, by F. Hoffmann-La Roche, Ltd.; LCL-161, an inhibitor of apoptosis protein (IAP), by Novartis; KRT-232, an inhibitor of MDM2, by Kartos Therapeutics, Inc.; GB2064, a LOXL2 inhibitor, by Galecto Biotech; elraglusib (9-ING-41), a glycogen synthase kinase-3 beta inhibitor, by Actuate Therapeutics, Inc.; XPOVIO (selinexor), a nuclear export inhibitor, by Karyopharm Therapeutics, Inc.; TL-895, an oral tyrosine kinase inhibitor, by Telios Pharma, Inc.; IMG-7289, a LSD1 inhibitor, by Imago Biosciences, Inc.; APG-1252, a dual BCL-2/BCL-XL inhibitor, by Ascentage Pharma; ilginatinib (NS-018), a JAK2 inhibitor by NS Pharma; DISC-0974, a monoclonal antibody against hemojuvelin (HJV) by DISC Management Inc.; KER-050 in combination with ruxolitinib, by Keros Therapeutics; CK0804, an allogeneic T-regulatory cell agent, by Cellenkos, Inc. in collaboration with Incyte; TP-3654, PIM kinase inhibitor by Sumitomo Pharma Co., Ltd.; and a mutated-CALR vaccine, a peptide-based vaccine, from the Icahn School of Medicine at Mount Sinai.

Many of our competitors, either alone or with their strategic partners, could have substantially greater financial, technical and human resources than we do and significantly greater experience in obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. We believe that the commercial success of imetelstat is subject to a number of factors, including: product efficacy and safety; method of product administration; cost of manufacturing; the timing and scope of regulatory consents; status of coverage and reimbursement; price; the level of generic competition; and our patent position.

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 myeloid hematologic 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 imetelstat. These companies and institutions compete with us in recruiting and retaining qualified development and management personnel as well as in acquiring technologies complementary to the imetelstat program.

As a result of the foregoing, competitors may develop more commercially desirable or affordable products than imetelstat, or achieve earlier patent protection or product commercialization than we may be able to achieve with imetelstat. 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 or superior 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 we 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 us to cease any further development or future commercialization of imetelstat, which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

Government Regulation

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the development, manufacture and potential future marketing of imetelstat. Imetelstat will require regulatory approval by regulatory authorities 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 at both the federal and state level also govern or influence testing, manufacturing, safety, labeling, storage, import, export, distribution, sale and recordkeeping related to such products and their marketing. 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. Moreover, compliance with government regulations governing personal information and information security requires the expenditure of substantial time and financial resources. The information provided in this section should be reviewed in the context of the sections entitled “Risks Related to the Development of Imetelstat” and “Risks Related to Regulatory Approval and Commercialization of Imetelstat” under Part I, Item 1A, “Risk Factors” of this annual report on Form 10-K.

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 Investigational New Drug, or IND, application, which must become effective before clinical testing in humans can begin. The FDA can place an IND on clinical hold at any time, which prevents the conduct of clinical trials under the IND until safety concerns or questions are addressed by the IND sponsor to the FDA’s satisfaction.

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. Human clinical trials must be conducted in compliance with Good Clinical Practice, or GCP, regulations and applicable laws, with the oversight of Institutional Review Boards for the protection of human subjects. The manufacture of drug product candidates is subject to requirements that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices, or cGMP, and applicable laws.

The results of the preclinical and clinical testing of drugs and complete manufacturing information are submitted to the FDA in the form of an NDA for review and approval prior to commencement of commercial sales. Submission of an NDA requires the payment of a substantial user fee to the FDA, which may be waived in certain cases. In responding to an NDA submission, the FDA may approve the drug for commercialization, impose

limitations on its indications for use and labeling, including in the form of Risk Evaluation and Mitigation Strategies or may issue a complete response letter. Even if an NDA is approved, its sponsor is subject to ongoing and pervasive regulatory compliance requirements.

European Union and Other Regulatory Approval Process

Prior to initiating clinical trials in a region outside of the U.S., a clinical trial application must be submitted and reviewed by the appropriate regulatory authority governing clinical trials in 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 the EU and other countries is necessary prior to marketing the product in such countries. The competent regulatory authorities 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 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 for Human Use, or CHMP, 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 a centralized procedure which is mandatory for orphan and oncology products and which grants a single marketing authorization valid in all EU member states.

Fraud and Abuse, and Transparency Laws and Regulations

We may also be subject to additional regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These additional regulations could affect our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors. Such laws include, without limitation, state and federal bribery/anti-kickback, the False Claims Act, privacy and data security laws, and healthcare professionals payment transparency laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare, Medicaid TRICARE, and the Veterans Health Administration. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals, the Anti-Kickback Statute has been violated. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act or ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation.

Federal civil and criminal false claims and false statement laws, including the federal civil False Claims Act and its whistleblower or *qui tam* provisions that permit private individuals to bring an action on behalf of the government to enforce the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, transmission and breach reporting of individually identifiable health information, upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates and their subcontractors that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, and information related to ownership and investment interests held by physicians and their immediate family members.

Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Additionally, we may be subject to state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and certain industry compliance guidance documents. Further, we may be subject to state and foreign laws that require drug manufacturers or other pharmaceutical companies to report information related to payments and other transfers of value to physicians, other healthcare providers and healthcare entities, or marketing expenditures, as well as state, foreign and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that require the reporting of information related to drug pricing; and state, federal and foreign laws governing the privacy and security of personal information (including key-coded data and health information), including the European Union's General Data Protection Regulation, or EU GDPR, many of which differ from each other in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of these or any other healthcare regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Data Privacy and Security

In the ordinary course of our business, we may process personal or sensitive data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy and security. Efforts to ensure that our current and future business arrangements will comply with applicable data privacy and data security laws and regulations will involve substantial costs. For example, foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose strict significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR imposes heightened and codified standards for data subject consent, requiring the implementation and maintenance of technical and organizational safeguards for personal data, mandating data breach notifications to relevant supervisory authority(ies), and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. Foreign privacy laws, such as the EU GDPR, also impose strict rules on the transfer of personal data out of the applicable jurisdiction. Further, the EU GDPR provides for significant penalties (such as restrictions or prohibitions on personal data processing) and large fines for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, we expect that there will continue to be new proposed data privacy and security laws, regulations and industry standards in the U.S. As one example, the California Consumer Privacy Act of 2018, or CCPA, imposes numerous obligations on covered business. Although the CCPA exempts certain data (such as some data processed in the context of clinical trials), the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal data

we maintain about California residents. The CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. Failure, or perceived failure, to comply with all applicable obligations could result in enforcement actions, fines, litigation, and other consequences. See the section titled *"We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration; fines and penalties; disruptions for our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts,"* under "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate that receives regulatory approval. In the U.S. and markets in other countries, sales of imetelstat, if approved for commercial sale, will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for imetelstat.

In the U.S., third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a product is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. A third-party payor could also require that certain lines of therapy be completed or failed prior to reimbursing our therapy. The principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of imetelstat, in addition to the costs required to obtain the FDA approvals. Nonetheless, imetelstat may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product, as there is no uniform coverage and reimbursement policy among third-party payors in the U.S. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in imetelstat. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Coverage policies and third-party payor reimbursement rates may change. Thus, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce demand for the product and also have a material adverse effect on future sales.

Healthcare Reform

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021,

HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by CMS's Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Additionally, at the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing.

The U.S. and some foreign jurisdictions are considering or have enacted legislative and regulatory proposals to contain healthcare costs, as well as to improve quality and expand access. For example, in March 2010, the ACA was signed into law, which included a number of provisions of importance to the biopharmaceutical industry. There have been judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that may be charged for imetelstat. It is unclear how any such healthcare reform measures will impact the pharmaceutical industry.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was enacted, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute will stay in effect through 2032 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. More recently, there has been heightened governmental scrutiny in the U.S. to control the rising cost of healthcare.

Information About Our Executive Officers

The following table sets forth certain information with respect to our executive officers and other members of management as of January 31, 2024:

Name	Age	Position
Executive Officers		
John A. Scarlett, M.D.	72	President, Chief Executive Officer and Chairman of the Board
Michelle Robertson	57	Executive Vice President, Finance, Chief Financial Officer and Treasurer
Faye Feller, M.D.	42	Executive Vice President, Chief Medical Officer
Andrew J. Grethlein, Ph.D.	59	Executive Vice President, Chief Operating Officer
Anil Kapur	54	Executive Vice President, Corporate Strategy and Chief Commercial Officer
Scott A. Samuels, Esq.	53	Executive Vice President, Chief Legal Officer and Corporate Secretary
Other Members of Management		
Melissa A. Kelly Behrs	60	Executive Vice President, Business Operations and Chief Alliance Officer
Edward E. Koval	61	Executive Vice President, Chief Business Officer
Shannon T. Odam	49	Senior Vice President, Chief People Officer

John A. Scarlett, M.D. has served as our Chief Executive Officer and a director since September 2011 and President since January 2012 and was appointed to Chairman of the Board in December 2018. Dr. Scarlett served as a director of CytomX Therapeutics, Inc., a biopharmaceutical company focused on developing antibody therapeutics for the treatment of cancer, from June 2016 to June 2022. He was also a director for Chiasma, Inc., a biopharmaceutical company focused on transforming injectable drugs into oral medications, from February 2015 until its acquisition by Amyrt Pharma plc, a biopharmaceutical company, in August 2021. 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.

Michelle Robertson has served as our Executive Vice President, Chief Financial Officer and Treasurer since September 2023. Prior to joining Geron, she served as the Chief Financial Officer and Treasurer of Editas Medicine, Inc., a CRISPR genome editing company, from January 2020 to May 2023. Before that, she served as Chief Financial Officer of Momenta Pharmaceuticals, Inc. from 2018 until 2020, when Momenta was acquired by Johnson & Johnson. Prior to joining Momenta, Ms. Robertson held multiple commercial finance roles of increasing responsibility, including Vice President, Oncology Finance for Baxalta Incorporated following its spin-off from Baxter International Inc., from 2015 to 2016; Head of Financial Planning and Analysis and Operations Excellence at Ironwood Pharmaceuticals, Inc. from 2012 to 2015; and various finance and commercial operations roles at Genzyme Corporation (acquired by Sanofi). She also currently serves as a member of the board of directors and as the chair of the audit committee for Verastem, Inc., a publicly-traded biopharmaceutical company. Ms. Robertson received her B.S. in Finance and A.S. in Accounting and Management from Bentley University.

Faye Feller, M.D. has served as our Executive Vice President, Chief Medical Officer since July 2022. Previously, she served as our Vice President of Clinical Development since she joined Geron in April 2019. In this role, Dr. Feller played a strategic role in designing and driving execution of Geron's Phase 3 clinical trials, served as the primary medical point of contact between Geron and our clinical investigators and led the preparation of data for assessment by the data monitoring committees. Prior to joining Geron, Dr. Feller was Senior Director at Janssen Research and Development, LLC (Janssen), a global pharmaceutical company, and both a Compound Lead and Study Responsible Physician for multiple clinical trials of early and late-stage development assets at Janssen from February 2015 to March 2019. Prior to Janssen, Dr. Feller was an instructor in the leukemia department of Memorial Sloan Kettering Cancer Center in New York from July 2013 to February 2015. She received a B.A. from New York

University and an M.D. from Mount Sinai School of Medicine. She completed her residency in internal medicine at Mount Sinai Hospital and her fellowship in medical oncology at Memorial Sloan Kettering Cancer Center.

Andrew J. Grethlein, Ph.D. has served as our Executive Vice President, Chief Operating Officer since January 2019. Previously, he served as our Executive Vice President, Development and Technical Operations, from July 2014 to January 2019. He joined Geron in September 2012 as our Executive Vice President, Technical Operations. 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, where 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. 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 non-profit 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.

Anil Kapur has served as our Executive Vice President, Corporate Strategy and Chief Commercial Officer since December 2019. Prior to joining Geron, Mr. Kapur was Chief Commercial Officer at Actinium Pharmaceuticals, Inc., a clinical stage biopharmaceutical company, from February 2018 to November 2019. From October 2016 until February 2018, Mr. Kapur was Vice President, Head of Early Assets, Biomarkers and External Innovation for Worldwide Oncology Commercialization at Bristol Myers Squibb Company, a global biopharmaceutical company. Mr. Kapur served as Vice President, Global Head of Commercial and Portfolio Strategy at Baxalta, Incorporated, a biopharmaceutical company, in a newly created Oncology Division, from November 2015 until after its acquisition by Shire plc in July 2016. Before joining Baxalta, Mr. Kapur held marketing and sales leadership roles of increasing responsibility during his 15-year tenure at the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen). As Vice President, Commercial Leader, Hematology Franchise in Janssen's Global Commercial Strategy Organization, he led the development and execution of commercial strategy and launch plans for in-market development, late development, and early pipeline assets, including imetelstat. Among Mr. Kapur's most recognized achievements while at Janssen were the successful global launches of two transformational blockbuster hematology-oncology drugs, Imbruvica and Darzalex. Mr. Kapur has served as a member of the board of directors of Verastem, Inc., a development-stage biopharmaceutical company, since October 2022. Mr. Kapur holds a Bachelor of Engineering from Birla Institute of Technology in India; an M.S. in Industrial Engineering from Louisiana Tech University; and an M.B.A. from the Fuqua School of Business at Duke University.

Scott A. Samuels, Esq. has served as our Executive Vice President, Chief Legal Officer and Secretary since August 2023. Prior to joining Geron, Mr. Samuels served as Chief Legal Officer and Chief Compliance Officer of Prilenia Therapeutics, Inc., a clinical-stage biotechnology company focused on novel therapeutics to slow the progression of neurodegenerative diseases and neurodevelopmental disorders, from March to May 2023. Before that, he served as the Senior Vice President, General Counsel of BeiGene, Ltd., from May 2017 to July 2022, where he built a large, global legal and compliance team, oversaw launches of three internally developed drug products in the U.S., Europe and China and development of a global healthcare compliance program, and led key strategic transactions with Amgen, Inc., Novartis AG and Celgene (now Bristol Myers Squibb). Prior to BeiGene, Mr. Samuels was assistant general counsel and then acting general counsel at ARIAD Pharmaceuticals, Inc., where he managed the company's legal affairs, including SEC compliance and corporate governance and key licensing and distribution agreements prior to ARIAD's acquisition by Takeda. Mr. Samuels also practiced law for 17 years in the corporate and life sciences practices at Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., a highly regarded national law firm. Mr. Samuels received his B.A. in philosophy from Cornell University and his J.D. from George Mason University School of Law.

Melissa A. Kelly Behrs has served as our Executive Vice President, Business Operations and Chief Alliance Officer since December 2021. Previously, she was our Executive Vice President, Chief Business Officer from January 2019 to December 2021, Executive Vice President, Business Development and Portfolio & Alliance Management, from February 2014 to January 2019, and 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 also served in various managerial positions, including General Manager, R&D Technologies; Vice President, Corporate 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.

Edward E. Koval has served as our Executive Vice President, Chief Business Officer since December 2021. From 2020 to 2021, he was Chief Business Officer at ZebiAI Therapeutics, a company spun out of X-Chem, Inc. in order to discover and develop advanced drug discovery programs based on novel machine learning technologies, until its acquisition by Relay Therapeutics, Inc., a clinical-stage precision medicine company, in April 2021. Prior to the spin-out of ZebiAI, from 2013 to 2020, he was Senior Vice President, Corporate Development, at X-Chem, Inc., a drug discovery company, where he closed multiple transactions with multinational pharmaceutical companies for programs in oncology, hematology/oncology, inflammation, infectious disease and rare diseases. From 2012 to 2015, Mr. Koval served as an independent corporate and business development consultant, advising multiple private and public biotech companies on partnering and fundraising. Mr. Koval's prior pharmaceutical experience from 1992 to 2012 includes serving roles in business and corporate development, strategic planning, alliance management and financial evaluation and analysis at Novartis Pharmaceuticals Corporation, a pharmaceutical company, Merck & Co., Inc., a pharmaceutical company, and Chiron Corporation, a pharmaceutical company, where he finalized negotiations and executed and managed multiple strategic corporate partnerships and alliances. Mr. Koval holds an M.Sc. in Engineering from Rensselaer Polytechnic Institute and an M.B.A. from the Sloan School of Management at the Massachusetts Institute of Technology.

Shannon T. Odam has served as our Senior Vice President, Chief People Officer since January 2024. Previously, she served as our Vice President, Human Resources since joining Geron in June 2019. Prior to joining Geron, Ms. Odam served as Vice President, Human Resources at BioElectron Technology Corp., a clinical-stage biotechnology company, where she created and executed upon a unified vision by streamlining organizational design structure, designed leadership development programs to drive skills needed for future growth and led and executed human resources operations. from May 2017 to July 2018, before its acquisition by PTC Therapeutics Inc. in 2019. Before that, Ms. Odam served in various human capital roles at PricewaterhouseCoopers, or PWC, a multinational professional services firm, from 2007 to 2017. While at PWC, Ms. Odam served as the Silicon Valley Diversity and Inclusion Leader, the Audit Human Resources Leader, as well as an executive coach for PWC's Coaching Center of Excellence. Ms. Odam received a B.S. in criminology from California State University, Fresno, an M.S. in Organizational Development from University of San Francisco and an Executive Coaching Credential from the Hudson Institute of Coaching.

Human Capital

Corporate Values

Fostering and maintaining a strong, healthy culture is a key strategic focus. Our corporate values are authenticity, accountability, excellence, integrity and respect, and we are committed to building a corporate culture that supports these values. These values reflect who we are and the way our employees interact with one another, our partners and our stockholders, and are the essential tenets that guide our decisions, govern our relationships, both internally and externally, and articulate what we stand for and who we are. These values dictate the ways in which we interact, work and communicate, how we resolve conflicts and ultimately, how we strive to make Geron successful. We are Authentic, having well-intentioned interactions that are genuine and real. We are Accountable, taking responsibility for our actions, including decisions, and the effect they have on Geron. We are Excellent, having relentlessly high standards. We have Integrity, requiring our employees to behave ethically in all situations and demanding the same from others. We encourage our employees to live out our core values and to discuss our core values with potential candidates looking to join our team. We believe that this is an important step in helping our culture stay strong and unique.

Our team of talented professionals is the foundation of our company and fuels our historical and prospective achievements for patients. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future opportunities. As of December 31, 2023, we had 141 full-time employees. Twenty of our employees hold Ph.D. degrees and 63 hold other advanced degrees. Of this current total workforce, 67 employees were engaged in, or directly supported, our research and development activities, and 74 employees were engaged in commercial, medical affairs, business development, legal, finance, human resources, information technology and administration. Every employee plays a vital role in furthering our goals and impacting our progress towards fully realizing our goal to develop and seek to commercialize imetelstat.

In addition to our employee base, we have established, and expect to continue to establish, consulting agreements with drug development professionals, clinicians, attorneys and regulatory experts with experience in numerous fields, including clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing and regulatory affairs. As of December 31, 2023, we had approximately 122 consultants.

To succeed in our mission, we must attract, recruit, retain, develop and motivate qualified clinical, nonclinical, scientific, manufacturing, regulatory, management and other personnel needed to support our business and operations. As a biotechnology company with locations in the San Francisco Bay Area and northern New Jersey, we operate in a highly competitive industry and geographies for employee talent. In 2023, we engaged in extensive recruiting efforts to source and interview a talented and diverse pipeline of candidates, and enhanced our capabilities by significantly expanding our employee base. We grew our workforce by 46 employees, 23 of whom are part of our commercial team, and expected to play a critical role in implementing our plans to commercialize imetelstat, if approved. We maintain a comprehensive dashboard of measurements, including recruitment productivity, diversity, equity and inclusion metrics, employee engagement scores, total rewards benchmarking, participation rates and satisfaction scores for internal training, turnover rates and exit interview results, to guide our human capital management efforts.

We believe that our ability to attract highly skilled and talented employees in a competitive labor market is enhanced by nurturing our workplace culture, providing competitive compensation and benefits programs and supporting employee career development and related management training. To that end, we continue to invest resources and energy into being an employer of choice – attracting and engaging individuals who are innovative, curious, driven, diligent, collaborative and of the highest integrity and ethics. Some of our key efforts in this area and management of our human capital assets generally are described here.

Compensation and Benefits

Our compensation philosophy is to provide pay and benefits that are competitive in the biotechnology and pharmaceutical industry where we compete for talent. We monitor our compensation programs closely and review them annually to provide what we consider a competitive mix of compensation and health, welfare and retirement benefits for all our employees. Our compensation package for all employees includes market-competitive base salaries, eligibility for annual performance bonuses and equity grants. Annual cash bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Any actual bonus payout is based on a combination of individual performance and corporate performance. All regular-status, full-time employees are eligible to participate in our comprehensive benefit program, pursuant to plan terms and conditions. Plan choices include medical, dental, vision, life insurance, flexible spending accounts, short and long-term disability insurance, a 401(k) retirement savings plan with a discretionary matching employer contribution, and an employee stock purchase plan. We also provide regular-status, full-time employees with a generous time off program that includes vacation, sick, holiday, and paid leave for certain life events.

Every year, we undertake a detailed review of our compensation by position and level and make adjustments necessary to ensure that we continue to provide competitive compensation. In conjunction with the California's Pay Transparency law (SB 1162), beginning January 1, 2023, we have published pay ranges in all job postings for jobs in California and also seek to comply with other states' pay disclosure requirements.

Diversity, Inclusion and Corporate Culture

We value workplace diversity, including diversity of personal background, perspective, experience and other characteristics, such as gender, gender identity, ethnicity, sexual orientation, age, and underrepresented communities – not only because it is the right thing to do, but because we believe doing so enhances our corporate culture and is key to our long-term success. As of December 31, 2023, approximately 56% of our employees in managerial roles were women, and approximately 48% of our executive management, vice president and above, were women.

During 2023, we furthered the development of our hybrid workforce program that provides a variety of virtual and in-person collaboration opportunities, such as leadership training and coaching resources. Since 2021, we have utilized a peer-centric employee recognition program to empower employees to champion our workplace culture and values, and promote direct praise to peers. In addition, we have implemented a reward program that enables managers to recognize employees who have demonstrated exceptional performance.

In addition, we pride ourselves on an open culture that respects co-workers, values employees' health and well-being and fosters professional development. We support employee growth and development in a variety of ways, including with group training, individual mentoring and coaching, conference attendance and tuition reimbursement. Our management conducts annual employee engagement surveys and reports to our board of directors on human capital management topics, including corporate culture, diversity, equity and inclusion, employee development and retention, and compensation and benefits. Similarly, our board of directors regularly provides input on important decisions relating to these matters, including with respect to employee compensation and benefits, talent retention and development.

Communication and Engagement

We believe that part of what sets us apart from other companies is our culture and, in particular, our focus on providing timely and transparent communications and creating a strong sense of belonging and inclusiveness. In 2023, after nearly three years of the COVID-19 pandemic, we were able to re-engage in periodic in-office meetings and interactions, as well as in-office training and development opportunities, to encourage cross-functional team-building and collaboration, in conjunction with which many of our teams engage in group lunches and dinners. We held a summer contest that encouraged our employees to share summer travel experiences and special events, building rapport and strengthening employee relationships, and we conduct organizational and team-specific holiday events to promote connectivity among our employees. We share information and news with employees through quarterly all-hands meetings, semi-monthly newsletters to employees, social media posts on our intranet and outward facing social media sites, such as LinkedIn, and regular employee chats with our Chief Executive Officer and other members of senior management. We survey our employees each year to measure their level of engagement at the Company. Our employee engagement scores have remained relatively steady over the past three years, despite the challenges we faced through the COVID-19 pandemic. These surveys provide rich feedback each year that helps us to continue to grow our culture and make Geron a great place to work.

Health, Wellness and Safety

In addition to specific support relating to health and safety during the COVID-19 pandemic, we continue other activities that promote our employees' whole health and wellness, including reimbursement for certain wellness costs, external support from our employee assistance programs and mental wellness services, which covers therapy and/or coaching for our employees and their dependents, including high school and college-aged children.

None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

Corporate and Available Information

Geron Corporation was incorporated in the State of Delaware on November 28, 1990. Geron UK Limited was incorporated in the United Kingdom on September 29, 2021. Geron Netherlands B.V. was incorporated in the Netherlands on February 17, 2023. Our principal executive offices are located at 919 E. Hillsdale Blvd., Suite 250, Foster City, CA 94404, and our telephone number is 650-473-7700. Our website address is http://www.geron.com.

We file or furnish electronically with the U.S. Securities and Exchange Commission, or the SEC, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We make copies of these reports available free of charge through the "SEC Filings" tab on the "Investors & Media" page of our website as soon as reasonably practicable after we file or furnish them with the SEC.

Information contained on or accessible through our website is not incorporated into, and does not form a part of, this Annual Report on Form 10-K or any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

We operate in a dynamic and rapidly changing environment involving numerous 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, financial condition or results of operations 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 THE DEVELOPMENT OF IMETELSTAT

Our future success depends solely on imetelstat, our only product candidate, and we cannot be certain that we will be able to continue to develop imetelstat or advance imetelstat to subsequent clinical trials, or that we will be able to receive regulatory approval for or to commercialize imetelstat, on a timely basis or at all.

Imetelstat is our sole product candidate, upon whose success we are wholly dependent. Our ability to develop imetelstat and launch it commercially is subject to significant risks and uncertainties, including, among other things, our ability to:

- receive regulatory approval to commercialize imetelstat in lower-risk MDS from the FDA and European Commission, without the requirement for the conduct and completion of additional pre-approval clinical trials or further analyses, testing or development commitments, if at all, any of which could result in increased costs to us, and delay, limit or preclude our ability to generate revenue;
- generate sufficient safety and efficacy data from the IMpactMF clinical trial to support any application for regulatory approval in relapsed/refractory MF, without clinically meaningful safety issues, side effects or dose-limiting toxicities related to imetelstat that may negatively impact its benefit-risk profile;
- ascertain that the use of imetelstat does not result in significant systemic or organ toxicities, including hepatotoxicity, or other safety issues resulting in an unacceptable benefit-risk profile;
- obtain additional capital when needed in order to enable us to further advance the imetelstat program;
- obtain and maintain required regulatory clearances and approvals to enable continued clinical development, as well as potential commercialization, of imetelstat;
- enter into and maintain commercially reasonable arrangements with third parties to provide services needed to further research and develop, and to potentially commercialize, imetelstat, including maintaining the agreements with our contract research organizations, or CROs, and third-party manufacturers;
- recruit and retain sufficient qualified and experienced personnel to support the development and potential commercialization of imetelstat in the U.S.;
- enter into and maintain arrangements with third parties to provide services needed to support the potential commercialization of imetelstat for territories outside of the U.S. in compliance with applicable laws;
- achieve acceptance of imetelstat, if approved, by patients and the relevant medical communities;
- compete effectively with other approved treatments in lower-risk MDS and relapsed/refractory MF if imetelstat is approved in those indications;
- obtain appropriate coverage and reimbursement levels for the cost of imetelstat from governmental authorities, private health insurers and other third-party payors; and
- obtain, maintain and enforce adequate intellectual property and regulatory exclusivity for imetelstat both in the U.S. and globally.

If we are not able to successfully achieve these goals and overcome other challenges that we may encounter in the research, development, manufacturing and potential commercialization of imetelstat, we may be forced to abandon our development and/or planned commercialization of imetelstat, which would severely harm our business, prospects and our ability to raise additional capital, and might cause us to cease operations.

Our clinical trials of imetelstat could be interrupted, delayed, terminated or abandoned for a variety of reasons which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.

The conduct and completion of our clinical trials could be interrupted, delayed or abandoned for a variety of reasons, including as a result of clinical trial failures, suspensions, terminations or delays related to:

- patient recruitment, enrollment and retention challenges and operational delays, including in connection with opening new clinical sites, while also competing with clinical trials for other investigational drugs in the same patient population;
- use of trial endpoints such as overall survival, that inherently require prolonged periods of clinical observation or analysis of the resulting data to determine trial outcomes, including the need for a certain number of events, or deaths, to occur in IMpactMF prior to the final analysis in that trial of overall survival;
- obtaining and/or maintaining regulatory clearances in the U.S. or other countries to commence, conduct or modify current or potential future clinical trials of imetelstat, in a timely manner, or at all;
- investigational new drug applications, or INDs, and equivalent submissions in other countries for imetelstat being placed on full or partial clinical hold, suspended or subject to other requirements by the FDA or other similar international regulatory authorities;
- contracting with a sufficient number of clinical trial sites to conduct current and potential future clinical trials, and ensuring that such contracts contain all necessary terms and conditions required by applicable laws, including providing for valid mechanisms to engage in cross-border data transfers, as well as identifying, recruiting and training suitable clinical investigators;
- obtaining or accessing necessary clinical data in accordance with appropriate clinical or quality practices and regulatory requirements, in a timely and accurate manner to ensure complete data sets;
- responding to safety findings, recommendations or conclusions by the data safety review committees, independent data monitoring committees and/or expert committees of current and potential future clinical trials of imetelstat based on emerging data occurring during such clinical trials;
- manufacturing sufficient quantities that meet our specifications, cost and quality requirements, and timelines for imetelstat, or other clinical trial materials, in a manner that meets the quality standards of the FDA and other similar international regulatory authorities, and responding to any disruptions to drug supply, clinical trial materials or quality issues that may arise;
- the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues;
- complying with current and future regulatory requirements, policies or guidelines, including domestic and international laws and regulations pertaining to fraud and abuse, transparency, and the privacy and security of health information;
- reaching agreement on acceptable terms and on a timely basis, if at all, with collaborators, physician investigators, vendors and other third parties located in the U.S. or other countries, including our CROs, laboratory service providers and clinical trial sites, on all aspects of clinical development and collaborating with them successfully; and
- third-party clinical contractors, including investigators or our CROs not performing our clinical trials according to our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements, or not performing data collection or analyses in a timely or accurate manner.

Failures or delays with respect to any of these events could adversely affect our ability to conduct or complete the clinical trials being conducted by us or our investigators, or to commence, conduct and complete potential future clinical trials of imetelstat, which could increase development costs, or interrupt, further delay or halt our development or potential commercialization of imetelstat, any of which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that could further delay or prevent the commencement and/or completion of clinical trials for imetelstat, delay or prevent its regulatory approval, or limit its commercial potential.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events affecting its safety or efficacy that could interrupt, further delay or halt current or potential future clinical trials of imetelstat, as well as our expanded access program. In this regard, adverse events and dose-limiting toxicities observed in previous and ongoing clinical trials of imetelstat include:

- hematologic toxicities, such as profound and/or prolonged thrombocytopenia or neutropenia;
- bleeding events, with or without thrombocytopenia, including Grade 3/4 bleeding events;
- febrile neutropenia;
- hepatotoxicity and liver function test abnormalities, as well as hepatic failure;
- gastrointestinal events;
- infection events, with or without neutropenia, including Grade 3/4 infection events;
- muscular and joint pain;
- fatigue;
- headache; and
- infusion-related reactions.

If patients in any clinical trials of imetelstat or our expanded access program experience similar or more severe adverse events, or new or unusual adverse events, or if the FDA or other similar international regulatory authorities determine that efficacy and safety data in clinical trials of imetelstat do not support an adequate benefit-risk profile to justify continued treatment of patients, then the FDA or other similar international regulatory authorities may place one or more of the INDs for imetelstat on clinical hold, as occurred in March 2014. If this were to occur, there would be a significant delay in, or possible termination of, one or more of the imetelstat clinical trials and any potential commercialization efforts, which might cause us to cease operations. For example, we are aware of a case in our IMpactMF clinical trial of a patient with myelofibrosis associated with underlying progressive bone marrow failure, who died from febrile neutropenia, pulmonary hemorrhage and bilateral pneumonia, which, at the time of reporting, the investigator related to imetelstat. If such toxicities or other safety issues in any clinical trial of imetelstat are determined by us, the FDA or similar international regulatory authorities to result in an unacceptable benefit-risk profile, then:

- additional information supporting the benefit-risk profile of imetelstat may be requested by the FDA or similar international regulatory authorities and if any such information is not available or, if available, not deemed acceptable, current clinical trials of imetelstat could be suspended, terminated, or placed on clinical hold by the FDA or similar international regulatory authorities;
- the ability to retain enrolled patients in our current clinical trials may be negatively affected, resulting in incomplete data sets and the inability to adequately assess the benefit-risk profile of imetelstat in a specific patient population;
- additional, unexpected clinical trials or non-clinical studies may be required to be conducted; or
- imetelstat may not receive or maintain any regulatory authorizations, including for commercial use.

Further, 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. Because remaining patients in ongoing clinical trials and in our expanded access program continue to receive imetelstat treatment, additional or more severe toxicities or safety issues may be observed, and the benefit-risk profile of imetelstat will continue to be assessed, including the risk of hepatotoxicity, severe cytopenias, fatal bleeding with or without any associated thrombocytopenia, patient injury or death.

The occurrence of any of these events could interrupt, further delay, or halt, any development, and as a result, impact or preclude the potential regulatory approval and commercialization of imetelstat, as well as increase costs to develop imetelstat, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat, any of which might cause us to cease operations.

Results and data we disclosed from prior non-clinical studies and clinical trials may not predict success in later clinical trials, and we cannot assure you that any ongoing or future clinical trials of imetelstat will lead to similar results and data that could potentially enable us to obtain any regulatory approvals.

The design of a clinical trial can determine whether its results will support regulatory approval of a product, and flaws in the trial design may not become apparent until the clinical trial is well advanced or during the approval process after the trial is completed. A clinical trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of imetelstat clinical trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results of clinical trials with smaller sample sizes less reliable than trials with a larger number of patients. As a result, there may be less certainty that imetelstat will achieve a statistically significant effect in any future clinical trials.

Further, success in non-clinical testing and early clinical trials, including Phase 2 clinical trials, such as IMbark, does not ensure that later clinical trials will be successful, nor does it predict final clinical trial results. In addition, even though we reported positive top-line results from IMerge Phase 3 in January 2023, this does not ensure that any other clinical trials of imetelstat will be successful. Later stage clinical trials of imetelstat may fail to show an acceptable benefit-risk profile despite having progressed through non-clinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have frequently suffered significant setbacks in later clinical trials, even after achieving promising results in earlier non-clinical studies or clinical trials.

In general, Phase 3 clinical trials with larger numbers of patients or longer durations of therapy may fail to replicate efficacy and safety results observed in earlier clinical trials, such as IMbark, and if this were to occur with IMpactMF, this would adversely affect future development prospects of imetelstat, and as a result, impact the potential commercialization of imetelstat in relapsed/refractory MF, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat, any of which might cause us to cease operations.

Furthermore, non-clinical and clinical data are often susceptible to varying interpretations and analyses. In some instances, there can be significant variability between different clinical trials of imetelstat due to numerous factors, including changes in trial procedures set forth in trial protocols, differences in the size and type of patient populations, and changes in and adherence to the dosing regimens. For example, although the statistical analyses comparing IMbark data to closely matched real world data, or RWD, published in the September 2021 issue of the Annals of Hematology, suggest potentially favorable overall survival in relapsed/refractory MF patients treated with imetelstat, compared to BAT using closely matched patients' RWD, such comparative analyses between RWD and our clinical trial data have several limitations. For instance, the analyses create a balance between treatment groups with respect to commonly available covariates, but do not take into account the unmeasured and unknown covariates that may affect the outcomes of the analyses. Potential biases are introduced by factors which include, for example, the selection of the patients included in the analyses, misclassification in the matching process, the small sample size, and estimates that may not represent the outcomes for the true treated patient population. Failure to achieve results supporting a positive benefit-risk profile in current or potential future imetelstat clinical trials would interrupt, further delay, or halt, any development, and as a result, prevent potential regulatory approval and commercialization of imetelstat, which would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat.

Further, preliminary data are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Additional or updated safety and efficacy data from current or potential future clinical trials of imetelstat may result in a benefit-risk profile that does not justify the continued development and/or potential regulatory approval of imetelstat in a particular patient population, or at all. Any data reported from IMpactMF may materially differ from and be less positive than data previously reported from IMbark. Thus, reported data should be considered carefully and with caution, and not relied upon as indicative of future clinical results. Such additional data could result in a lower

benefit-risk profile than initially expected, which could hinder the potential success of IMpactMF, IMproveMF or IMpress, or cause us to abandon further development of imetelstat entirely.

Top-line results and data may differ from future results of the same study, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Moreover, as remaining patients in IMerge Phase 3 continue to be treated and followed under the extension phase of the trial and longer-term outcomes are assessed, these additional and more mature data may alter the benefit-risk profile of imetelstat in an adverse manner, including with respect to overall survival. Material adverse differences in future results, compared to preliminary, interim or top-line data, could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, including the potential commercialization of imetelstat, and might cause us to cease operations.

We rely on third parties to conduct our current and potential future clinical trials of imetelstat. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to continue the development of, obtain regulatory approval for, or commercialize imetelstat.

We do not have the ability to independently conduct clinical trials. Therefore, we rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, service providers, vendors, suppliers and consultants, to conduct clinical trials of imetelstat. The third parties we contract with for execution of our current and potential future clinical or investigator-sponsored trials of imetelstat play a critical role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control their performance, or the amount or timing of resources that they devote to imetelstat. For example, we have retained CROs to support our imetelstat clinical development activities, and any failure by our CROs to perform their contractual obligations, or disputes with our CROs about the quality of their performance or other matters, could further delay or halt our imetelstat clinical development activities. These third parties may also have relationships with other commercial entities, some of which may compete with us. Under certain circumstances, these third parties may terminate their agreements with us without cause and upon immediate written notice.

Although we rely on third parties to conduct our imetelstat clinical trials, we remain responsible for ensuring that each clinical trial is conducted in accordance with its investigational plan and protocol, and applicable laws. Moreover, the FDA and similar international regulatory authorities require us to comply with GCP regulations and standards for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the rights, integrity and confidentiality of patients participating in clinical trials are protected, including being adequately informed of the potential risks. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, or similar international regulatory authorities, may require us to perform additional clinical trials before approving any application for regulatory approval. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or other applicable regulations. In addition, our clinical trials must be conducted with imetelstat produced under applicable GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would further delay the process for any regulatory approval. Our ability to comply with these regulations and standards may be contingent upon activities conducted by third parties, and if they fail to perform in accordance with contractual obligations and legal requirements, our development of imetelstat may be interrupted, further delayed or halted. Any failures by us or third parties noted above would have a severe adverse effect on our results of operations, financial condition and ability to raise additional capital, business prospects and the future of imetelstat, including the potential commercialization of imetelstat, any of which might cause us to cease operations.

Furthermore, the execution of clinical trials and the subsequent compilation and analysis of the data produced, including the interim and final analyses for IMpactMF, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. If the quality or accuracy of the clinical data obtained, compiled or analyzed by third parties is compromised due to their failure to adhere to our clinical trial protocols, GCP or GMP requirements, or for any other reason, we may need to enter into new arrangements with alternative third parties, which would cause delay, and could be difficult, costly or impossible.

Switching or adding CROs, investigators, vendors and other third parties involves additional costs and delays because of the time it takes to finalize a contract with a new CRO and for their commencement of work. Although we carefully manage our relationships with our CROs, investigators, vendors and other third parties, we and any of

these third parties may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, business prospects and the future of imetelstat.

In addition, certain principal investigators for our clinical trials serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected conduct of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of any applications for approval by the FDA and may ultimately lead to the denial of approval of imetelstat.

We do not control the conduct of current or any potential future investigator-led clinical trials, and data from such trials could show marginal efficacy and/or clinically relevant safety concerns related to imetelstat resulting in an unfavorable benefit-risk assessment that could materially and adversely impact our ongoing clinical trials, our imetelstat development program as a whole, and/or the prospect for approval for imetelstat.

We do not control the design or administration of the investigator-led clinical trial, IMpress, or any potential future investigator-led trials, nor the submission, approval or maintenance of any IND or international equivalent filings required to conduct these clinical trials. In addition, we do not have control over the timing and reporting of the data from any such investigator-led clinical trials. A delay in the timely completion of or reporting of data from any potential future investigator-led clinical trial could have a material adverse effect on our ability to further develop imetelstat or to advance imetelstat to subsequent clinical trials.

Investigator-led clinical trials may be conducted under less rigorous clinical standards than those used in company-sponsored clinical trials. Accordingly, regulatory authorities may closely scrutinize the data collected from these investigator-led clinical trials. In addition, any investigator-led clinical trials could show marginal efficacy and/or clinically relevant safety concerns that could delay, limit or preclude the further clinical development or marketing approval of imetelstat in any indication, including lower-risk MDS. To the extent that the results of any investigator-led clinical trials raise safety or other concerns regarding imetelstat, regulatory authorities may question the results of such investigator-led clinical trials, or question the results of any of our clinical trials. Safety concerns arising from future investigator-led clinical trials could result in partial or full clinical holds being placed on the imetelstat INDs by the FDA or other similar international regulatory authorities, as occurred in March 2014, which would further delay or prevent us from advancing imetelstat into further clinical development, would delay or preclude any marketing approvals for imetelstat and could cause us to discontinue our development of imetelstat, any of which would severely harm our business and prospects, including the potential commercialization of imetelstat, and could potentially cause us to cease operations.

RISKS RELATED TO REGULATORY APPROVAL AND COMMERCIALIZATION OF IMETELSTAT

Our inability to obtain and maintain regulatory clearances and approvals to continue the clinical development of, and to potentially commercialize, imetelstat, would severely and adversely affect imetelstat's future value, and our business and business prospects, and might cause us to cease operations.

Federal, state and local governments in the U.S. and governments in other countries have significant regulations in place that govern drug research and development and may prevent us from successfully conducting development efforts or potentially commercializing imetelstat. Delays in obtaining or failure to maintain regulatory clearances and approvals, or limitations in the scope of such clearances or approvals, could:

- impede, halt or increase the costs of our plans for clinical development and commercialization;
- significantly harm the commercial potential of imetelstat;
- diminish any competitive advantages that may have been available to us; or
- delay or preclude any revenue we may receive from the future commercialization of imetelstat, if any.

The occurrence of any such event would significantly harm our business, business prospects, including any potential commercialization of imetelstat, and the future value of imetelstat and might cause us to cease operations.

If we are unable to obtain regulatory approval for and successfully commercialize imetelstat, or experience significant delays in doing so, our business will be severely harmed.

The process of obtaining marketing approvals, both in the U.S. and in other countries, is lengthy, expensive and uncertain. It may take many years to obtain approval, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Of the large number of drugs in development, only a small percentage complete the regulatory approval process and are successfully commercialized. In addition, the lengthy review process as well as the unpredictability of future clinical trial results may result in a delay in obtaining, or our failure to obtain, regulatory approval for imetelstat in lower-risk MDS, relapsed/refractory MF, or any other indication, which would significantly harm our business, business prospects, including the potential commercialization of imetelstat, and the future value of imetelstat and might cause us to cease operations.

Securing marketing approval requires the submission of extensive non-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish to the satisfaction of such regulatory authorities the product candidate's safety and efficacy, as well as information about the product manufacturing process and any inspections of manufacturing facilities conducted by regulatory authorities through the filing of an NDA in the U.S. and an MAA in Europe. Although the FDA has accepted for standard review our NDA for imetelstat for the treatment of transfusion-dependent anemia in adult patients with lower-risk MDS who have failed to respond or have lost response to or are ineligible for ESAs, and the EMA has validated our MAA for imetelstat for the same proposed indication, there can be no assurance that we will receive regulatory approval by the FDA or the European Commission for the commercialization of imetelstat in a timely manner or at all. Further, because non-clinical and clinical data are often susceptible to varying interpretations and analyses, regulatory authorities, including the FDA and EMA, may disagree with our interpretation of the data and may require additional clinical testing and/or further analyses from completed clinical or non-clinical trials before we can obtain regulatory approval and begin commercialization of imetelstat, if at all, any of which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. For example, in connection with the anticipated FDA oncology drug advisory committee meeting concerning the NDA for imetelstat in lower-risk MDS, the FDA will release its review of our data, which may differ, perhaps materially, from our interpretation of our data. Additionally, many sponsors experience volatility in the stock price surrounding the advisory committee's discussion and vote, even though FDA is not obligated to follow the advisory committee's input.

Furthermore, in IMerge Phase 3 we shortened the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable an earlier clinical cut-off date for the primary analysis. Although we reported positive top-line results from IMerge Phase 3 in January 2023, our decision to shorten the follow-up period after the last patient has been enrolled may result in further clinical responses that may have occurred after the 12-month clinical cut-off date being excluded from the primary analysis. The exclusion of this future data from the primary analysis could reduce the overall efficacy results, including durability of transfusion independence, which could otherwise delay, limit or prevent marketing approval of imetelstat in lower-risk MDS by the FDA or similar international regulatory authorities or require additional clinical trials and further testing prior to granting any regulatory approval to market imetelstat in lower-risk MDS.

Even though we reported positive top-line results from IMerge Phase 3 in January 2023, those results are not necessarily predictive of imetelstat activity in other indications and for other pivotal trials that may be needed to support any application to the FDA or similar international regulatory authorities for such other indications, such as from IMpactMF.

Any of these events may result in a failure to further develop, obtain regulatory approval for or commercialize imetelstat, which would severely and adversely affect our business and business prospects, and might cause us to cease operations.

In addition, with respect to the trial design for IMpactMF, the FDA urged us to consider adding a third dosing arm to the trial to assess a lower dose and/or a more frequent dosing schedule that might improve the trial's chance of success by identifying a less toxic regimen and/or more effective spleen response, one of the trial's secondary endpoints. Based on data from IMbark, we believe that testing a lower dose regimen would likely result in a lower median OS, which is the trial's primary endpoint, in the imetelstat treatment arm. Existing data also suggest that lowering the dose would not result in a clinically meaningful reduction in toxicity, and for these reasons we determined not to add a third dosing arm to the trial design and the FDA did not object to our proposed imetelstat dose and schedule of 9.4 mg/kg every three weeks. Our belief may ultimately be incorrect. Therefore, our failure to add a third dosing arm could result in a failure to maintain regulatory clearance from the FDA and similar international regulatory authorities, could result in the trial's failure, or could otherwise delay, limit or prevent

marketing approval of imetelstat for relapsed/refractory MF by the FDA or similar international regulatory authorities.

Imetelstat must receive all relevant regulatory approvals before it may be marketed in the U.S. or other countries. Regulatory authorities have substantial discretion in the approval process and can delay, limit or deny approval of imetelstat or require us to conduct additional non-clinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design or implementation of our clinical trials, including our statistical analysis of trial results;
- failure to demonstrate to the FDA or similar international regulatory authorities that imetelstat's efficacy results provide sufficient evidence of overall clinical benefit;
- unfavorable benefit-to-risk assessment, in the case of marginal efficacy and/or clinically relevant safety concerns, for any proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to imetelstat;
- disagreement with our interpretation of data from non-clinical studies or clinical trials, including disagreement from the oncology drug advisory committee that the FDA has scheduled for March 14, 2024 in connection with the review of the NDA for imetelstat in lower-risk MDS;
- rejection by the FDA of foreign data included in the NDA and the non-applicability of this data to the U.S. population and U.S. medical practice;
- identification of critical issues as a result of a pre-approval health authority inspection that could negatively impact the integrity of data in an NDA or MAA and lead to a rejection by the FDA, European Commission, or similar international health authorities;
- a determination by the FDA, EMA, or similar international regulatory authorities that the appropriate indication for commercial use of imetelstat is narrower or more restrictive than anticipated;
- failure to satisfy the requirement to develop a risk evaluation and mitigation strategy, or REMS, for the U.S. and a risk management plan for the EU including post-marketing studies, as a potential condition to approval;
- disagreement regarding the formulation, labeling and/or the specifications for imetelstat;
- the failure of the quality or stability of imetelstat to meet acceptable regulatory standards;
- the FDA, EMA, the competent authorities of the individual EU Member States or similar international regulatory authorities may lack resources or be delayed in conducting pre-approval inspections due to lack of resources or other reasons;
- we or any third-party service providers may be unable to demonstrate compliance with GMP, GCP, or other applicable regulatory and other requirements to the satisfaction of the FDA, the competent authorities of the individual EU Member States or similar international regulatory authorities; or
- changes in regulatory policies or approval processes, or potential reduction of unmet medical need with the entry of competitive therapies to the market, could render our clinical efficacy or safety data insufficient for approval.

Furthermore, in recent years, there has been increased public and political scrutiny on the FDA and similar international regulatory authorities with respect to the approval process for new drugs, and as a result regulatory authorities may apply more stringent regulatory standards, especially regarding drug safety, when reviewing regulatory submissions for new drugs.

Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that increase our costs or render imetelstat not commercially viable, which would harm imetelstat's future value and our business and business prospects.

Regulatory authorities may also not approve the labeling claims that are necessary or desirable for the successful commercialization of a drug, such as imetelstat. For example, regulatory authorities may not agree with our belief in the disease-modifying properties of imetelstat, and future regulatory clearances, if any, that we might obtain for imetelstat may be limited to fewer or narrower indications than we might request, or may be granted

subject to the performance of post-marketing studies, which may impose further requirements or restrictions on the distribution or use of imetelstat, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria, and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for imetelstat and affect reimbursement by third-party payors. Future regulatory clearances, if any, may be limited to a smaller patient population, or may require a different drug formulation or a different manufacturing process, than we might in the future decide to seek.

In addition, failure by our former collaborator to comply with applicable regulatory guidelines prior to our assumption of sponsorship of the imetelstat program, or to provide information if requested by regulatory authorities, could result in administrative or judicially imposed sanctions on us, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of manufacturing activities, and the potential refusal to approve any NDAs, including the NDA for imetelstat in lower-risk MDS.

Any delay in obtaining or failure to obtain required approvals of imetelstat, or limitations on any regulatory approval that we might receive in the future, if any, could reduce the potential commercial use of imetelstat, and potential market demand for imetelstat and therefore result in decreased revenue for us from any commercialization of imetelstat, any of which would severely and adversely affect our financial results and ability to raise additional capital, the price of our common stock, our business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat, and might cause us to cease operations.

Any regulatory approval that we may potentially receive for imetelstat could be subject to restrictions, and we may be subject to penalties or product withdrawal if we fail to comply with regulatory requirements or if we experience unanticipated problems with imetelstat.

Any regulatory approval that we may potentially receive for imetelstat could be subject to restrictions or conditions of approval that may require potentially costly post-marketing clinical trials or surveillance to monitor safety and efficacy of the drug candidate. In addition, imetelstat and the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities related to imetelstat will be subject to continual requirements of, and review by, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, current Good Manufacturing Practice (cGMP) requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding promotional interactions with healthcare professionals.

Failure to comply with these regulatory requirements or later discovery of previously unknown problems with imetelstat, or our manufacturers, or manufacturing processes for imetelstat, may result in actions such as restrictions on imetelstat manufacturing, distribution or use; restrictions on labeling or marketing; requirements to conduct post-marketing studies or clinical trials; warning letters, withdrawal of imetelstat from the market; refusal to approve our pending regulatory applications, or any supplements to approved applications that we might submit; recalls; suspension or termination of ongoing clinical trials; fines, restitutions or disgorgement of profits or revenues; refusal to permit the import or export of imetelstat; product seizure or detentions; injunctions or the imposition of civil or criminal penalties; and adverse publicity.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We also cannot predict the likelihood, nature, or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad.

If we are unable to fulfill any potential post approval commitments that may be applied to the approval and commercialization of imetelstat by any regulatory authority, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies,there may be a negative impact to our business and continued regulatory approval of imetelstat. Under such circumstances, we or our respective clinical investigators may be subject to the actions listed above, including losing marketing approval for imetelstat, which would severely and adversely affect our business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat, and might cause us to cease operations.

If imetelstat is approved for commercialization and we are unable to establish and maintain effective sales, marketing and distribution capabilities or enter into agreements with third parties to commercialize imetelstat, we will be unable to successfully commercialize imetelstat if and when it is approved.

We need to complete substantial preparations to be ready for any potential future commercialization of imetelstat, and we are in the process of establishing sales, marketing and distribution capabilities. As a company, we have no experience in selling and marketing products. To advance imetelstat to potential marketing approval and commercialization, we will be required to complete our commercialization preparatory activities, including obtaining and maintaining state licenses where required for us to sell imetelstat, and continue to incur related expenses, before we obtain any marketing approval. These activities include, among other things, the development of an in-house marketing and sales force, which will continue to require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain qualified marketing and sales personnel. If we are unable to adequately prepare for the potential future commercialization of imetelstat, we may not be able to generate product revenue if marketing authorization is obtained.

There are risks involved with both establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of imetelstat for which we recruit a sales and marketing force and establish distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which would be costly. Even if imetelstat is approved in lower-risk MDS and we are able to establish our own sales and marketing capabilities, imetelstat will be a newly-marketed drug. If we are unable to effectively train sales personnel and equip them with compliant and effective materials, our efforts to successfully commercialize imetelstat could be adversely affected, which would negatively impact our business, business prospects and the future value of imetelstat.

If we enter into arrangements with third parties to perform commercialization services like sales, marketing and distribution, we will be reliant on the efforts of such third parties, and our sales revenue from sales of imetelstat or the profitability from such sales to us are likely to be lower than if we were to market and sell imetelstat ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize imetelstat or may be unable to do so on terms that are favorable to us. In entering into third-party commercialization arrangements, any revenue we receive will depend upon the efforts of the third parties, and we cannot assure you that such third parties will establish adequate commercialization capabilities or devote the necessary resources and attention to commercialize imetelstat effectively. We also face competition in our search for third parties to assist us with the commercialization efforts of imetelstat.

Our inability to successfully establish and maintain effective commercialization capabilities for imetelstat, if we receive regulatory approval to do so, would severely and adversely affect our financial results, business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat.

If we do not obtain acceptable prices or adequate reimbursement for imetelstat, the use of imetelstat could be severely limited.

The ability to successfully commercialize imetelstat, if approved, will depend significantly on obtaining acceptable prices and the availability of coverage and adequate reimbursement to the patient from third-party payors. Government payors, such as the Medicare and Medicaid programs, and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and the reimbursement levels. Assuming we obtain coverage for imetelstat by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. If imetelstat is approved for commercial sale, patients are unlikely to use it unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of its cost. Therefore, coverage and adequate reimbursement will be critical to new product acceptance.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. The Inflation Reduction Act of 2022, or the Inflation Reduction Act, includes several provisions to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government, which may ultimately

have a negative effect on the pricing for imetelstat, should it receive regulatory approval. However, the Medicare drug pricing negotiation program provisions of the law are currently subject to legal challenges. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the U.S. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of imetelstat to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We cannot be sure that coverage and reimbursement will be available for imetelstat, if approved for commercial sale, and, if reimbursement is available, what the level of reimbursement will be. There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar international regulatory authorities. Coverage and reimbursement may impact the demand for, or the price of imetelstat, if marketing approval is obtained. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize imetelstat, even if marketing approval is obtained, which would negatively impact our business and business prospects.

Although orphan drug designation has been granted to imetelstat for the treatment of MF and MDS in the U.S. and in the EU, these designations may not be maintained, which would eliminate the benefits associated with orphan drug designation, including the potential for market exclusivity, which would likely result in decreased sales revenue from commercialization of imetelstat, if any, and would likely harm our business and business prospects.

The FDA granted orphan drug designation to imetelstat in June 2015 for the treatment of MF and for the treatment of MDS in December 2015, and the European Commission granted orphan drug designation in December 2015 to imetelstat for the treatment of MF and in July 2020 for the treatment of MDS. The designation of imetelstat as an orphan drug does not guarantee that any regulatory authority will accelerate regulatory review of, or ultimately approve, imetelstat, nor does it limit the ability of any regulatory authority to grant orphan drug designation to product candidates of other companies that treat the same indications as imetelstat prior to imetelstat receiving any exclusive marketing approval.

We may lose orphan drug exclusivity for certain reasons, including if the FDA or the European Commission determines that the request for orphan drug designation was materially defective or if we cannot ensure sufficient quantities of imetelstat to meet the needs of patients with MF or MDS. Failure to maintain orphan designation status, or failure to agree to and complete any agreed upon pediatric plan, would lead to the inability to obtain or the loss of such regulatory exclusivity.

Even if we maintain orphan drug exclusivity for imetelstat, the exclusivity may not effectively protect imetelstat from all competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug product is approved, the FDA or the European Commission can subsequently approve a different drug with the same active moiety for the same condition, if the FDA or the European Commission concludes that the later drug is safer, more effective, or makes a major contribution to patient care. The occurrence of any of these events could result in decreased sales of imetelstat, should it ever receive marketing approval, and may harm our business and business prospects. In addition, orphan drug designation will neither shorten the development time nor regulatory review time for imetelstat, and it does not give imetelstat any advantage in the regulatory review or approval process.

Although imetelstat has received Fast Track designation by the FDA for MDS and MF, this does not guarantee marketing approval and may not lead to a faster development, regulatory review or approval process.

In October 2017, the FDA granted Fast Track designation to imetelstat for the treatment of adult patients with transfusion-dependent low red blood cell counts, or anemia, due to non-del(5q) lower-risk MDS and who are refractory or resistant to treatment with an ESA. In September 2019, the FDA granted Fast Track designation to imetelstat for the treatment of adult patients with relapsed/refractory MF.

Fast Track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review of the sponsor's NDA. Fast Track designation is intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions. However, Fast Track designation does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that any imetelstat NDA will be approved or that any approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track designation for any indication if it believes that the designation is no longer supported by data emerging from the imetelstat clinical development program.

Failure to achieve continued compliance with government regulations could delay or halt potential commercialization of imetelstat.

Approved products and their manufacturers are subject to continual review, and discovery of previously unknown problems with a product or its manufacturer may result in restrictions on the product or manufacturer, including import restrictions, seizure and withdrawal of the product from the market. If approved for commercial sale, future sales of imetelstat will be subject to government regulation related to numerous matters, including the processes of:

- manufacturing;
- advertising and promoting;
- selling and marketing;
- medical information;
- labeling; and
- distribution.

If, and to the extent that, we are unable to comply with these regulations, our ability to earn potential revenue from the commercialization of imetelstat, if any, would be materially and adversely impacted.

In addition, if imetelstat causes serious or unexpected side effects or is associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of imetelstat;
- we may be required to recall imetelstat, seek to change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- regulatory authorities may require revisions to the labeling of imetelstat, including limitations on approved uses or the addition of further warnings, contraindications or other safety information, or may impose restrictions on distribution in the form of REMS in connection with approval, if any;
- we may experience manufacturing delays and supply disruptions if regulatory inspectors identify regulatory noncompliance by third-party manufacturers requiring remediation;
- imetelstat may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- the FDA or similar international regulatory authorities may refuse to approve pending applications or supplements to approved applications filed by us, or may suspend or revoke license approvals; or
- we may be required to change or stop ongoing clinical trials of imetelstat, which would negatively impact the development of imetelstat for other potential indications.

Any of these events could prevent us from achieving or maintaining market acceptance for imetelstat or could substantially increase the costs and expenses of commercializing imetelstat, which in turn could delay or prevent us from generating any revenues from the sale of the imetelstat.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce regulations prohibiting the promotion of any drug product for off-label uses. If we were found to have improperly promoted off-label use of imetelstat, we would be subject to significant civil, criminal and administrative penalties, which would inhibit our ability to commercialize imetelstat and generate revenue, require us to expend significant time and resources in response, and generate negative publicity. Enforcement actions include, among others:

- adverse regulatory inspection findings;

- fines, warning letters, or untitled letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing imetelstat;
- restrictions on, or prohibitions against, importation or exportation of imetelstat;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for imetelstat;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

The imposition of any of these penalties or other commercial limitations, including equivalent penalties or commercial limitations imposed by foreign regulatory authorities, would severely and adversely affect our financial results, business and business prospects, including the potential commercialization of imetelstat, and the future of imetelstat, and might cause us to cease operations.

We are seeking regulatory approval to market imetelstat in Europe, and as a result, we may experience additional risks related to marketing outside of the U.S. that would materially adversely affect our business.

We are seeking regulatory approval to market imetelstat in Europe, and may be subject to additional risks, including, if regulatory approval is obtained from the European Commission, risks related to operating outside of the U.S., such as:

- European Commission and other foreign regulatory approvals, if any, may take longer and be more costly to obtain than approvals in the U.S., due to differing regulatory requirements in foreign countries;
- EMA and other regulatory authorities outside of the U.S. may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of EMA or other regulatory authorities outside of the U.S. may significantly change in a manner rendering our clinical data insufficient for potential approval;
- we may experience unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- risks of potential noncompliance with legal requirements applicable to privacy, data protection, information security and other matters;
- risks of potential noncompliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- increased taxes outside of the U.S., including withholding and payroll taxes;
- significant foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of the U.S.;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable regulations outside of the U.S.;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Uncertainty in the regulatory framework and future legislation could lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Changes to existing regulations may add considerably to the time from clinical development to marketing authorization and commercialization of products in the EU and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

If we fail to comply with federal, state and international healthcare laws, including fraud and abuse, transparency, and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including federal and state fraud and abuse laws, including anti-kickback and false claims laws; data privacy and security laws, including the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH; and transparency laws related to payments and/or other transfers of value made to physicians, other healthcare professionals and teaching hospitals. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute imetelstat, if marketing approval is obtained. For details regarding the restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate, see Item 1 "Business—Government Regulation— Fraud and Abuse, and Transparency Laws and Regulations."

Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. If our operations are found to be in violation of any of these or any other healthcare and privacy-related regulatory laws that may apply to us, our ability to operate our business and our results of operations could be adversely affected by:

- the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement and imprisonment;
- possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs;
- reputational harm;
- diminished profits and future earnings;
- additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws; and
- curtailment of our operations.

Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

RISKS RELATED TO MANUFACTURING IMETELSTAT

Failure by us to establish and/or maintain a manufacturing supply chain to appropriately and adequately supply imetelstat for future clinical and commercial uses would result in a further delay in or cessation of clinical trials and a delay in our ability to obtain regulatory approvals of imetelstat, and affect our ability to commercialize imetelstat, and our business and business prospects could be severely harmed, and we could cease operations.

The manufacture of imetelstat must comply with applicable regulatory standards for current and potential future clinical trials and potential commercial uses. The process of manufacturing imetelstat is complex and subject to several risks, including:

- the ability to scale-up and attain sufficient production yields with appropriate quality control and quality assurance to meet the needs of our clinical trials and potential future market demand, and to establish commercial supply agreements;
- reliance on third-party manufacturers and suppliers, whose efforts we do not control;
- supply chain issues, including the timely availability and shelf life requirements of raw materials and other supplies, any of which may be impacted by a number of factors, including the effects of macroeconomic or other global conditions;
- shortage of qualified personnel; and
- regulatory acceptance and compliance with regulatory requirements, which are less well-defined for oligonucleotide products than for small molecule drugs and vary in each country where imetelstat might be sold or used.

As a result of these and other risks, we may be unable to establish and/or maintain a manufacturing infrastructure and supply chain capable of providing imetelstat for our clinical trials, our expanded access program, and potential future commercial uses, which would delay or result in a cessation of such current or potential future clinical trials, potential regulatory approvals and commercialization of imetelstat and cause financial and reputational harm.

If third parties that manufacture imetelstat fail to perform as needed, the clinical and commercial supply of imetelstat will be limited, and we may be unable to conduct or complete current or potential future clinical trials of imetelstat or to commercialize imetelstat in the future.

Our imetelstat manufacturing supply chain relies, and will continue to rely, solely upon third-party manufacturers to perform certain process development or other technical and scientific work with respect to imetelstat, as well as to supply starting materials and manufacture drug substance and drug product. While we have established arrangements with third parties for the manufacture of imetelstat, our manufacturing supply chain is highly specialized, and as such we are reliant upon a small group of third-party manufacturers to supply starting materials, drug substance and drug product. Failure by such third-party manufacturers to perform in a timely manner and in compliance with all regulatory requirements, or at all, could further delay, perhaps substantially, or preclude our ability to pursue imetelstat development on our own, increase our costs and otherwise negatively affect our financial results, business and business prospects. In this regard, recent FDA inspections of one of our third-party manufacturers identified certain deficiencies in the manufacturer's processes and facilities which, while not directly related to the production of imetelstat, could impact the manufacturer's ability to produce and deliver products, including imetelstat, if not remediated by the manufacturer, and could lead to delays or shortages in drug supply, or the inability to manufacture or ship drug supply necessary for non-clinical and clinical activities and commercialization. We expect to rely on third-party manufacturers to produce and deliver sufficient quantities of imetelstat and other materials to support clinical trials and potential commercialization on a timely basis and to comply with applicable regulatory requirements. We do not have direct control over these third-party personnel or operations. Reliance on these third-party manufacturers is subject to numerous risks, including:

- the inability to execute timely contracts with third-party manufacturers and suppliers on acceptable terms, or at all;
- delays and disruptions experienced by third-party manufacturers that adversely impact the ability of such parties to fulfill their contractual obligations to us;
- capacity limitations and scheduling constraints experienced by third-party manufacturers due to scheduling and other commitments, and queued manufacturing activities in contracted facilities;

- requirements by regulatory authorities to validate and qualify significant activities for any current or replacement manufacturer, which could involve new testing and compliance inspections;
- the inability of third-party manufacturers to timely formulate and manufacture imetelstat or to produce or ship imetelstat in the quantities or of the quality required to meet clinical and commercial needs;
- the possible mislabeling by third-party manufacturers of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or comparator not being properly identified;
- decisions by third-party manufacturers to exit the contract manufacturing business during the time required to supply clinical trials or to successfully produce, store and distribute imetelstat to meet commercial needs;
- compliance by third-party manufacturers with GMP standards mandated by the FDA and state agencies and other government regulations, including foreign governing regulations, corresponding to similar international regulatory authorities, including any deficiencies identified during regulatory inspections, such as those identified in a recent FDA inspection of one of our third-party manufacturers;
- breach or termination of manufacturing or supply contracts;
- inadequate storage or maintenance at contracted facilities resulting in theft or spoilage; and
- natural disasters that affect contracted facilities.

Each of these risks could lead to delays or shortages in drug supply, or the inability to manufacture or ship drug supply necessary for non-clinical and clinical activities, and commercialization, which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat and cause reputational harm.

In addition, third-party manufacturers and/or any other manufacturers 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 of imetelstat. These third-party manufacturers may not be willing or able to achieve such capacity increases, cost reductions, or regulatory and compliance standards, and even if they do, such achievements may not be at commercially reasonable costs. Changing manufacturers may be prolonged and difficult due to inherent technical complexities and because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms, or at all.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

Our failure to obtain additional capital would force us to further delay, reduce or eliminate development and potential future commercialization of imetelstat, any of which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

Successful drug development and commercialization requires significant amounts of capital. As of December 31, 2023, we had approximately $378.1 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities. Based on our current operating plan and our assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower-risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of outstanding warrants, and potential future drawdowns under the Loan Agreement, will be sufficient to fund our projected operating requirements into the third quarter of 2025. Our ability to generate revenues from sales of imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner or at all. In addition, we cannot predict with any certainty whether and to what extent the remaining outstanding warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all. Our ability to drawdown any remaining tranches under the Loan Agreement is subject to our achievement of certain regulatory milestones and satisfaction of certain capitalization requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche. In addition, even if imetelstat is approved in lower-risk MDS and commercialized by us in the U.S. in that indication and we are able to drawdown the remaining tranches under the Loan Agreement in full, we will still require substantial additional funding to further advance the imetelstat program, including through the completion of our ongoing clinical trials and any potential future clinical trials, as well as conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other indications we are pursuing or may pursue, and our need for additional funds

may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

Because the outcome of any clinical activities and/or regulatory approval process is highly uncertain, we cannot reasonably estimate whether any development activities we may undertake will succeed; whether we will obtain regulatory approval for imetelstat in any indication we pursue, including in lower-risk MDS; or, if approved, whether we will be able to effectively commercialize imetelstat, if at all. We may never recoup our investment in any imetelstat development which would adversely affect our financial condition and our business and business prospects, and might cause us to cease operations. In addition, our plans and timing expectations could be further delayed or interrupted by the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues. Further, our future capital requirements are difficult to forecast and will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs;
- the scope, progress, timing, magnitude and costs of non-clinical and clinical development, manufacturing and potential commercialization of imetelstat, including the number of indications being pursued, subject to clearances and approvals by the FDA and similar international regulatory authorities;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in our current or any potential future clinical trials of imetelstat;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, including with respect to our NDA and EMA submissions for imetelstat in lower-risk MDS;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing, developing, commercializing and marketing imetelstat, including with respect to third-party vendors and service providers and our ability to achieve any meaningful reduction in manufacturing costs, if imetelstat receives future regulatory approval or clearance, in the U.S., EU or other countries;
- the sales price for imetelstat, if any;
- the availability of coverage and adequate third-party reimbursement for imetelstat, if any;
- the extent to which we acquire or in-license other drugs and technologies, or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions, or to which we out-license imetelstat;
- the extent to which we are able to enter into and conduct successful strategic partnerships, collaborations and alliances or licensing arrangements with third parties, including for the commercialization and marketing of imetelstat in certain global regions;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation;
- our level of indebtedness and associated debt service obligations;
- the costs of maintaining and operating facilities in California and New Jersey, as well as higher expenses for travel;
- macroeconomic or other global conditions that may reduce our ability to access debt capital or financing on preferable terms, which may adversely affect future capital requirements and forecasts; and
- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

Until we can generate a sufficient amount of revenue from imetelstat to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, which may not be possible. Availability of such financing sources may be negatively impacted by any further delays in our clinical trials, regulatory developments, or the other risks described in this section.

Additional financing through public or private debt or equity financings, including pursuant to the 2023 Sales Agreement with B. Riley Securities, Inc., or B. Riley, the remaining tranches of up to $45.0 million available under the Loan Agreement, which are subject to the achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche; capital lease transactions or other financing sources, may not be available on acceptable terms, or at all. We may be unable to raise equity capital, or may be forced to do so at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private debt and equity markets to proposed financings has been substantially affected by uncertainty in the general economic, market and political climate due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, and may in the future be affected by other factors which are unpredictable and over which we have no control. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, which could reduce or eliminate our ability to raise additional funds through financings, and could negatively impact the terms upon which we may raise those funds. Similarly, these macroeconomic conditions have created extreme volatility and disruption in the capital markets and is expected to have further global economic consequences. If the equity and credit markets deteriorate, including as a result of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development and potential commercialization of imetelstat may be further delayed, altered or abandoned, which might cause us to cease operations.

In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Due to uncertainty in the general economic, market and political climate, we may determine that it is necessary or appropriate to raise additional funds proactively to meet longer-term anticipated operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the 2023 Sales Agreement, your ownership interest as a stockholder may be diluted, and the terms may include liquidation or other preferences that materially and adversely affect your rights as a stockholder. In addition, we have borrowed, and in the future may borrow, additional capital from institutional and commercial banking sources to fund imetelstat development and our future growth, including pursuant to our Loan Agreement or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as the Loan Agreement, that include restrictive covenants, including covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Moreover, if we raise additional funds through alliance, collaborative or licensing arrangements with third parties, we may have to relinquish valuable rights to imetelstat or our technologies or grant licenses on terms that are not favorable to us.

We cannot assure you that our existing capital resources, future interest income, future revenues from sales of imetelstat, if approved, potential future sales of our common stock, including under the 2023 Sales Agreement, and potential future drawdowns, if available, of the remaining tranches under the Loan Agreement, will be sufficient to fund our operating plans. Moreover, while we did not hold cash deposits or securities at SVB, if other banks and financial institutions enter receivership, become insolvent or otherwise fail in the future in response to financial conditions affecting the banking system and financial markets or otherwise, our ability to access our cash, cash equivalents and marketable securities may be delayed or precluded, which could have a material adverse effect on our business, business prospects and financial position.

We currently have no source of product revenue and may never become profitable.

Although in the past we have received license and other payments under former license and collaboration agreements, we do not currently have any material revenue-generating license or collaboration agreements, have no products approved for commercialization and have never generated any revenue from product sales. In addition, we are incurring and have incurred operating losses every year since our operations began in 1990, except for one. As of December 31, 2023, our accumulated deficit was approximately $1.6 billion. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations.

Substantially all of our revenues to date have been payments under collaboration agreements and milestones, royalties and other revenues from our licensing arrangements. Our license agreements related to our human telomerase reverse transcriptase, or hTERT, technology have expired or been terminated due to expiration of the underlying hTERT patents, and will not generate any further revenues. We have no ongoing collaborations related to imetelstat and have no current plans to enter into any corporate collaboration, partnership or license agreements that result in revenues, although we may seek a collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat, especially outside the U.S., and to provide funding for such activities.

We also expect to experience increased negative cash flow for the foreseeable future as we fund our operations and imetelstat clinical development activities and research programs continue, and we prepare for potential commercialization of imetelstat. This will result in decreases in our working capital, total assets and stockholders' equity. We will need to generate significant revenues to achieve consistent future profitability. We may never achieve consistent future profitability. Even if we do become profitable in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve consistent future profitability could negatively impact the market price of our common stock and our ability to sustain operations.

RISKS RELATED TO OUR INDEBTEDNESS

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

As of December 31, 2023, the total outstanding principal amount under the Loan Agreement was $80.0 million. The tranches for the remaining $45.0 million available to us under the Loan Agreement are as follows: (a) the first remaining tranche of $20.0 million is available until December 15, 2024, subject to the achievement of a certain regulatory milestone, and satisfaction of certain capitalization requirements; and (b) the second remaining tranche of $25.0 million is available through December 31, 2024, subject to approval by an investment committee comprised of Hercules and SVB. Without the achievement of the required regulatory milestone and satisfaction of certain capitalization and other requirements, we will not be eligible to draw funds under the first remaining tranche. If we do not receive investment committee approval, we will not be eligible to draw funds under the second remaining tranche under the Loan Agreement. In addition, before we would consider drawing down any of the remaining tranches under the Loan Agreement, if available, we must first satisfy ourselves that we will have access to future alternate sources of capital, such as from commercial revenues or the equity capital markets or debt capital markets, in order to repay any additional principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

All obligations under the Loan Agreement are secured by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge. Further, the terms of the Loan Agreement place restrictions on our operating and financial flexibility, and limit or prohibit our ability to dispose of certain assets, change our line of business, and engage in other significant transactions. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing the outstanding debt obligations at maturity. If we are able to draw down any of the remaining tranches under the Loan Agreement, our indebtedness will increase, which would further increase our risk of being unable to pay off or refinance our outstanding debt obligations at maturity.

Our indebtedness could also have important negative consequences, including:

- we will need to repay the indebtedness by making payments of interest and principal, which will reduce the amount of cash available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the obligations of our affirmative and restrictive covenants in the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules and SVB could seek to enforce their security interest in the assets securing such indebtedness.

In addition, we may borrow additional capital in the future to fund imetelstat development and our future growth, including pursuant to the Loan Agreement or potentially pursuant to new arrangements with different lenders. To the extent additional debt is added to our current debt levels, the risks described above could increase.

The terms of the Loan Agreement place restrictions on our operating and financial flexibility.

The Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiaries to, among other things:

- dispose of certain assets;
- change our line of business;
- engage in mergers, acquisitions or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make contributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

The Loan Agreement also contains financial covenants, including that we must maintain a minimum cash balance. The breach of any of these restrictive covenants or any other terms of the Loan Agreement would accelerate our obligation to repay our indebtedness under the Loan Agreement, which could have a material adverse effect on our business, business prospects and financial position.

We may not have cash available in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the state of the capital and lending markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Failure to satisfy our current and future debt obligations under the Loan Agreement or to comply with certain covenants in the Loan Agreement could result in an event of default, the occurrence and continuance of which provide Hercules and SVB with the right to demand immediate repayment of all outstanding obligations under the Loan Agreement, and to exercise remedies against us and the collateral securing the Loan Agreement. These events of default include, among other things:

- insolvency, liquidation, bankruptcy or similar events;
- failure to observe any covenant or secured obligation under the Loan Agreement, which failure, in most cases, is not cured within 15 days;
- occurrence of an event that could reasonably be expected to have a material adverse effect on our business, operations, properties, assets or financial condition;
- material misrepresentations;
- occurrence of any default under any other agreement involving indebtedness in excess of specified amounts, or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect on us; and
- certain money judgments being entered against us or any portion of our assets are attached or seized.

In the event of default, Hercules and SVB could accelerate all of the amounts due under the Loan Agreement. Under such circumstances, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate imetelstat development or potential commercialization efforts or grant to others rights to develop and market imetelstat. Hercules and SVB could also exercise their rights to take possession and dispose of the collateral securing the Loan Agreement, which collateral includes substantially all of our property other than intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat, both in the U.S. and in other countries, our competitors could develop and commercialize products similar or identical to imetelstat, and our ability to successfully commercialize imetelstat may be adversely affected.

Protection of our proprietary technology is critically important to our business. Our success and the success of our planned future development and commercialization of imetelstat will depend on our ability to protect our technologies and imetelstat through patents and other intellectual property rights. Our success will depend in part on our ability to obtain, maintain, enforce, and extend our patents and maintain trade secrets, both in the U.S. and in other countries.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and in other countries. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing imetelstat or our technology and/or limit the duration of the patent protection for imetelstat and our technology. In the event that we are unsuccessful in obtaining, maintaining, enforcing and extending our patents and other intellectual property rights or having our licensors maintain the intellectual property rights we have licensed, the value of imetelstat and/or our technologies will be adversely affected, and we may not be able to further develop or potentially commercialize imetelstat.

While we have method-of-use patents that protect the use of imetelstat for the treatment of certain diseases, this type of patent does not prevent a generic competitor from making and marketing a product that is identical to imetelstat for an indication that is outside the scope of our approved use after our composition-of-matter patents or their patent term extensions have expired. Moreover, even if competitors do not actively promote their product for our approved indications, physicians may prescribe or use these generic products "off-label," which would result in decreased sales for us.

Loss or impairment of our intellectual property rights related to imetelstat might further delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval, and might further delay or preclude any future development or commercialization of imetelstat by us. Furthermore, if imetelstat is approved for commercial sale, such loss of intellectual property rights could impair our ability to exclude others from commercializing products similar or identical to imetelstat and therefore result in decreased sales for us. Occurrence of any of these events would materially and adversely affect our financial results, business and business prospects and the future of imetelstat, and might cause us to cease operations.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The U.S. Patent and Trademark Office, or the Patent Office, and various governmental patent agencies in other countries require compliance with a number of procedural, documentary, fee payment, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications. Failure to respond to official actions within prescribed time limits, and nonpayment of fees, for example, maintenance fees, renewal fees, and annuity fees could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the jurisdiction. In such an event, potential competitors might be able to enter the market with imetelstat or similar products, and this circumstance could harm our financial condition, business and business prospects and the future of imetelstat. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us or jointly owned with us, any of the foregoing could expose us to liability to the applicable patent owner or patent co-owner.

Patent terms may be inadequate to protect our competitive position on imetelstat for an adequate amount of time.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after its first effective nonprovisional filing date. Given the amount of time required for the development, testing and regulatory review of imetelstat, patents protecting imetelstat might expire before imetelstat is commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to imetelstat.

In the U.S., the Hatch-Waxman Act permits one patent per approved product to receive a patent term extension of up to five years beyond its normal expiration. The length of the patent term extension is typically

calculated as one half of the clinical trial period plus the entire period of time during the review of the NDA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. Only one U.S. patent may be eligible for patent term extension under the Hatch-Waxman Act. We plan to apply to the Patent Office for patent term extension of one or more patent(s). Once the Patent Office and the FDA determine the extension period for each proposed eligible patent, we will select the one patent to be extended. Currently, communication of patent term extension approval and the length of the granted extension period by the Patent Office may occur up to five years from filing of an application for patent term extension. Accordingly, we will decide on the specific patent to be extended only after such communication from the Patent Office.

Similar extensions are also available in certain countries and territories outside the U.S., such as in Japan, and in Europe as Supplementary Protection Certificates, or SPCs. If we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the Patent Office in the U.S., and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. Should we seek a patent term extension, we may not be granted any such patent term extension and/or the applicable time period of such patent term extension could be less than five years. Moreover, in some countries, including the U.S., the scope of protection for claims under such patent term extensions, if any, does not extend to the full scope of the claims but is limited to the product composition as approved and, for a method of treatment patent, is limited to the approved indication. Thus, for example, if we do not receive a patent term extension for our U.S. composition-of-matter patent for imetelstat, as approved by the regulatory authorities, our U.S. composition-of-matter patent will expire in December 2025. If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

In Europe and other countries, our composition of matter patent coverage expires in September 2024, and our method of treatment patent rights for MDS and MF expire in November 2033. Our method of treatment patents may be eligible for patent term extension under a Supplementary Protection Certificate, or SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation, upon receipt of drug product approval, such as, for example, our method of treatment patent for MDS. Since we do not expect to receive marketing approval and submit a request for an SPC before September 2024, our European composition of matter patent will expire in countries of the European Economic Area, or EEA, and we must rely on regulatory exclusivity and our method of treatment patents.

If regulatory approval of imetelstat occurs after a patent has expired in a country that does not allow interim patent term extensions, as is the case in many countries and territories including Europe, we will be unable to obtain any patent term extension of that expired patent, and the duration of our patent rights may be limited.If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

Also, there are regulations for the listing of patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. If we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If imetelstat is approved for commercial sale and an appropriate patent covering imetelstat is not listed in the Orange Book or is subsequently removed from the Orange Book, a manufacturer of generic drugs would not be required to provide advance notice to us of any abbreviated NDA filed with the FDA to obtain permission to sell a generic version of imetelstat. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Changes in U.S. or international patent law or interpretations of such patent laws could diminish the value of our patents in general, thereby impairing our ability to protect our technologies and imetelstat.

The patent positions of pharmaceutical and biopharmaceutical companies, including ours, are highly uncertain and involve complex legal and technical questions. In particular, legal principles for biotechnology and pharmaceutical patents in the U.S. and in other countries are evolving, and the extent to which we will be able to obtain patent coverage to protect our technologies and imetelstat, or enforce or defend issued patents, is uncertain.

The U.S. has enacted and implemented wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act, or the AIA, signed into law on September 16, 2011. The U.S. Supreme Court has ruled on

several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on actions by Congress, the federal courts, and the Patent Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our existing patents or patents that we may obtain in the future. Occurrence of these events and/or significant impairment of our imetelstat patent rights would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, which might cause us to cease operations.

As a result of the AIA, in March 2013, the U.S. transitioned to a first-inventor-to-file system under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, since the publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years, we are not able to be certain upon filing a patent application that the persons or entities that we name as inventors or applicants in our patent applications were the first to invent the inventions disclosed therein, or the first to file patent applications for these inventions. Thus, our ability to protect our patentable intellectual property depends, in part, on our ability to be the first to file patent applications with respect to our inventions, or inventions that were developed by our former collaboration partner and assigned to us, for the future development, commercialization and manufacture of imetelstat. As a result, if we are not the first inventor-to-file, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be significant to the future success of imetelstat. Delay in the filing of a patent application for any purpose, including further development or refinement of an invention, may result in the risk of loss of patent rights.

In 2012, the European Patent Package, or EU Patent Package, was approved and included regulations with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. The EU Patent Package was ratified in February 2023 and currently covers certain EU states. As of June 1, 2023, all European patents, including those issued prior to ratification, by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions and be at risk of central revocation at the UPC in participating UPC states. Under the EU Patent Package, patent holders are permitted to "opt out" of the UPC on a patent-by-patent basis during an initial seven year transitional period after June 1, 2023. Owners of European patent applications who receive notice of grant after the EU Patent Package came into effect could, for the UPC contracting states, either obtain a Unitary Patent or validate the patent nationally and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

Filing, prosecuting, maintaining, defending and enforcing patents for imetelstat and our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. are less extensive than those in the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover imetelstat and our technologies.

We may not be able to protect our intellectual property rights in the U.S or worldwide and challenges to our owned or licensed patent rights would result in costly and time-consuming legal proceedings that could prevent or limit development or potential commercialization of imetelstat.

Our patents or those patent rights we have licensed, including patent rights that we may seek with respect to inventions made by past or future collaborators, may be challenged through administrative or judicial proceedings, which could result in the loss of important patent rights. For example, where more than one party seeks U.S. patent protection for the same technology in patent applications that are subject to the law before the implementation of the AIA, the Patent Office may declare an interference proceeding in order to ascertain the party to which the patent should be issued. Patent interferences are typically complex, highly contested legal proceedings, subject to appeal. They are usually expensive and prolonged and can cause significant delay in the issuance of patents. Our pending patent applications or our issued patents, or those we have licensed and may license from others, may be drawn into interference proceedings or be challenged through post-grant review procedures or litigation, any of which could delay or prevent the issuance of patents, or result in the loss of issued patent rights. We may not be able to obtain from our past or future collaborators the information needed to support our patent rights which could result in the loss of important patent rights.

Under the AIA, interference proceedings between patent applications filed on or after March 16, 2013, have been replaced with other types of proceedings, including derivation proceedings. The AIA also includes post-grant review procedures subjecting U.S. patents to post-grant review procedures similar to European oppositions, such as *inter partes* review, or IPR, covered business method post-grant reviews and other post-grant reviews. This applies to all our U.S. patents and those we have licensed and may license from others, even those issued before March 16, 2013. A third party could attempt to use the Patent Office procedures to invalidate patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. U.S. patents owned or licensed by us may therefore be subject to post-grant review procedures, as well as other forms of review and re-examination. In addition, the IPR process under the AIA permits any person, whether they are accused of infringing the patent at issue or not, such as entities associated with hedge funds, to challenge the validity of certain patents. Significant impairment of our imetelstat patent rights would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, which might cause us to cease operations.

Certain jurisdictions, such as Europe, New Zealand and Australia, permit oppositions to be filed against granted patents or patents proposed to be granted. Because we seek to enable potential global commercialization of imetelstat, securing both proprietary protection and freedom to operate outside of the U.S. is important to our business. Opposition proceedings require significant time and costs, and if we are unsuccessful or are unable to commit these types of resources to protect our imetelstat patent rights, we could lose our patent rights and we could be prevented or limited in the development and commercialization of imetelstat.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions outside the U.S. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, many countries outside the U.S. have compulsory licensing laws under which a patent owner must grant licenses to third parties. Proceedings to enforce our patent rights in jurisdictions outside the U.S. could result in substantial costs and divert our efforts and attention from other aspects of our business, and could put our patents at risk of being invalidated or interpreted narrowly.

As more groups become engaged in scientific research and product development in the areas of telomerase biology and hematologic malignancies, the risk of our patents, or patents that we have in-licensed, being challenged through patent interferences, derivation proceedings, IPRs, post-grant proceedings, oppositions, re-examinations, litigation or other means will likely increase. Challenges to our patents through these procedures would be extremely expensive and time-consuming, even if the outcome was favorable to us. An adverse outcome in a patent dispute could severely harm our ability to further develop or commercialize imetelstat, or could otherwise have a material adverse effect on our business, and might cause us to cease operations, by:

- causing us to lose patent rights in the relevant jurisdiction(s);
- subjecting us to litigation, or otherwise preventing us from commercializing imetelstat in the relevant jurisdiction(s);
- requiring us to obtain licenses to the disputed patents;
- forcing us to cease using the disputed technology; or
- requiring us to develop or obtain alternative technologies.

We may be subject to infringement claims that are costly to defend, and such claims may limit our ability to use disputed technologies and prevent us from pursuing research, development, manufacturing or commercialization of imetelstat.

The commercial success of imetelstat will depend upon our ability to research, develop, manufacture, market and sell imetelstat without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and many pharmaceutical companies, including potential competitors, have substantial patent portfolios. Since we cannot be aware of all intellectual property rights potentially relating to imetelstat and its uses, we do not know with certainty that imetelstat, or the intended commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property. For example, we are aware that certain third parties have or may be prosecuting patents and patent estates that may relate to imetelstat, and while we believe these patents will expire before imetelstat is able to be commercialized and/or that these patents are invalid and/or would not be

infringed by the manufacture, use or sale of imetelstat, it is possible that the owner(s) of these patents will assert claims against us in the future.

In the event our technologies infringe the rights of others or require the use of discoveries and technologies controlled by third parties, we may be prevented from pursuing research, development, manufacturing or commercialization of imetelstat, or may be required to obtain unblocking licenses from such third parties, develop alternative non-infringing technologies, which we may not be able to do at an acceptable cost or on acceptable terms, or at all, or cease the development of imetelstat. If we are unable to resolve an infringement claim successfully, we could be subject to an injunction that would prevent us from potentially commercializing imetelstat and could also require us to pay substantial damages. In addition, while our past collaboration agreements have terminated, we are still subject to indemnification obligations to certain collaborators, including with respect to claims of third-party patent infringement.

In addition to infringement claims, in the future we may also be subject to other claims relating to intellectual property, such as claims that we have misappropriated the trade secrets of third parties. Provided that we are successful in continuing the development of imetelstat, we expect to see more efforts by others to obtain patents that are positioned to cover imetelstat. Our success therefore depends significantly on our ability to operate without infringing patents and the proprietary rights of others.

We may become aware of discoveries and technologies controlled by third parties that are advantageous or necessary to further develop or manufacture imetelstat. Under such circumstances, we may initiate negotiations for licenses to other technologies as the need or opportunity arises. We may not be able to obtain a license to a technology required to pursue the research, development, manufacturing or commercialization of imetelstat on commercially favorable terms, or at all, or such licenses may be terminated on certain grounds, including as a result of our failure to comply with any material obligations under such licenses. If we do not obtain a necessary license or if such a license is terminated, we may need to redesign such technologies or obtain rights to alternative technologies, which may not be possible, and even if possible, could cause further delays in the development efforts for imetelstat and could increase the development and/or production costs of imetelstat. In cases where we are unable to license necessary technologies, we could be subject to litigation and prevented from pursuing research, development, manufacturing or commercialization of imetelstat, which would materially and adversely impact our business. Failure by us to obtain rights to alternative technologies or a license to any technology that may be required to pursue research, development, manufacturing or commercialization of imetelstat would further delay current and potential future clinical trials of imetelstat and any applications for regulatory approval, impair our ability to sell imetelstat, if approved, and therefore result in decreased sales of imetelstat for us. Occurrence of any of these events would materially and adversely affect our business and might cause us to cease operations.

We are seeking registered trademarks for a commercial trade name for imetelstat in the U.S. and jurisdictions outside of the U.S. and failure to secure and maintain such registrations could adversely affect our business.

We have secured a global trademark for a commercial trade name for imetelstat. During trademark registration proceedings, we may receive rejections or fail to maintain such registrations. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If our United States application which forms the basis for our international registration, or IR, for our commercial trade name is refused, withdrawn, or abandoned within the first 5 years of our IR we will lose our IR registrations which could adversely affect our business. Our product trademark is approved by the EMA and provisionally approved by the FDA. If the FDA or EMA should reject the trademark, we may be required to expend additional time and resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA and the EMA.

We may become involved in disputes with past or future collaborator(s) over intellectual property inventorship, ownership or use, and publications by us, or by investigators, scientific consultants, research collaborators or others. Such disputes could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant impact on our business.

Inventions discovered under research, material transfer or other collaboration agreements may become jointly owned by us and the other party to such agreements in some cases and may be the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who invents and owns a particular invention, or whether it is jointly owned, and disputes can arise regarding inventorship, ownership and use of those inventions. These disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business if we are not able to protect or license rights to these inventions. In addition, clinical trial investigators, scientific consultants and research collaborators generally have contractual

rights to publish data and other proprietary information, subject to review by the trial sponsor. Publications by us, or by investigators, scientific consultants, previous employees, research collaborators or others, either with permission or in contravention of the terms of their agreements with us or with our past or future collaborators, may impair our ability to obtain patent protection or protect proprietary information which would have a material adverse effect on our business, and might cause us to cease operations.

Much of the information and know-how that is critical to our business is not patentable, and we may not be able to prevent others from obtaining this information and establishing competitive enterprises.

We rely on trade secrets to protect our proprietary technology, especially in circumstances in which we believe patent protection is not appropriate or available. We attempt to protect our proprietary technology in part by confidentiality agreements with our employees, consultants, collaborators and contractors. However, we cannot provide assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors, any of which would harm our business significantly.

In May 2016, the Defend Trade Secrets Act of 2016, or the DTSA, was enacted, providing a federal cause of action for misappropriation of trade secrets. Under the DTSA, an employer may not collect enhanced damages or attorney fees from an employee or contractor in a trade secret dispute brought under the DTSA, unless certain advanced provisions are observed. We cannot provide assurance that our existing agreements with employees and contractors contain notice provisions that would enable us to seek enhanced damages or attorneys' fees in the event of any dispute for misappropriation of trade secrets brought under the DTSA.

RISKS RELATED TO MANAGING OUR GROWTH AND OTHER BUSINESS OPERATIONS

We may be unable to successfully retain or recruit key personnel to support the development and potential future commercialization of imetelstat or to otherwise successfully manage our growth.

Our ability to successfully develop imetelstat in the future and to potentially commercialize imetelstat depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our staff. In addition, we need to recruit, maintain, motivate and integrate additional personnel with expertise and experience in clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing, regulatory affairs, medical affairs, legal affairs, compliance, market access, pricing, commercial operations, sales, and marketing, to enable us to further develop and potentially commercialize imetelstat.

We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions, and competition in our geographic regions is particularly intense. The substantial risks and uncertainties related to our development and the potential approval and commercialization of imetelstat, and the risks and uncertainties regarding our future business viability could have an adverse impact on our ability to retain and recruit qualified personnel. We may also face higher than expected personnel costs in order to attract new personnel due to shortages in qualified applicants, or to maintain our current management and personnel due to the increased number of opportunities in the biotechnology sector. If we are unable to successfully retain, motivate and incentivize our existing personnel, or to attract, assimilate and retain other highly qualified personnel in the future on acceptable terms, our ability to further develop and potentially commercialize imetelstat will be impaired, and our business and the price of our common stock would be adversely impacted.

In addition, our personnel are currently performing their duties in multiple jurisdictions, and if we are unable or fail to comply with employment, tax, benefits and other laws in such jurisdictions, we may face penalties, fines or litigation.

Our future financial performance and our ability to develop, manufacture and commercialize imetelstat will depend, in part, on our ability to effectively manage any future growth. Our management may have to divert financial and other resources, as well as devote a substantial amount of time, to managing growth activities, such as enhancing operational, financial and management processes and systems. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure and ability to comply with applicable legal and regulatory requirements and regulations, operational mistakes or shortcomings, loss of business opportunities, loss of employees and reduced productivity among remaining employees.

If we seek to establish potential future collaborative arrangements for imetelstat, we may be unable to establish such collaborative arrangements on acceptable terms, or at all, and may have to delay, alter or abandon our imetelstat development and commercialization plans.

We intend to develop imetelstat broadly for hematologic malignancies, and to potentially commercialize, market and sell imetelstat in the U.S. and the EU. We may seek a collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat, especially in the EU and other regions outside the U.S., and to provide funding for such activities. We face significant competition in seeking appropriate collaborative partners, and these potential collaborative arrangements are complex and time consuming to negotiate, document and implement. Our ability to seek and establish potential collaborative arrangements may be impacted by delays in marketing approvals of imetelstat in lower-risk MDS in the U.S. and/or EU and in reporting results from IMpactMF, as well as the period of the patent term for our intellectual property portfolio and market exclusivity for imetelstat. We may not be able to establish collaborative arrangements on acceptable terms, or at all. In this regard, collaborative arrangements with third parties may require us to relinquish material rights, including revenue from potential commercialization, or assume material ongoing development obligations that we would have to fund or otherwise support.

If we are unable to negotiate collaborative arrangements, we may have to:

- delay or curtail the additional development of imetelstat;
- further delay or abandon the potential commercialization of imetelstat outside of the U.S.;
- reduce the scope of potential future sales or marketing activities; or
- increase our expenditures and undertake development or commercialization activities at our own expense, which will require additional capital than our current resources.

We have established subsidiaries in the United Kingdom and the Netherlands, which exposes us to additional costs and risks.

The wholly-owned subsidiaries we have established in the U.K. and the Netherlands subject us to certain additional costs and risks associated with doing business outside the U.S., including:

- the increased complexity and costs inherent in managing international operations in geographically disparate locations;
- challenges and costs of complying with diverse regulatory, financial and legal requirements, which are subject to change at any time;
- potentially adverse tax consequences, including changes in applicable tax laws and regulations;
- potentially costly trade laws, tariffs, export quotas, custom duties or other trade restrictions, and any changes to them;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- natural disasters, political and economic instability, including terrorism and civil and political unrest, outbreak of health epidemics, including any resurgence of COVID-19, and the resulting global economic and social impacts; and
- workforce uncertainty in countries where labor unrest is more common than in the U.S.

In addition, our international operations in the U.K. and the Netherlands expose us to fluctuations in currency exchange rates between the British pound, the Euro and the U.S. dollar. Given the volatility of currency exchange rates, there is no assurance that we will be able to effectively manage currency transaction and/or conversion risks. To date, we have not entered into derivative instruments to offset the impact of foreign exchange fluctuations, which fluctuations could have an adverse effect on our financial condition and results of operations.

We may not be able to obtain or maintain sufficient insurance on commercially reasonable terms or with adequate coverage against potential liabilities in order to protect ourselves against product liability claims or claims related to clinical trial conduct, or claims related to data protection.

Our business exposes us to potential product liability and other risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We may become subject to product liability claims or claims related to clinical trial conduct or the potential commercialization of imetelstat, if any, including if the use of

imetelstat is alleged to have injured patients, such as injuries alleged to arise from any hepatotoxicity or hemorrhagic event associated with the use of imetelstat. We currently have limited product liability and clinical trial liability insurance, and we may not be able to maintain this type of insurance for the potential commercialization of imetelstat, if any, or any of our current or potential future clinical trials of imetelstat. In addition, this type of insurance may become too expensive for us to afford because of the highly risky and uncertain nature of potential commercialization of imetelstat, clinical trials generally and the high cost of insurance for our business activities. We may be unable to obtain or maintain clinical trial insurance in all of the jurisdictions where we conduct current or potential future clinical trials. In addition, business liability, product liability and cybersecurity insurance are becoming increasingly expensive, particularly for biotechnology and pharmaceutical companies, and the pool of insurers offering insurance coverage to biotechnology and pharmaceutical companies generally is becoming smaller, making it more difficult to obtain insurance for our business activities at a reasonable price, or at all. Being unable to obtain or maintain product liability, clinical trial liability, cybersecurity or other insurance for our business activities in the future on acceptable terms or with adequate coverage against potential liabilities would have a material adverse effect on our business, and could cause us to cease our development of imetelstat.

In the past, we and certain of our officers have been named as defendants in securities class action lawsuits and shareholder derivative lawsuits. Potential similar or related lawsuits that may be filed in the future, 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. Any such lawsuits, or other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome.

Securities-related class action lawsuits and/or derivative lawsuits have often been brought against companies, including biotechnology and biopharmaceutical companies, that experience volatility in the market price of their securities. This risk is especially relevant for us because we often experience significant stock price volatility in connection with our activities. In 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, were consolidated by the Court. In September 2022, the parties agreed to a settlement and entered into a Stipulation and Agreement of Settlement, which was subject to court approval. The Court granted final approval of the settlement on September 28, 2023 and final judgment was entered on October 3, 2023. In 2020 and 2021, seven shareholder derivative actions were filed in a number of courts, naming as defendants certain of our then current officers and certain of our then current and former members of our board. On May 17, 2023, the Delaware Court of Chancery approved a settlement of the derivative case pending before it, and the case was dismissed with prejudice. Subsequently, each of the remaining derivative cases were dismissed with prejudice.

While we have settled these lawsuits, it is possible that additional lawsuits might be filed, or allegations might be received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Such 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 such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of any additional lawsuits, and we may not prevail. In addition, we have and may continue to incur substantial legal fees and costs in connection with such lawsuits. Monitoring, initiating and defending against legal actions is time-consuming for our management, is likely to be expensive and may detract from our ability to fully focus our internal resources on our business activities. We could be forced to expend significant resources in any potential future lawsuits, and we may not prevail in such lawsuits. Additionally, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage.

A decision adverse to our interests in similar or related litigation, could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our business, our stock price, cash flow, results of operations and financial condition.

We may be subject to third-party litigation, and such litigation would be costly to defend or pursue and uncertain in its outcome.

Our business may 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. We may experience employment-related disputes as we seek to expand our personnel resources. We may become involved in performance or other disputes with the CROs we have retained to support our imetelstat clinical development activities, or with other third parties such as service providers, vendors, manufacturers, suppliers or consultants, which could result in a further delay or cessation of current and potential future clinical trials and otherwise significantly further delay our ability to develop or potentially commercialize imetelstat. 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.

Lawsuits are subject to inherent uncertainties, and defense and disposition costs depend upon many unknown factors. Despite the availability of insurance, we may incur substantial legal fees and costs in connection with litigation. Lawsuits could result in judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise negatively affect our legal or contractual rights, which could have a significant adverse effect on our business. In addition, the inherent uncertainty of such litigation could lead to increased volatility in our stock price and a decrease in the value of our stockholders' investment in our securities.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

RISKS RELATED TO COMPETITIVE FACTORS

If our competitors develop products, product candidates or technologies that are superior to or more cost-effective than imetelstat, this would significantly impact the development and commercial viability of imetelstat, which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

The pharmaceutical and biotechnology industries are characterized by intense and dynamic competition with rapidly advancing technologies and a strong emphasis on proprietary products. While we believe our proprietary oligonucleotide chemistry; experience with the biological mechanisms related to imetelstat, telomeres and telomerase; clinical data to date; and knowledge and expertise around the development of potential treatments for myeloid hematologic malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Imetelstat will compete, if approved, with other products and therapies that currently exist, are being developed or will in the future be developed, some of which we may not currently be aware of. For a description of the competition that imetelstat may face in our lead indications of lower-risk MDS and relapsed/refractory MF, see Item 1, "Business – Competition."

Many of our competitors, either alone or with their strategic partners, could have substantially greater financial, technical and human resources than we do and significantly greater experience in obtaining FDA and other regulatory approvals of treatments and commercializing those treatments.

Competitors may develop more commercially desirable or affordable products than imetelstat, or achieve earlier or longer patent protection or product commercialization than we may be able to achieve with imetelstat. Some of these products may have an entirely different approach or means of accomplishing therapeutic effects similar or superior 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. In addition, competitors may price their products below what we 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 us to cease any further development or future commercialization of imetelstat, which would severely and adversely affect our

financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

To be commercially successful, imetelstat must be accepted by the healthcare community, which can be very slow to adopt or unreceptive to new technologies and products.

Even if approved for marketing, imetelstat may not achieve market acceptance, or the potential U.S. or international revenue we believe may be possible, since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize imetelstat. If approved for commercial sale, imetelstat will compete with a number of conventional and widely accepted drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of imetelstat will depend on a number of factors, including:

- the clinical indications for which imetelstat is approved, if any;
- the countries and/or regions within which imetelstat is approved, if any;
- the establishment and demonstration to the medical community of the clinical efficacy and safety of imetelstat;
- the ability to demonstrate that imetelstat is superior to alternatives on the market at the time, including with respect to efficacy, safety, cost or route of administration;
- the willingness of medical professionals to prescribe, and patients to use, imetelstat, or to continue to use imetelstat;
- the publication of unfavorable safety or efficacy data concerning imetelstat by third parties or us;
- restrictions on use of imetelstat in combination with other products;
- the label and promotional claims allowed by the FDA or similar international regulatory authorities for imetelstat, if any, including usage for only certain indications and any limitations or warnings about the prevalence or severity of any side effects;
- the timing of market introduction of imetelstat as well as competitive products, including sequencing of available products;
- the effectiveness of sales, marketing and distribution support for imetelstat;
- the extent to which imetelstat is approved for inclusion on National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology and formularies in hospitals and managed care organizations;
- the pricing of imetelstat, both in absolute terms and relative to alternative treatments;
- the availability of coverage and adequate reimbursement by government and third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including governmental authorities.

We may be unable to demonstrate any therapeutic or economic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for myeloid hematologic malignancies. Third-party payors may decide that any potential benefit that imetelstat may provide to clinical outcomes in myeloid hematologic malignancies is not adequate to justify the costs of treatment with imetelstat. If the healthcare community does not accept imetelstat for any of the foregoing reasons, or for any other reasons, our ability to further develop or potentially commercialize imetelstat may be negatively impacted or precluded altogether, which would seriously and adversely affect our business and business prospects.

If the market opportunities for imetelstat are smaller than we believe, our potential revenue may be adversely affected, and our business may suffer.

Our initial focus for imetelstat development has been on the lead indications of lower-risk MDS and relapsed/refractory MF. The addressable patient populations, if imetelstat is approved in those indications, are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new information from us or others may change the estimated incidence or prevalence of those indications.

Any regulatory approval of imetelstat would be limited to the therapeutic indications examined in our clinical trials and as determined by the FDA and similar international regulatory authorities, which would not permit us to market imetelstat for any other indications not expressly approved by those regulatory authorities. Additionally, the potentially addressable patient population for imetelstat may not ultimately be amenable to treatment with imetelstat. Even if we receive regulatory approval for imetelstat, such approval could be conditioned upon label restrictions that materially limit the addressable patient population.

Our market opportunity may also be limited by the pricing we are able to achieve for imetelstat, if approved, the quality and expiration of our intellectual property rights and licenses, duration of imetelstat treatment in an indication and future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunities for imetelstat that we or any potential future collaborative partners develop could be significantly diminished which would have a material adverse impact on our business and business prospects.

The adoption of health policy changes and healthcare reform both in the U.S. and outside the U.S. may adversely affect our business and financial results.

In the U.S. and some jurisdictions outside the U.S., there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could impact our business. Generally, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing, including specialty drug pricing practices, in light of the rising cost of prescription drugs and biologics. Specifically, there have been U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, and reform government program reimbursement methodologies for drugs and biologics. For details regarding these legislative and regulatory changes and proposed changes regarding the healthcare system that may affect our ability to operate, see Item 1 “Business - Reimbursement and Healthcare Reform.”.

If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on future worldwide sales of imetelstat, if approved.

RISKS RELATED TO INFORMATION TECHNOLOGY SYSTEMS, DATA SECURITY AND DATA PRIVACY

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; reputational harm; loss of revenue and profits; and other adverse consequences.

In the ordinary course of our business, we (and third parties upon which we rely) collect, receive, store, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose, or otherwise process (commonly known as processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data and participant study related data), intellectual property, and trade secrets (collectively, sensitive information). In addition, we rely on third-party service providers to establish and maintain appropriate information technology and data security protections over the information technology systems they provide us to operate our critical business systems, including cloud-based infrastructure and systems, employee email, and data storage and management systems. However, except for contractual duties and obligations, we have limited ability to control or monitor third parties’ safeguards and actions related to such matters, and these third parties may not have adequate information security measures in place. Furthermore, while we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Most of our employees work remotely, resulting in increased risks to our information technology systems and data, as employees utilize network connections, computers, and devices outside our premises and networks, including working at home and while in transit and in public locations.

Additionally, the prevalent use of mobile devices that access our sensitive information increases the risk of security incidents.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Our information technology systems, including in our remote work environment, and those of the third parties upon which we rely, may be vulnerable to evolving threats. These threats are prevalent, continue to increase, and come from a variety of sources such as traditional "hackers," threat actors, ""hacktivist," organized criminal threats actors, or internal bad actors, personnel (such as through theft, error or misuse), sophisticated nation states and nation-state-supported actors. These threats include, but are not limited to, social-engineering attacks, malicious code or malware, unauthorized intrusions, denial-of-service attacks, personnel misconduct or errors, ransomware attacks, supply-chain attacks, software bugs, computer viruses, server malfunctions, software, hardware or data center failures, loss of data or other information technology assets, natural disasters, terrorism, war, telecommunication and electrical failures and attacks enhanced or facilitated by artificial intelligence, or AI, and other similar threats. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in operations, loss of data and income, reputational harm, and diversion of funds. If we were to experience such an attack, extortion payments might alleviate the negative impact of a ransomware attack, but we might be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks and attacks on clinical trial sites as well as regulatory and health authorities have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains, or of clinical trial sites and regulatory and health authorities, have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including those related to imetelstat) or the third-party information technology systems that support us and the services provided to us. Any of these threats may result in unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive information, such as clinical trial data or information, intellectual property, proprietary business data and personal data. The costs to us to attempt to protect against such security incidents could be significant, including potentially requiring us to modify our business, and while we have implemented security measures designed to protect our information technology systems and to identify and remediate vulnerabilities, such measures may not be successful. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are sophisticated in nature, and may not be detected until after a security incident has occurred. Unremediated high risk or critical vulnerabilities pose material risks to our business.

If we or third parties upon which we rely experience or are perceived to have experienced a breach, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), interruptions in our operations, including disruption of our imetelstat development program, interruptions or restrictions on processing sensitive data (which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the data), reputational harm, litigation (including class action claims), indemnification obligations, negative publicity, financial loss, and other harms. In addition, such a breach may require public notification of the breach. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Many of our contracts with relevant stakeholders include obligations relating to the safeguard of sensitive information, and a breach could lead to claims against us by such stakeholders. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities, damages, or claims relating to our data privacy and security obligations. In addition, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny.

We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts.

In the ordinary course of business, we process personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, clinical trial participant data, and other sensitive third-party data. We are therefore subject to or affected by numerous data privacy and security obligations, such as federal, state, local and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations governing the processing of personal data. These obligations may change, are subject to differing interpretations and may be inconsistent among jurisdictions or conflict. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business; affect us or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal data; necessitate the acceptance of more onerous obligations in our contracts; result in liability; or impose additional costs on us. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (GDPR) (EU) 2016/679, or the EU GDPR, imposes strict requirements on the processing of personal data. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines in the event of violations.

In addition, we may be unable to transfer personal data from the EEA and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. The EEA and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some EEA regulators have prevented companies from transferring personal data out of the EEA for allegedly violating the GDPR's cross-border data transfer limitations.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to data privacy and security in the U.S. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health data. Additionally, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or CPRA, collectively CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance. While the CCPA contains limited exceptions for clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. In addition, the CPRA establishes a California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of an enforcement action, and applies to personal information of business representatives and employees. Other states have also enacted data privacy and security laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and became effective in 2023. If we become subject to new data privacy and security laws, at the state level or otherwise, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

It is possible that, in the future, we may fail or be perceived to have failed to comply with applicable data privacy and security obligations. Moreover, despite our best compliance efforts, we may not be successful in achieving compliance if our personnel or third parties whom we rely on fail to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions; litigation; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations including, as relevant, clinical trials; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize imetelstat; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. Moreover, clinical trial participants or research subjects about whom we or our vendors obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

RISKS RELATED TO OUR COMMON STOCK AND FINANCIAL REPORTING

Historically, our stock price has been extremely volatile and your investment may suffer a decline in value.

Historically, our stock price has been extremely volatile. Between January 1, 2014 and December 31, 2023, our stock has traded as high as $6.38 per share and as low as $0.89 per share. Between January 1, 2023 and December 31, 2023, the price has ranged between a high of $3.84 per share and a low of $1.68 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- announcements regarding the potential regulatory approval or non-approval of imetelstat and the timing thereof, specific label indications for or restrictions, warnings or limitations in its use, or delays in the regulatory review and commercialization process;
- announcements regarding the research and development of imetelstat, or adverse efficacy or safety results of, further delays in the commencement, enrollment or conduct of, discontinuation of, or further modifications or refinements to any current clinical trials of imetelstat, as well as for our expanded access program or for potential future clinical trials of imetelstat, for any reason, or our inability, for any reason, to successfully continue the development of imetelstat;
- our ability to obtain additional capital when needed to further advance the imetelstat program;
- changes in laws or regulations applicable to imetelstat, including but not limited to clinical trial requirements for approval or other regulatory developments related to imetelstat;
- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, potential future collaborative partners or our competitors;
- adverse developments concerning our manufacturers, including our inability to obtain adequate product supply for imetelstat or inability to do so at acceptable prices;
- the size and growth of the market for our lead imetelstat indications of lower-risk MDS and relapsed/refractory MF;
- disputes or other developments relating to imetelstat proprietary rights, including patents, litigation matters and our ability to obtain, enforce and defend patent protection for our technologies;

- the terms and timing of any future collaboration agreements for the development and potential commercialization of imetelstat that we may establish;
- announcements of significant acquisitions, strategic partnerships, collaborations, joint ventures or capital commitments by us or our competitors;
- the demand in the market for our common stock;
- increased or continuing operating losses;
- general domestic and international market conditions or market conditions relating to the biopharmaceutical and pharmaceutical industries, especially given the volatility caused by macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises and supply chain and resource issues;
- perceptions of the biotechnology and pharmaceutical industry by the public, legislature, regulators and the investment community;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of commentary, articles or research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage, by securities analysts, bloggers, news media or other third parties;
- large stockholders increasing or exiting their position in our common stock or an increase in the short interest in our common stock;
- announcements of or developments concerning any litigation;
- actions instituted by activist shareholders or others;
- the issuance of common stock to partners, vendors or investors to raise additional capital or as a result of option or warrant exercises;
- other events or factors that are beyond our control; and
- the occurrence of any other risks and uncertainties discussed under the heading "Risk Factors."

Provisions in our charter, bylaws and Delaware law may inhibit potential acquisition bids for us, which may adversely affect the market price of our common stock and/or prevent holders of our common stock from benefiting from what they believe may be the positive aspects of acquisitions and takeovers.

Provisions of our charter documents and bylaws may make it substantially more difficult for a third party to acquire control of us and may prevent changes in our management, including provisions that:

- prevent stockholders from taking actions by written consent;
- divide the board of directors into separate classes with terms of office that are structured to prevent all of the directors from being elected in any one year; and
- set forth procedures for nominating directors and submitting proposals for consideration at stockholders' meetings.

In addition, our certificate of incorporation provides our board of directors with the authority to issue up to 3,000,000 shares of undesignated preferred stock and to determine or alter the rights, preferences, privileges and restrictions granted to or imported upon these shares without further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction without further action by our stockholders. As a result, the market price of our common stock may be adversely affected.

If in the future, we issue preferred stock that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the rights of holders of our common stock or the market price of our common stock could be adversely affected.

Provisions of Delaware law may also inhibit potential acquisition bids for us or prevent us from engaging in business combinations. In addition, we have individual severance agreements with our executive officers and a company-wide severance plan, either of which could require a potential acquirer to pay a higher price. Either collectively or individually, these provisions may prevent holders of our common stock from benefiting from what they may believe are the positive aspects of acquisitions and takeovers, including the potential realization of a higher rate of return on their investment from these types of transactions.

The exclusive forum provisions in our amended and restated bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or any of our directors, officers, or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our amended and restated bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for:

- any derivative claim or cause of action or proceeding brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees, or our stockholders, to us or to our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, or our stockholders, arising pursuant to any provision of the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws;
- any claim or cause of action as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any claim or cause of action against us or any of our current or former directors, officers or other employees, or our stockholders, governed by the internal affairs doctrine or otherwise related to our internal affairs.

In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act of 1933, as amended, or the Securities Act, or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. The application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions, and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such an instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions, which costs could be borne by stockholders, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to the exclusive forum provisions in our amended and restated bylaws, including the Federal Forum Provision. These provisions could limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or our stockholders or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with

respect to such claims. Furthermore, if a court were to find the exclusive forum provisions contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material and adverse impact on our business and our financial condition.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors, and will be at the discretion of our board of directors. In addition, the terms of our Loan Agreement prevent us from paying dividends and any future debt agreements may continue to preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Our employees, independent contractors, principal investigators, clinical trial sites, contract research organizations, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, clinical trial sites, CROs, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the FDA's or similar international regulatory authorities' regulations, including those laws requiring the reporting of true, complete and accurate information; manufacturing standards; healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our non-clinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could adversely affect our business, financial condition, results of operations or prospects through:

- the imposition of civil, criminal and administrative penalties, damages and monetary fines;
- possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs;
- contractual damages;
- reputational harm;
- diminished potential profits and future earnings; and
- curtailment of our operations.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our Annual Reports on Form 10-K must contain an annual assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. In addition, our independent registered public accounting firm must provide an opinion annually on the effectiveness of our internal control over financial reporting.

The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops, including as we prepare to potentially launch and commercialize imetelstat. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial

reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot assure you that material weaknesses or significant deficiencies will not exist or otherwise be discovered in the future, particularly in light of our increased reliance on personnel working remotely. If material weaknesses or other significant deficiencies occur, such weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign sales and earnings. Any new taxes could adversely affect our domestic and international business operations and our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to such legislation may adversely affect us, and certain aspects of such legislation could be repealed or modified in the future, which could have an adverse effect on us. For example, the Inflation Reduction Act includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of earnings from other countries, and the deductibility of expenses or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense.

For example, effective January 1, 2022, research and experimental expenses must be capitalized for tax purposes and amortized over five years for research activities conducted in the United States and over fifteen years for research activities conducted outside the United States, instead of being deducted in the year incurred. Unless this provision is deferred, modified, or repealed by Congress, or the U.S. Department of the Treasury issues regulations narrowing its application, our future tax obligations could be increased, which could harm our operating results. The impact of this provision will depend on multiple factors, including the amount of research and experimental expenses we incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and experimental activities inside or outside the United States.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our net operating loss carryforwards attributable to tax years beginning before January 1, 2018 could expire unused and be unavailable to offset future income tax liabilities. In addition, under current U.S. federal income tax law, federal net operating losses incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point cumulative change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change taxable income or taxes may be limited. Changes in our stock ownership, some of which are outside of our control, may have resulted in, or other future changes could result in, an ownership change. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods, and a portion of the carryforwards may expire before being available to reduce future income tax liabilities, which could adversely impact our financial position. At the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. It is also uncertain if and to what extent various states will conform to current U.S. federal income tax law.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We operate in the biopharmaceutical sector, which is a highly regulated sector subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; disruption of our clinical trials, manufacturing or supply chain; violation of privacy laws and other litigation and legal risk; and reputational risk. We rely primarily on industry-leading third parties and a cloud-based infrastructure for our information technology systems, and accordingly are dependent on these third parties' own cybersecurity risk management practices and strategy. We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including clinical trial data, intellectual property, confidential information that is proprietary, strategic, financial or competitive in nature, and personal data ("Information Systems and Data").

We take a risk-based approach to identify and assess the cybersecurity threats and risks that could affect our business and Information Systems and Data. Our Information Technology personnel help identify, assess and manage our cybersecurity threats and risks, and support our efforts to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment. We use various methods and tools to identify, assess and manage cybersecurity threats and risks, including, for example, automated tools, industry reports, third party threat assessments and penetration testing. In addition, we encrypt data at rest and maintain network security controls, such as firewalls and virtual private networks. We also conduct computerized system monitoring and access control, including asset management, tracking and disposal associated with onboarding and offboarding of personnel. We maintain cybersecurity insurance.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data. For example, we have implemented and maintain an incident response plan, and we utilize automated tools designed to maintain email security. We have also implemented a computerized system security and password policy that defines security for access to computer systems managed and controlled by us, and a procedure for computerized system incident management to address any unplanned issues in regulated computerized systems that could impact subject safety, product quality, and data integrity. We periodically conduct cybersecurity incident tabletop training exercises involving our personnel and plan to conduct similar training in 2024.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our head of Information Technology evaluates material risks from cybersecurity threats and reports periodically to our Audit Committee, which evaluates our overall enterprise risk. We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, cybersecurity software providers such as Crowdstrike, cybersecurity service providers such as Mimecast, penetration testing firms, auditors, and professional services firms, including legal counsel. These relationships enable us to leverage specialized knowledge and insights, enabling our cybersecurity strategies and processes to remain consistent with industry best practices.

We rely on third-party service providers to perform a variety of functions throughout our business, such as contract manufacturing organizations, contract research organizations, suppliers and consultants. If we successfully obtain regulatory approval to commercialize imetelstat, we will rely on third party logistics organizations and distributors to distribute imetelstat. We conduct quality audits of regulated vendors, which typically include an assessment of such vendor's information technology systems, and we impose appropriate contractual obligations on vendors pertaining to information security. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our efforts may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

We have not encountered cybersecurity challenges that have materially impaired our business, operations or financial standing.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*Risks Related to Information Technology Systems, Data Security and Data Privacy.*"

Governance

Our Board of Directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee of our Board is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our Audit Committee, as well as our Chief Financial Officer, Chief Legal Officer, and other members of our executive management as appropriate, receives periodic reports from our head of Information Technology concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The Audit Committee also receives various periodic presentations related to cybersecurity threats, risk and mitigation.

Risk Management Personnel

Our Information Technology personnel responsible for cybersecurity risk assessment and management processes are managed by certain members of our executive management, including our Chief Financial Officer. Together with our executive management, our Information Technology personnel are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. We seek to hire information technology personnel with skills appropriate to help us prepare for cybersecurity incidents, approve cybersecurity processes, and review security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including executive management. When appropriate given the nature of any potential cybersecurity incident, our executive management works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified, and to make any legally required notifications to individuals or regulatory agencies, including making any required disclosures under the Securities Exchange Act of 1934, as amended.

ITEM 2. PROPERTIES

In April 2019, we entered into an operating lease agreement for office space located at 3 Sylvan Way, Parsippany, New Jersey, or the New Jersey Lease. The initial term of the New Jersey Lease is 11 years with an option to extend for an additional five years and a one-time option to terminate the New Jersey Lease without cause as of the 103rd month anniversary of the commencement date of the lease. The New Jersey Lease commenced on October 1, 2019, upon our control of the office space on that date.

In October 2019, we entered into an operating lease agreement for office space located at 919 East Hillsdale Boulevard, Foster City, California, or the Foster City Lease. The initial term of the Foster City Lease is 87 months with an option to extend for an additional five years. The Foster City Lease commenced on March 10, 2020, upon our control of the office space on that date.

ITEM 3. LEGAL PROCEEDINGS

See Note 6 on Commitments and Contingencies in Notes to Consolidated Financial Statements of this annual report on Form 10-K for information on legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the Nasdaq Global Select Market under the symbol GERN. As of February 23, 2024, there were approximately 451 stockholders of record of our common stock. This number does not include "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never paid cash dividends on our capital stock and do not anticipate paying cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business. Any future determination to pay cash dividends will be at the discretion of the board of directors and will be dependent upon our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

During the year ended December 31, 2023, there were no unregistered sales of equity securities by us.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the section entitled "Business" in Part I, Item 1 and the audited financial statements and notes thereto included in Part II, Item 8 of this annual report on Form 10-K. The information provided should be reviewed in the context of the sections entitled "Risks Related to the Development of Imetelstat", and "Risks Related to Regulatory Approval and Commercialization of Imetelstat" under "Risk Factors" in Part I, Item 1A and elsewhere in this annual report on Form 10-K.

Company Overview

Summary

We are a late-stage biopharmaceutical company pursuing therapies with the potential to extend and enrich the lives of patients living with hematologic malignancies. Our investigational first-in-class telomerase inhibitor, imetelstat, harnesses Nobel Prize winning science in a treatment that may alter the underlying course of these diseases.

Our lead indication for imetelstat is in Low or Intermediate-1 risk myelodysplastic syndromes, or lower-risk MDS. In August 2023, our New Drug Application, or NDA, for the treatment of transfusion-dependent anemia in adult patients with low-to-intermediate-1 risk MDS who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents, or ESAs, was accepted by the United States, or U.S., Food and Drug Administration, or FDA, for review and assigned a Prescription Drug User Fee Act, or PDUFA, action date of June 16, 2024. In addition, the FDA has scheduled an advisory committee meeting as part of the NDA review on March 14, 2024. If imetelstat is approved for commercialization by the FDA, we anticipate commercial launch of imetelstat in lower-risk MDS in the U.S. could occur at the time of approval. In September 2023, we submitted a marketing authorization application, or MAA, in Europe that was validated for review by the European Medicines Agency, or EMA, for imetelstat for the same proposed indication as in the U.S. We expect a review of the MAA could be completed in early 2025, and subject to approval by the European Commission, we believe EU commercial launch of imetelstat would occur in 2025.

Our NDA and EMA filings are based on positive data from the IMerge Phase 3 clinical trial. The trial met its primary endpoint of ≥ 8-week transfusion independence rate and a key secondary endpoint of 24-week transfusion independence rate, demonstrating highly statistically significant (i.e., $p<0.001$ for both) and clinically meaningful benefits with imetelstat treatment versus placebo. Furthermore, statistically significant and clinically meaningful

efficacy results were observed in the trial across key subtypes, including patients who were ringed sideroblast positive, or RS positive, and ringed sideroblast negative, or RS negative; patients with high and very high baseline transfusion burden; and patients classified as Low or Intermediate-1 risk according to the International Prognostic Scoring System, or IPSS. Consistent with prior imetelstat clinical experience, the most common serious adverse events were primarily short-lived, manageable thrombocytopenia and neutropenia.

In addition to lower-risk MDS, we are developing imetelstat for the treatment of several myeloid hematologic malignancies, including a Phase 3 clinical trial, named IMpactMF, in relapsed/refractory MF with overall survival, or OS, as the primary endpoint, that currently is enrolling patients. In November 2023, the trial reached 50% enrollment. Based on our current planning assumptions for enrollment and event (death) rates in the trial, we expect the interim analysis for OS in IMpactMF may occur in the first half of 2025, and the final analysis may occur in the first half of 2026.

We are also conducting a Phase 1 combination therapy clinical trial, named IMproveMF, in first-line Intermediate-1, Intermediate-2 or High-Risk myelofibrosis, or frontline MF, that currently is enrolling patients and imetelstat is being studied in an investigator-led Phase 2 clinical trial, named IMpress, in Intermediate-2 or High-Risk myelodysplastic syndromes, or higher risk MDS, and acute myeloid leukemia, or AML, in which the first patient was dosed in June 2023.

We believe that the positive data from IMerge Phase 3 and IMerge Phase 2, as well as our prior Phase 2 clinical trial of imetelstat in patients with Intermediate-2 or High-Risk myelofibrosis who have relapsed after or are refractory to treatment with a janus associate kinase inhibitor, or JAK inhibitor, or relapsed/refractory MF, provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells enabling recovery of bone marrow and normal blood cell production, which suggest potential disease-modifying activity. We believe this potential for disease modification could differentiate imetelstat from currently approved treatments in myeloid hematologic malignancies.

Financial Overview

Since our inception, we have primarily financed our operations through the sale of equity securities, interest income on our marketable securities and payments we received under our collaborative and licensing arrangements. As of December 31, 2023, we had approximately $378.1 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities, and a long-term debt principal balance of $80.0 million.

On January 10, 2023, we completed an underwritten public offering of 68,007,741 shares of our common stock and a pre-funded warrant to purchase 25,000,000 shares of our common stock, or the 2023 pre-funded warrant. The net cash proceeds from this offering were approximately $213.3 million, after deducting the underwriting discount and other offering expenses paid by us. In addition, in the year-ended December 31, 2023, we received $105.9 million in cash proceeds from the exercise of outstanding warrants.

In June 2021, we drew down the remaining $10.0 million available under Tranche A of the Loan Agreement with Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)), or SVB. In August 2021, we amended the Loan Agreement to adjust the timing threshold for certain clinical milestones associated with Tranche B under the Loan Agreement. In addition, under the first amendment to the Loan Agreement, the minimum cash covenant requirement beginning as of June 1, 2022, was increased from $25.0 million to $30.0 million, and the minimum cash covenant required upon the execution of certain licensing transactions being executed was increased from $30.0 million to $35.0 million.

In December 2021, we drew down $15.0 million available under Tranche B of the Loan Agreement with Hercules and SVB.

On June 30, 2022, we entered into a second amendment to the Loan Agreement. Under the second amendment, the aggregate principal amount available to us increased from $75.0 million to $125.0 million, with such principal being available in a series of tranches, subject to certain terms and conditions.

On December 14, 2023, we entered into a third amendment to the Loan Agreement. After giving effect to the third amendment, the aggregate principal amount drawn down and remaining available to us under the term loan facility, or Term Loan, remains at $125 million, with such principal being available in a series of tranches, subject to certain terms and conditions. The third amendment also provides that (i) the fourth tranche of the Term Loan was increased from $10.0 million to $30.0 million, (ii) the commitment period for the fifth tranche of the Term Loan of $20 million, which is available subject to achievement of a regulatory milestone and satisfaction of certain capitalization requirements, was extended through December 15, 2024, (iii) the variable annual interest rate on the

outstanding loans has been decreased to the greater of: (x) 9.0%, or (y) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0%; and (iv) the interest only period of the Term Loan has been extended through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. In connection with the third amendment, on the third amendment effective date, we borrowed and received the entire fourth tranche of the Term Loan in the amount of $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Loan Agreement is $80.0 million. As of February 23, 2024, remaining tranches of up to $45.0 million are available under the Loan Agreement, subject to certain conditions. See Note 8 on Debt in Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional information on the Loan Agreement.

Substantially all of our revenues to date have been payments under collaboration agreements, and milestones, royalties and other revenues from our licensing arrangements. We currently have no source of product revenue. We have incurred significant net losses since our inception in 1990, resulting principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. As of December 31, 2023, we had an accumulated deficit of approximately $1.6 billion.

The significance of future losses, future revenues and any potential future profitability will depend primarily on the clinical and commercial success of imetelstat, our sole product candidate. In any event, imetelstat may require significant additional clinical testing prior to possible regulatory approval in the U.S. and other countries. We expect research and development expenses, general and administrative expenses, and losses to substantially increase in future periods as we continue to support the imetelstat development program, including the conduct and completion of IMpactMF, IMproveMF and IMpress, as well as the potential U.S. commercialization of imetelstat in lower-risk MDS, subject to receipt of regulatory approval.

Based on our current operating plan and our assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower-risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of outstanding warrants, and potential future drawdowns under the Loan Agreement, will be sufficient to fund our projected operating requirements into the third quarter of 2025. Our ability to generate revenues from sales of imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner, or at all. In addition, we cannot predict with any certainty whether and to what extent the remaining outstanding warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all. Our ability to drawdown any remaining tranches under the Loan Agreement is subject to our achievement of certain regulatory milestones and satisfaction of certain capitalization requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche. In addition, even if imetelstat is approved in lower-risk MDS and commercialized by us in the U.S. in that indication and we are able to draw down the remaining tranches under the Loan Agreement in full, we will still require substantial additional funding to further advance the imetelstat program, including through the completion of our ongoing clinical trials, as well as conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other future indications, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

If approved for marketing by regulatory authorities outside of the U.S., we may seek potential commercialization partners for such territories. Until the FDA or similar international regulatory authorities approve imetelstat for marketing in lower-risk MDS, if at all, we cannot begin commercialization.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying

value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

Note 1 of Notes to Consolidated Financial Statements of this annual report on Form 10-K describes the significant accounting policies used in the preparation of our consolidated financial statements. Certain of these significant accounting policies are important to understanding and evaluating our reported financial results.

Clinical Trial Accruals

Our current imetelstat clinical trials are being supported by CROs and other vendors. Invoicing from CROs for services rendered can be delayed. We accrue the cost of services rendered in connection with CRO activities, which include, management, monitoring costs, project management costs, and investigator fees. We accrue expenses for clinical trial activities performed by CROs based upon the amount of work completed on each trial. We maintain regular communications with our CROs to assess the reasonableness of our accrual. To date, differences between actual clinical trial expenses and accrued clinical trial expenses recorded have not been material and are adjusted for in the period in which they become known. However, if we incorrectly accrue activity levels associated with the CRO services at a given point in time, we could be required to record material adjustments in future periods.

Results of Operations

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future. Results of operations for any period may be unrelated to results of operations for any other period. Thus, historical results should not be viewed as indicative of future operating results.

Revenue based on sales of imetelstat is dependent on obtaining regulatory approval to commercialize imetelstat in the U.S. and other countries. We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in research and development efforts, including the development, manufacture, regulatory approval for and commercialization of, imetelstat; uncertainty of non-clinical and clinical trial results or regulatory approvals or clearances; the future development of imetelstat by us, including any future efficacy or safety results that may cause the benefit-risk profile of imetelstat to become unacceptable; the uncertain and unpredictable drug research and discovery process; overcoming disruptions and/or delays due to macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises, and supply chain and resource issues; our need for substantial additional capital; enforcement of our patent and proprietary rights; reliance upon our CROs, contract manufacturing organizations, or CMOs, consultants, licensees, investigators and other third parties; and potential competition. In order for imetelstat to be commercialized, we must conduct non-clinical tests and clinical trials to demonstrate the safety and efficacy of imetelstat, obtain regulatory approvals or clearances, and enter into manufacturing, distribution and marketing arrangements, as well as obtain market acceptance.

Revenues

We previously entered into license or collaboration agreements with companies involved with oncology, diagnostics, research tools and biologics production, whereby we granted certain rights to our non-imetelstat related technologies. As of December 31, 2020, our license agreements related to our hTERT technology have been terminated or expired due to patent expirations on such technology. The remaining active license agreement was a license related to our specialized oligonucleotide backbone chemistry, as well as patent rights covering the synthesis of monomers, the building blocks of oligonucleotides. This license was terminated effective April 2021. In connection with these agreements, we were eligible to receive license fees, option fees, milestone payments and royalties on future sales of products, or any combination thereof. As of December 31, 2023, all of our patent license agreements have now expired or been terminated, and we expect no further revenue under such agreements in the future. However, in connection with the divestiture of our human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc. which acquired Asterias Biotherapeutics, Inc.), or Lineage, in 2013, we are entitled to receive royalties on sales from certain research or commercial products utilizing our divested intellectual property.

We did not recognize any license fee revenues during the year ended December 31, 2023 and 2022 and recognized license fee revenues of $28,000 in the year ended December 31, 2021, related to our various agreements.

We recognized royalty revenues of $237,000, $596,000 and $1.4 million during the years ended December 31, 2023, 2022 and 2021, respectively. Royalty revenues reflect estimated royalties from sales of cell-based research products from our divested stem cell assets.

Future license fee and royalty revenues are dependent on additional agreements being signed, if any, our current license agreement with Lineage being maintained, and the underlying patent rights for the license remaining active. We expect royalty revenues in 2024 to be lower than 2023 as a result of reduced royalties from sales of cell-based research products from our divested stem cell assets.

Research and Development Expenses

During the years ended December 31, 2023, 2022 and 2021, we supported the imetelstat development programs and a research discovery program related to potential next generation telomerase inhibitors. For the imetelstat program, we incur direct external, personnel-related and other research and development costs. For the years ended December 31, 2023, 2022 and 2021, direct external expenses included costs for our CROs, consultants and other clinical-related vendors, as well as expenses for contract manufacturing and quality activities. Personnel-related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for our employees involved with ongoing research and development efforts. Other research and development expenses primarily consist of research-related overhead associated with allocated expenses for rent and maintenance of facilities and other supplies.

Research and development expenses for the years ended December 31, 2023, 2022 and 2021 were as follows:

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Direct external research and development expenses:			
Clinical program: Imetelstat	$ 86,914	$ 65,699	$ 61,516
Personnel related expenses	31,595	24,042	19,716
All other research and development expenses	6,537	5,777	4,495
Total	$ 125,046	$ 95,518	$ 85,727

The increase in research and development expenses in 2023 as compared to 2022 primarily reflects the net result of increased manufacturing costs due to the timing of imetelstat manufacturing batches, and increased personnel-related expenses for additional headcount.

The increase in research and development expenses in 2022 as compared to 2021 primarily reflects the net result of increased personnel-related expenses for additional headcount and higher consulting costs related to compilation and analysis of data for top-line results and preparations for regulatory submissions in lower-risk MDS, partially offset by decreased manufacturing costs due to the timing of imetelstat manufacturing batches and reduced clinical trial expenses due to declining number of patients in IMerge Phase 3.

We expect research and development expenses to remain consistent in the future as we support IMpactMF, IMproveMF and IMpress, as well as the long-term treatment and follow-up of remaining patients in IMerge Phase 3. The risks and uncertainties associated with the development of imetelstat are discussed in the sub-sections entitled "Risks Related to the Development of Imetelstat" and "Risks Related to Regulatory Approvals and Commercialization of Imetelstat" under "Risk Factors" in Part I, Item 1A and elsewhere in this annual report on Form 10-K. As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of imetelstat research and development projects, anticipated completion dates, or when and to what extent we will receive cash inflows from the commercialization and sale of imetelstat, if at all.

General and Administrative Expenses

General and administrative expenses were $69.1 million, $43.6 million and $29.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The increase in general and administrative expenses in 2023 as compared to 2022 primarily reflects the net result of higher personnel-related expenses of approximately $19.0 million for additional headcount and expenses related to commercial launch readiness, as well as increased costs for commercial preparatory activities of approximately $9.7 million; partially offset by lower legal expenses in 2023 primarily related to $7.0 million that was recorded in the third quarter of 2022 for our portion of the settlement in connection with a class action lawsuit. We expect general and administrative expenses to increase in the future as the imetelstat program matures and stage-gated commercialization activities continue.

The increase in general and administrative expenses in 2022 as compared to 2021 primarily reflects the net result of increased costs for commercial preparatory activities of approximately $3.1 million; higher personnel-related expenses of approximately $5.4 million for additional headcount; and approximately $6.2 million related to our portion of settlement costs related to the class action and derivative lawsuits, net of lower legal fees in 2022 compared to 2021; partially offset by lower consulting expenses of $1.6 million.

Interest Income

Interest income was $18.2 million, $2.5 million and $527,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

The increase in interest income in 2023 compared to 2022 primarily reflects a larger marketable securities portfolio, with the receipt of net cash proceeds from the underwritten public offering completed in January 2023 and cash proceeds from warrant exercises in 2023, as well as higher yields from marketable securities purchases. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

The increase in interest income in 2022 compared to 2021 primarily reflects a larger marketable securities portfolio, with the receipt of net cash proceeds from the underwritten public offering completed in April 2022 and higher yields due to increasing interest rates.

Interest Expense

Interest expense was $8.3 million, $6.9 million and $3.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The increase in interest expense primarily reflects rising interest rates and an increased principal debt balance under the Loan Agreement. Currently, we have $80.0 million in principal debt outstanding. Interest expense reflects interest owed under the Loan Agreement, as well as amortization of associated debt issuance costs and debt discounts using the effective interest method and accrual for an end of term charge.

Other (Loss) Income, Net

Other (loss) income, net was a loss of $23,000 for the year ended December 31, 2023, and income of $1.0 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively. Net other (loss) income and expense primarily reflects bank charges related to our cash operating accounts and marketable securities portfolio and foreign currency transaction adjustments.

In the second quarter of 2022, we recognized other income of approximately $1.3 million related to the reimbursement of certain legal expenses under our insurance policies. During the first quarter of 2021, we sold our entire equity investment in a diagnostics company, resulting in a net realized gain of $1.2 million, including foreign currency translation adjustments. See Note 2 on Fair Value Measurements – Equity Investment in Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional information about the sales of our equity investment. Net other income also includes bank charges related to our cash operating accounts and marketable securities portfolio.

Liquidity and Capital Resources

As of December 31, 2023, we had cash, restricted cash, cash equivalents and marketable securities of $378.1 million, compared to $173.1 million at December 31, 2022. The increase in cash, restricted cash, cash equivalents, and current and noncurrent marketable securities from December 31, 2022 was primarily the net result of the receipt of net cash proceeds of $213.3 million from the underwritten public offering of common stock and pre-funded warrants completed in January 2023, $105.9 million of cash proceeds from the exercise of outstanding warrants, and aggregate drawdowns of $29.7 million under the Loan Agreement with Hercules and SVB.

In 2023, warrants to purchase 77,349,858 shares of our common stock were exercised for net cash proceeds of approximately $105.9 million. The warrants were issued in connection with underwritten public offerings of our securities in 2020 and 2022.

As of December 31, 2023, we had a long-term principal debt balance of $80.0 million under the Loan Agreement with Hercules and SVB. In June 2022, we entered into a second amendment to the Loan Agreement with Hercules and SVB. Under the second amendment, the aggregate principal amount available to us increased from $75.0 million to $125.0 million. On December 14, 2023, we entered into a third amendment to the Loan Agreement.

After giving effect to the third amendment, the aggregate principal amount draw down and remaining available to us under the Loan Agreement remains at $125 million, with such principal being available in a series of tranches, subject to certain terms and conditions. The third amendment also provides that (i) the fourth tranche of the Loan Agreement was increased from $10.0 million to $30.0 million, (ii) the commitment period for the fifth tranche of the Loan Agreement of $20 million, which is available subject to achievement of a regulatory milestone and satisfaction of certain capitalization requirements, was extended through December 15, 2024, (iii) the variable annual interest rate on the outstanding loans has been decreased to the greater of: (x) 9.0%, or (y) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0%; and (iv) the interest only period of the Term Loan has been extended through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. In connection with the third amendment, on the third amendment effective date, we borrowed and received the entire fourth tranche of the Term Loan in the amount of $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Amended Loan Agreement is $80.0 million. See Note 8 on Debt in Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional information on the third amendment.

On January 10, 2023, we completed an underwritten public offering of 68,007,741 shares of our common stock and a pre-funded warrant to purchase 25,000,000 shares of our common stock, or the 2023 pre-funded warrant. The net cash proceeds from this offering were approximately $213.3 million, after deducting the underwriting discount and other offering expenses paid by us.

We have an investment policy to invest our cash in liquid, investment-grade securities, such as interest-bearing money market funds, certificates of deposit, U.S. Treasury securities, municipal securities, government and agency securities, corporate notes and commercial paper. Our investment portfolio does not contain securities with exposure to sub-prime mortgages, collateralized debt obligations, asset-backed securities or auction rate securities and, to date, we have not recognized any other-than-temporary impairment charges on our marketable securities or any significant changes in aggregate fair value that would impact our cash resources or liquidity. To date, we have not experienced lack of access to our invested cash and cash equivalents; however, access to our invested cash and cash equivalents may be impacted by adverse conditions in the financial and credit markets.

On September 4, 2020, we entered into an At Market Issuance Sales Agreement, or the 2020 Sales Agreement, with B. Riley Securities, Inc., or B. Riley Securities, pursuant to which we were able to elect to issue and sell shares of our common stock having an aggregate offering price of up to $100.0 million in such quantities and on such minimum price terms as we set from time to time through B. Riley Securities as our sales agent. B. Riley Securities was eligible to receive an aggregate commission equal to up to 3.0% of the gross proceeds of the sales under the agreement. We did not sell any shares of our common stock pursuant to the 2020 Sales Agreement during 2023. Approximately $79.1 million of our common stock remained available for issuance under the 2020 Sales Agreement as of September 4, 2023, when the 2020 Sales Agreement expired. No further common stock will be sold pursuant to the 2020 Sales Agreement.

On November 1, 2023, we entered into a new At Market Issuance Sales Agreement, or the 2023 Sales Agreement, with B. Riley Securities, pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $100.0 million in such quantities and on such minimum price terms as we set from time to time through B. Riley Securities as our sales agent. We have agreed to pay B. Riley Securities an aggregate commission equal to up to 3.0% of the gross proceeds of the sales under the agreement. To date, no sales of common stock have occurred under the 2023 Sales Agreement.

Financing Strategy

We may, from time to time, consider additional funding through a combination of new collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. We will continue to manage our capital structure and consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

Future Funding Requirements

Based on our current operating plan and our assumptions regarding the timing of the potential approval and commercial launch of imetelstat in lower-risk MDS in the U.S., we believe that our existing cash, cash equivalents, and current and noncurrent marketable securities, together with projected revenues from U.S. sales of imetelstat, if approved, potential proceeds from the exercise of outstanding warrants, and potential future drawdowns under the Loan Agreement, will be sufficient to fund our projected operating requirements into the third quarter of 2025. Our ability to generate revenues from sales of imetelstat in the U.S., if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities and gain acceptance in the marketplace, which we may be unable to do in a timely manner or at all. In addition, we cannot predict with any certainty whether and to what extent the remaining outstanding warrants will be exercised for cash, or the timing or availability of additional funds under the Loan Agreement, if at all. Our ability to drawdown any remaining tranches under the Loan Agreement is subject to our achievement of certain regulatory milestones and satisfaction of certain capitalization requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche. In addition, even if imetelstat is approved in lower-risk MDS and commercialized by us in the U.S. in that indication and we are able to drawdown the remaining tranches under the Loan Agreement in full, we will still require substantial additional funding to further advance the imetelstat program, including through the completion of our ongoing clinical trials and any potential future clinical trials, as well as conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in relapsed/refractory MF and any other indications we are pursuing or may pursue, and our need for additional funds may arise sooner than planned. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development or potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

Because the outcome of any clinical activities and/or regulatory approval process is highly uncertain, we cannot reasonably estimate whether any development activities we may undertake will succeed; whether we will obtain regulatory approval for imetelstat in any indication we pursue, including lower-risk MDS; or, if approved, whether we will be able to effectively commercialize imetelstat, if at all. We may never recoup our investment in any imetelstat development, which would adversely affect our financial condition and our business and business prospects, and might cause us to cease operations. In addition, our plans and timing expectations could be further delayed or interrupted by the effects of macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects of a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises, and supply chain and resource issues. Further, our future capital requirements are difficult to forecast and will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs;
- the scope, progress, timing, magnitude and costs of non-clinical and clinical development, manufacturing and potential commercialization of imetelstat, including the number of indications being pursued, subject to clearances and approvals by the FDA and similar international regulatory authorities;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in our current or any potential future clinical trials of imetelstat;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, including with respect to our NDA and MAA submissions for imetelstat in lower-risk MDS;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing, developing, commercializing and marketing imetelstat, including with respect to third-party vendors and service providers and our ability to achieve any meaningful reduction in manufacturing costs, if imetelstat receives future regulatory approval or clearance, in the U.S., EU or other countries;
- the sales price for imetelstat, if any;
- the availability of coverage and adequate third-party reimbursement for imetelstat, if any;

- the extent to which we acquire or in-license other drugs and technologies, or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions, or to which we out-license imetelstat;

- the extent to which we are able to enter into and conduct successful strategic partnerships, collaborations and alliances or licensing arrangements with third parties including for the commercialization and marketing of imetelstat in certain global regions;

- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation;

- our level of indebtedness and associated debt service obligations;

- the costs of maintaining and operating facilities in California and New Jersey, as well as higher expenses for travel;

- macroeconomic or other global conditions that may reduce our ability to access equity or debt capital or other financing on preferable terms, which may adversely affect future capital requirements and forecasts; and

- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

Until we can generate a sufficient amount of revenue from imetelstat to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt or other financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, which may not be possible. Availability of such financing sources may be negatively impacted by any further delays in our clinical trials and regulatory developments, as well as macroeconomic or other global conditions, including those resulting from inflation, rising interest rates, prospects or a recession, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises, and supply chain and resource issues.

Additional financing through public or private debt or equity financings, including pursuant to the 2023 Sales Agreement with B. Riley Securities, the remaining tranches of up to $45.0 million available under the Loan Agreement, which are subject to the achievement of certain clinical and regulatory milestones and satisfaction of certain capitalization and other requirements, as well as approval by an investment committee comprised of Hercules and SVB for the final $25.0 million tranche; capital lease transactions or other financing sources, may not be available on acceptable terms, or at all. We may be unable to raise equity capital, or may be forced to do so at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private debt and equity markets to proposed financings has been substantially affected by uncertainty in the general economic, market and political climate due to the effects of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises, and supply chain and resource issues, and may in the future be affected by other factors which are unpredictable and over which we have no control. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, which could reduce or eliminate our ability to raise additional funds through financings, and could negatively impact the terms upon which we may raise those funds. Similarly, these macroeconomic conditions have created extreme volatility and disruption in the capital markets and is expected to have further global economic consequences. If the equity and credit markets deteriorate, including as a result of macroeconomic or other global conditions, such as inflation, rising interest rates, prospects of a recession, government shutdowns, bank failures and other disruptions to financial systems, civil or political unrest, military conflicts, pandemics or other health crises, and supply chain and resource issues, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly, or more dilutive. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development and potential commercialization of imetelstat may be further delayed, altered or abandoned, which might cause us to cease operations.

In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Due to uncertainty in the general economic, market and political climate, we may determine that it is necessary or appropriate to raise additional funds proactively to meet longer-term anticipated operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the 2023 Sales Agreement, your

ownership interest as a stockholder may be diluted, and the terms may include liquidation or other preferences that materially and adversely affect your rights as a stockholder. In addition, we have borrowed, and in the future may borrow, additional capital from institutional and commercial banking sources to fund imetelstat development and our future growth, including pursuant to our Loan Agreement or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms under agreements, such as the Loan Agreement, that include restrictive covenants, including covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Moreover, if we raise additional funds through alliance, collaborative or licensing arrangements with third parties, we may have to relinquish valuable rights to imetelstat or our technologies or grant licenses on terms that are not favorable to us.

We cannot assure you that our existing capital resources, future interest income, future revenues from potential sales of imetelstat, if approved, potential future sales of our common stock, including under the 2023 Sales Agreement, and potential future drawdowns, if available, of the remaining tranches under the Loan Agreement, will be sufficient to fund our operating plans. Moreover, while we did not hold cash deposits or securities at SVB, if other banks and financial institutions enter receivership, become insolvent or otherwise fail in the future in response to financial conditions affecting the banking system and financial markets or otherwise, our ability to access our cash, cash equivalents and marketable securities may be delayed or precluded, which could have a material adverse effect on our business, business prospects and financial position.

Cash Flows Used In Operating Activities

Net cash used in operating activities was $167.7 million, $127.4 million and $95.6 million in 2023, 2022 and 2021, respectively. The increase in net cash used in operating activities in 2023 and 2022 primarily reflects higher payments for research and development expenses in connection with supporting the clinical trials, IMerge Phase 3, IMpactMF, IMproveMF and IMpress, and increases in headcount.

Cash Flows Used In/Provided By Investing Activities

Net cash used in investing activities was $180.3 million in 2023, which primarily reflects a higher rate of purchases than maturities of marketable securities. Net cash provided by investing activities was $62.1 million and $71.9 million in 2022 and 2021, respectively, which primarily reflects a higher rate of maturities than purchases of marketable securities.

For the three years ended December 31, 2023, we purchased approximately $829,000 in property and equipment, none of which was financed through equipment financing arrangements.

Cash Flows from Financing Activities

Net cash provided by financing activities in 2023, 2022 and 2021 was $362.0 million, $87.3 million and $48.6 million, respectively. Financing activities in 2023 primarily reflects the receipt of net cash proceeds of $213.3 million from the underwritten public offering of common stock and pre-funded warrants completed in January 2023, $105.9 million of cash proceeds from the exercise of outstanding warrants, and aggregate drawdowns of $29.7 million under the Loan Agreement with Hercules and SVB.

Financing activities in 2022 and 2021 primarily reflect the receipt of net cash proceeds of $69.9 million from the underwritten public offering of common stock, pre-funded warrant and stock purchase warrants completed in April 2022; cash proceeds from the exercise of warrants, receipt of net cash proceeds from the sales of our common stock under the 2020 Sales Agreement in 2021 and aggregate drawdowns of $25.0 million in 2021 under the Loan Agreement with Hercules and SVB.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist of the following operational and manufacturing expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources and may consider additional funding through a combination of additional equity and debt financings, new collaborative arrangements, strategic alliances, or from other sources.

Operating expenditures

Our primary uses of cash and operating expenses relate to paying employees and consultants, administering clinical trials, ensuring an adequate supply of imetelstat, and providing technology and facility infrastructure to

support our operations. Our research and development expenses in 2023 were $125.0 million, and we expect our investment in research and development expenses to remain consistent in 2024. Our general and administrative expenses were $69.1 million in 2023, and we expect our general, and administrative expenses to increase in 2024 to support our planned growth, subject to FDA approval of imetelstat. On a long-term basis, we plan to manage future cash requirements relative to our long-term business plans.

Contractual Obligations

The leases for our office facilities in New Jersey and California contain rate escalations and options for us to extend the leases. Our operating expenditures primarily consist of our obligations under non-cancellable operating leases. The aggregate amount of future operating lease payments over the term of our leases is $4.0 million as of December 31, 2023. Refer to Note 7 on Operating Leases in Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional detail of our lease obligations.

As of December 31, 2023, we had a long-term principal debt balance of $80.0 million under the Loan Agreement with Hercules and SVB. In June 2022, we entered into a second amendment to the Loan Agreement with Hercules and SVB. Under the second amendment, the aggregate principal amount available to us increased from $75.0 million to $125.0 million. On December 14, 2023, we entered into a third amendment to the Loan Agreement and borrowed and received $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Amended Loan Agreement is $80.0 million. See Note 8 on Debt in Notes to Consolidated Financial Statements of this annual report on Form 10-K for additional information on the third amendment.

In the normal course of business, we enter into agreements with CROs for clinical trials and CMOs for clinical and commercial supply manufacturing and with other vendors for preclinical research studies, investigator-led trials and other services and products for operating purposes. We have not considered these commitments to be contractual obligations since the contracts are generally cancelable at any time by us upon less than 180 days' prior written notice. We also have certain in-license agreements that require us to pay milestones to such third parties upon achievement of certain development, regulatory or commercial milestones. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones, which may not be achieved.

Manufacturing and Supply Agreements.

Imetelstat, our sole product candidate, requires long lead times to manufacture. Therefore, we make substantial and often long-term investments in our supply chain in order to ensure we have enough drug product to meet potential future commercialization requirements, as well as clinical trial needs.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our market risk disclosures contains forward-looking statements. Actual results could differ materially from those projected in the forward-looking statements. We are exposed to credit risk and interest rate risk. We do not use derivative financial instruments for speculative or trading purposes.

Credit Risk. We currently place our cash, restricted cash, cash equivalents and marketable securities with multiple financial institutions in the United States. Deposits with banks may exceed the amount of insurance provided on such deposits. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail or could be subject to other adverse conditions in the financial markets. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and marketable securities. Cash equivalents and marketable securities currently consist of money market funds, U.S. government-sponsored enterprise securities, commercial paper and corporate notes. Our investment policy, approved by the audit committee of our board of directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. We limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. To date, we have not experienced any loss or lack of access to cash in our operating accounts or to our cash equivalents and marketable securities in our investment portfolio. The effect of a hypothetical decrease of 1% in the average yield earned on our cash equivalents and marketable securities would have resulted in an immaterial impact on our interest income for the year ended December 31, 2023.

Interest Rate Risk. The primary objective of our investment activities is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio through the full investment of available funds without significantly increasing risk. To achieve this objective, we primarily invest in widely diversified investments with fixed interest rates, which carry a degree of interest rate risk. Fixed rate securities may have their fair value adversely impacted due to a rise in interest rates. Due in part to these factors, our future interest income may fall short of expectations due to changes in market conditions and in interest rates or we may suffer losses in principal if forced to sell securities which may have declined in fair value due to changes in interest rates. The fair value of our cash equivalents and marketable securities at December 31, 2023 was $378.1 million. These investments include $16.8 million of cash equivalents which are due in less than 90 days, $263.7 million of short-term investments which are due in less than one year and $43.3 million of long-term investments which are due in one to two years. We primarily invest our marketable securities portfolio in securities with at least an investment grade rating to minimize interest rate and credit risk as well as to provide for an immediate source of funds. Although changes in interest rates may affect the fair value of the marketable securities portfolio and cause unrealized gains or losses, such gains or losses would not be realized unless the investments are sold. Due to the nature of our investments, which are primarily money market funds, U.S. government-sponsored enterprise securities, commercial paper and corporate notes, we have concluded that there is no material interest rate risk exposure and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The following financial statements and the related notes thereto, of Geron Corporation and its consolidated subsidiaries, and the Report of Independent Registered Public Accounting Firm, Ernst & Young LLP, are filed as a part of this annual report on Form 10-K.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Geron Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Geron Corporation (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for accrued CRO and clinical trial costs

Description of the Matter

The Company recorded accrued CRO and clinical trial costs of $23.5 million as of December 31, 2023. As described in Note 1, accrued expenses for clinical trial activities performed and managed by CROs are based upon the amount of work completed on each trial. Amounts recorded are determined based on contracted amounts agreed to with CROs and through monthly reporting provided by CROs. The Company monitors activities conducted and managed by the CROs through internal reviews, review of contractual terms and correspondence with CROs.

Auditing the accounting for accrued CRO and clinical trial costs is challenging because the evaluation of the activities being performed under the Company's research and development agreements is dependent upon the accumulation of a high volume of information from third-party service providers.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accounting for accrued CRO and clinical trial costs, including controls over management's review of the information provided by the CROs related to clinical trial progress and activities performed in comparison to contractual terms and invoices received from third-party service providers.

To test the Company's accounting for accrued CRO and clinical trial costs, our audit procedures included, among others, obtaining direct confirmation from third parties of contract terms and conditions and the research and development activities performed for significant clinical trials and comparing such data to the inputs used in management's analyses to determine the costs incurred. We inspected key terms, timelines of completion, activities and costs for a sample of vendor contracts, including amendments, and compared these to management's analyses used in tracking the progress of service agreements. We met with internal clinical personnel to understand the status of significant clinical trial activities. We also tested a sample of subsequent payments by agreeing the invoice to the original accrual and the invoice payments to bank statements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1992.
San Jose, California
February 28, 2024

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Geron Corporation

Opinion on Internal Control Over Financial Reporting

We have audited Geron Corporation's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Geron Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 28, 2024, expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Jose, California
February 28, 2024

GERON CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,023	$ 56,845
Restricted cash	1,115	364
Marketable securities	263,676	115,901
Interest and other receivables	1,655	3,144
Prepaid and other current assets	4,879	3,992
Total current assets	341,348	180,246
Noncurrent marketable securities	43,298	—
Property and equipment, net	1,177	793
Operating leases, right-of-use assets	3,556	4,147
Deposits and other assets	4,697	5,389
	$ 394,076	$ 190,575
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,161	$ 10,190
Accrued compensation and benefits	13,759	11,534
Operating lease liabilities	949	925
Debt	46,893	20,945
Accrued liabilities	40,308	33,100
Total current liabilities	108,070	76,694
Noncurrent operating lease liabilities	3,006	3,671
Noncurrent debt	35,051	30,212
Total liabilities	146,127	110,577
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 3,000,000 shares authorized; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value; 1,350,000,000 shares authorized; 544,912,215 and 390,262,524 shares issued and outstanding at December 31, 2023 and 2022, respectively	545	390
Additional paid-in capital	1,844,988	1,493,469
Accumulated deficit	(1,597,769)	(1,413,642)
Accumulated other comprehensive loss	185	(219)
Total stockholders' equity	247,949	79,998
	$ 394,076	$ 190,575

See accompanying notes.

GERON CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2023	2022	2021
	(In thousands, except share and per share data)		
Revenues:			
License fees and royalties	$ 237	$ 596	$ 1,393
Operating expenses:			
Research and development	125,046	95,518	85,727
General and administrative	69,135	43,628	29,665
Total operating expenses	194,181	139,146	115,392
Loss from operations	(193,944)	(138,550)	(113,999)
Interest income	18,152	2,529	527
Interest expense	(8,312)	(6,882)	(3,740)
Other income, net	(23)	1,002	1,100
Net loss	$ (184,127)	$ (141,901)	$ (116,112)
Basic and diluted net loss per share	$ (0.32)	$ (0.37)	$ (0.35)
Shares used in computing basic and diluted net loss per share	570,645,405	380,784,846	327,631,814

See accompanying notes.

GERON CORPORATION

STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,		
	2023	2022	2021
	(In thousands)		
Net loss	$ (184,127)	$ (141,901)	$ (116,112)
Net unrealized loss on marketable securities	431	(68)	(251)
Foreign currency translation adjustments	(27)	22	—
Comprehensive loss	$ (183,723)	$ (141,947)	$ (116,363)

See accompanying notes.

GERON CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
	(In thousands, except share data)					
Balances at December 31, 2020	310,566,853	$ 310	$ 1,366,188	$ (1,155,629)	$ 78	210,947
Net loss	—	—	—	(116,112)	—	(116,112)
Other comprehensive loss	—	—	—	—	(251)	(251)
Issuance of common stock in connection with at market offering, net of issuance costs of $470	10,571,556	11	20,374	—	—	20,385
Issuance of common stock in connection with exercise of warrants	1,906,341	2	2,477	—	—	2,479
Stock-based compensation related to issuance of common stock and options in exchange for services	20,783	—	91	—	—	91
Issuances of common stock under equity plans	666,058	1	796	—	—	797
Stock-based compensation for equity-based awards to employees and directors	—	—	8,080	—	—	8,080
Balances at December 31, 2021	323,731,591	324	1,398,006	(1,271,741)	(173)	126,416
Net loss	—	—	—	(141,901)	—	(141,901)
Other comprehensive loss	—	—	—	—	(68)	(68)
Foreign currency translation adjustment	—	—	—	—	22	22
Issuance of common stock, pre-funded warrant and warrants to purchase common stock in public offering, net of issuance costs of $5,066	53,333,334	53	69,863	—	—	69,916
Issuance of common stock in connection with exercise of warrants	11,663,387	12	15,151	—	—	15,163
Stock-based compensation related to issuance of common stock and options in exchange for services	15,962	—	264	—	—	264
Issuances of common stock under equity plans	1,518,250	1	2,184	—	—	2,185
Stock-based compensation for equity-based awards to employees and directors	—	—	8,001	—	—	8,001
Balances at December 31, 2022	390,262,524	390	1,493,469	(1,413,642)	(219)	79,998
Net loss	—	—	—	(184,127)	—	(184,127)
Other comprehensive loss	—	—	—	—	431	431
Foreign currency translation adjustment	—	—	—	—	(27)	(27)
Issuance of common stock, pre-funded warrant and warrants to purchase common stock in public offering, net of issuance costs of $14,507	68,007,741	68	213,269	—	—	213,337
Issuance of common stock in connection with exercise of warrants	77,349,858	78	105,834	—	—	105,912
Stock-based compensation related to issuance of common stock and options in exchange for services	36,864	1	828	—	—	829
Issuances of common stock under equity plans	9,255,228	8	13,062	—	—	13,070
Stock-based compensation for equity-based awards to employees and directors	—	—	18,526	—	—	18,526
Balances at December 31, 2023	544,912,215	$ 545	$ 1,844,988	$ (1,597,769)	$ 185	$ 247,949

See accompanying notes.

GERON CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Cash flows from operating activities:			
Net loss	$ (184,127)	$ (141,901)	$ (116,112)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	442	288	215
Accretion and amortization on investments, net	(11,150)	(965)	1,424
Amortization of debt issuance costs/debt discount	1,088	1,327	893
Net gain on exchange and sales of equity investment	—	—	(1,233)
Stock-based compensation for services by non-employees	828	264	91
Stock-based compensation for employees and directors	18,526	8,001	8,080
Amortization of right-of-use assets	591	580	568
Changes in assets and liabilities:			
Interest and other receivables	1,490	(1,381)	(1,041)
Prepaid and other current assets	(886)	(2,630)	1,317
Deposit and other assets	692	(594)	(3,807)
Accounts payable	(4,029)	3,503	(232)
Accrued compensation and benefits	2,224	3,435	(119)
Accrued liabilities	7,208	3,266	14,909
Operating lease liabilities	(640)	(572)	(509)
Net cash used in operating activities	(167,743)	(127,379)	(95,556)
Cash flows from investing activities:			
Purchases of property and equipment	(830)	(431)	(207)
Purchases of marketable securities	(475,594)	(258,007)	(177,434)
Proceeds from maturities of marketable securities	296,102	320,505	247,994
Proceeds from sales of equity investment	—	—	1,594
Net cash provided by (used in) investing activities	(180,322)	62,067	71,947
Cash flows from financing activities:			
Proceeds from issuances of common stock from equity plans	13,072	2,185	797
Proceeds from issuance of common stock and warrants in public offering, net of paid issuance costs	213,337	69,916	—
Proceeds from issuances of common stock from at market offerings, net of paid issuance costs	—	—	20,385
Proceeds from exercise of warrants	105,912	15,163	2,479
Proceeds from debt financing, net of paid debt issuance costs and debt discounts	29,700	—	24,895
Net cash provided by financing activities	362,021	87,264	48,556
Net effect of exchange rates on cash, cash equivalents and restricted cash	(27)	22	—
Net increase (decrease) in cash, cash equivalents and restricted cash	13,929	21,974	24,947
Cash, cash equivalents and restricted cash at the beginning of the period	57,209	35,235	10,288
Cash, cash equivalents and restricted cash at the end of the period	$ 71,138	$ 57,209	$ 35,235

See accompanying notes.

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

The terms “Geron”, the “Company”, “we” and “us” as used in this report refer to Geron Corporation, which was incorporated in the State of Delaware on November 28, 1990, and its wholly-owned subsidiaries, Geron UK Limited, or Geron UK, a United Kingdom company, and Geron Netherlands B.V., or Geron Netherlands, a Netherlands company. Geron UK was incorporated in September 2021, and its operations commenced in January 2022. Geron Netherlands was incorporated in February 2023, and its operations commenced in June 2023. We are a late-stage clinical biopharmaceutical company that is focused on the development and potential commercialization of imetelstat, an innovative therapeutic for hematologic malignancies. We have global rights to imetelstat, an investigational first-in-class telomerase inhibitor, which was discovered and developed at Geron. Principal activities to date have included obtaining financing, securing operating facilities and conducting research and development.

Principles of Consolidation

The consolidated financial statements include the accounts Geron Corporation and its wholly-owned subsidiaries, Geron UK and Geron Netherlands. We have eliminated intercompany accounts and transactions. We prepare the financial statements of Geron UK and Geron Netherlands using the local currency as the functional currency. We translate the assets and liabilities of Geron UK and Geron Netherlands at rates of exchange at the balance sheet date and translate income and expense items at average monthly rates of exchange. The resultant translation adjustments are included in accumulated other comprehensive income (loss), a separate component of stockholders’ equity, on our consolidated balance sheets.

Net Loss Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the periods presented without consideration of potential common shares. In April 2022, we entered into an underwriting agreement in connection with a public offering of our common stock, pursuant to which we issued a pre-funded warrant to purchase 18,095,238 shares of our common stock, also known as the 2022 pre-funded warrant, together with accompanying warrants to purchase shares of our common stock. In May 2020, we entered into an underwriting agreement in connection with a public offering of our common stock, pursuant to which we issued a pre-funded warrant to purchase 8,335,239 shares of our common stock, or the 2020 pre-funded warrant, together with accompanying warrants to purchase shares of our common stock. The 2022 pre-funded warrant and 2020 pre-funded warrant each are exercisable immediately at an exercise price of $0.001 per share. In January 2023, we completed an underwritten public offering of 68,007,741 shares of our common stock and a pre-funded warrant to purchase 25,000,000 shares of our common stock, or the 2023 pre-funded warrant. We included the 2023 pre-funded warrant, the 2022 pre-funded warrant and the 2020 pre-funded warrant in the computation of basic net loss per share, as applicable, since their exercise price is negligible, and they may be exercised at any time. See Note 9 on Stockholders' Equity for further discussion of our public offerings.

Diluted net income per share would be calculated by adjusting the weighted-average number of shares of common stock outstanding for the dilutive effect of additional shares of common stock that would have been outstanding if potentially dilutive securities had been issued, as determined using the treasury-stock method. Potential dilutive securities consist of outstanding stock options and warrants to purchase our common stock. Diluted net loss per share excludes potential dilutive securities for all periods presented as their effect would be anti-dilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented in the accompanying consolidated statements of operations. Since we incurred a net loss for 2023, 2022, and 2021, the diluted net loss per share calculation excludes potential dilutive securities of 75,458,854, 145,726,765 and 105,725,875 shares, respectively, related to outstanding stock options and warrants, as their effect would have been anti-dilutive.

Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to accrued liabilities, revenue recognition, fair value of marketable securities and equity investments, operating leases, right-of-use assets, lease liabilities, income taxes, and stock-based compensation. We base our estimates on historical experience and on various other market specific and relevant assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

Fair Value of Financial Instruments

Cash Equivalents and Marketable Securities

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. Our marketable debt securities include U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper and corporate notes.

We classify our marketable debt securities as available for sale. We record available for sale debt securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in interest income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest income on our consolidated statements of operations. We recognize a charge when the declines in the fair values below the amortized cost bases of our available for sale securities are judged to be other than temporary. We consider various factors in determining whether to recognize an other than temporary charge, including whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. Declines in market value judged as other than temporary result in a charge to interest income. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the years ended December 31, 2023, 2022 and 2021. See Note 2 on Fair Value Measurements.

Equity Investments

We measure our investment in equity securities at fair value at each reporting date. Changes in fair value resulting from observable price changes are included in change in fair value of equity investment and changes in fair value resulting from foreign currency translation are included in other expense on our consolidated statements of operations.

Leases

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating leases are included in operating leases, right-of-use assets and lease liabilities on our consolidated balance sheets. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of remaining lease payments over the expected lease term. The present value of remaining lease payments within the 12 months following the balance sheet date are classified as current lease liabilities. The present value of lease payments not within the 12 months following the balance sheet date are classified as noncurrent lease liabilities. The interest rate implicit in lease contracts is typically not readily determinable. As such, to calculate the net present value of lease payments, we apply our incremental borrowing rate, which is the estimated rate to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment as of the lease commencement date. We may adjust the right-of-use assets for certain adjustments, such as initial direct costs paid or incentives received. In addition, we include any options to extend or terminate the lease in the expected lease term when it is reasonably certain that we will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term.

For lease agreements entered into after January 1, 2019 that include lease and non-lease components, such components are generally accounted for separately. We have also elected not to recognize on our consolidated balance sheets leases with terms of one year or less.

Debt Issuance Costs and Debt Discounts

Debt issuance costs include legal fees, accounting fees, and other direct costs incurred in connection with the execution of our debt financing. Debt discounts represent costs paid to the lenders. Debt issuance costs and debt discounts are deducted from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt using the effective interest method.

Revenue Recognition

We recognize revenue in accordance with the provisions of Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, or Topic 606. In determining the appropriate amount and timing of revenue to be recognized under this guidance, we perform the following five steps: (i) identify the contract(s) with our customer; (ii) identify the promised goods or services in the agreement and determine whether they are performance obligations, including whether they are distinct in the context of the agreement; (iii) measure the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations based on stand-alone selling prices; and (v) recognize revenue when (or as) we satisfy each performance obligation.

A performance obligation is a promise in an agreement to transfer a distinct good or service to the customer and is the unit of account in Topic 606. Significant management judgment is required to determine the level of effort required and the period over which completion of the performance obligations is expected under an agreement. If reasonable estimates regarding when performance obligations are either complete or substantially complete cannot be made, then revenue recognition is deferred until a reasonable estimate can be made. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

We allocate the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or services underlying each performance obligation. Estimated selling prices for license rights are calculated using an income approach model and include the following key assumptions, judgments and estimates: the development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success.

Following is a description of the principal activities from which we generate revenue. License fees and royalty revenue primarily represent amounts earned under agreements that out-license our technology to various companies.

License Agreements

We previously entered into several license agreements with various oncology, diagnostics, research tools and biologics production companies, whereby we granted certain rights to our non-imetelstat related technologies. Under these agreements, non-refundable upfront fees and annual license maintenance fees were considered fixed consideration, while milestone payments and royalties were identified as variable consideration. Since June 30, 2021, no active license agreements remain. The license related to our specialized oligonucleotide backbone chemistry, as well as patent rights covering the synthesis of monomers, the building blocks of oligonucleotides, terminated effective April 2021.

In connection with the divestiture of our human embryonic stem cell assets, including intellectual property and proprietary technology, to Lineage Cell Therapeutics, Inc. (formerly BioTime, Inc. which acquired Asterias Biotherapeutics, Inc.) in 2013, we are entitled to receive royalties on sales of certain research or commercial products utilizing our divested intellectual property.

Licenses of Intellectual Property. If we determine the license to intellectual property is distinct from the other performance obligations identified in the agreement and the licensee can use and benefit from the license, we recognize revenue from non-refundable upfront fees allocated to the license upon the completion of the transfer of the license to the licensee. For such licenses, we recognize revenue from annual license maintenance fees upon the start of the new license period. For licenses that are bundled with other performance obligations, we assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable upfront fees or annual license maintenance fees. At each reporting date, we reassess the progress and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments. At the inception of each agreement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. For milestones that we do not deem to be probable of being achieved, the associated milestone payments are fully constrained and the value of the milestone is excluded from the transaction price with no revenue being recognized. For example, milestone payments that are not within our control, such as regulatory-related accomplishments, are not considered probable of being achieved until those accomplishments have been communicated by the relevant regulatory authority. Once the assessment of probability of achievement becomes probable, we recognize revenue for the milestone payment. At each reporting date, we assess the probability of achievement of each milestone under any current agreements.

Royalties. For agreements with sales-based royalties, including milestone payments based on the level of sales, where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation, to which some or all of the royalty has been allocated, has been satisfied (or partially satisfied). At each reporting date, we estimate the sales incurred by each licensee during the reporting period based on historical experience and accrue the associated royalty amount.

Restricted Cash

Restricted cash consists of funds maintained in separate money market or certificate of deposit accounts for credit card purchases.

Research and Development Expenses

Research and development expenses currently consist of expenses incurred in developing and testing imetelstat and research related to potential next generation telomerase inhibitors. These expenses include, but are not limited to, payroll and personnel expense, lab supplies, non-clinical studies, clinical trials, including support for investigator-led clinical trials, raw materials to manufacture clinical trial drugs, manufacturing costs for research and clinical trial materials, sponsored research at other labs, consulting, costs to maintain technology licenses and research-related overhead.

Our current imetelstat clinical trials are being supported by contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed and managed by CROs based upon the amount of work completed on each trial. Expenses are recorded based on contracted amounts agreed to with our CROs and through monthly reporting provided by CROs. We monitor activities conducted and managed by the CROs to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We record expense on the best information available at the time. However, additional information may become available to us which may require us to record adjustments to research and development expenses in future periods.

Depreciation and Amortization

We record property and equipment at cost and calculate depreciation using the straight-line method over the estimated useful lives of the assets, generally four years. Leasehold improvements are amortized over the shorter of the estimated useful life or remaining term of the lease.

Stock-Based Compensation

We maintain various stock incentive plans under which stock options and restricted stock awards can be granted to employees, non-employee directors and consultants. We also have an employee stock purchase plan for all eligible employees. We recognize stock-based compensation expense based on grant-date fair values of service-based stock options on a straight-line basis over the requisite service period, which is generally the vesting period. For performance-based stock options with vesting based on the achievement of certain strategic milestones, stock-based compensation expense is recognized over the period from the date the performance condition is determined to be probable of occurring through the date the applicable condition is expected to be met and is reduced for estimated forfeitures, as applicable. If the performance condition is not considered probable of being achieved, no stock-based compensation expense is recognized until such time as the performance condition is considered probable of being met, if at all. If the assessment of probability of the performance condition changes, the impact of the change in estimate would be recognized in the period of the change. The determination of grant-date fair values for our service-based and performance-based stock options and employee stock purchases using the Black-Scholes option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. The grant-date fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant. We evaluate whether an adjustment to the assumptions of fair value of our common stock and historical volatility are required if observed prices of our common stock materially differ from historical information.

We measure share-based payments to non-employees based on the grant-date fair value of the equity awards to be issued. We recognize stock-based compensation expense for the fair value of the vested portion of non-employee stock-based awards on our consolidated statements of operations. For additional information, see Note 9 on Stockholders' Equity.

Accumulated Other Comprehensive Gain (Loss)

Accumulated other comprehensive gain (loss) includes certain changes in stockholders' equity which are excluded from net income (loss). Accumulated other comprehensive loss on our consolidated balance sheets as of December 31, 2023 and 2022, respectively, is comprised of net unrealized losses on marketable securities and cumulative translation adjustments.

Income Taxes

We maintain deferred tax assets and liabilities that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and are subject to tests of recoverability. Our deferred tax assets include net operating loss carryforwards, federal and state tax credits and capitalized research and development. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Our net deferred tax asset has been fully offset by a valuation allowance because of our history of losses. Any potential accrued interest and penalties related to unrecognized tax benefits would be recorded as income tax expense.

Segment Information

Our executive management team represents our chief decision maker. We view our operations as a single segment, the development of therapeutic products for oncology. As a result, the financial information disclosed herein materially represents all of the financial information related to our principal operating segment.

Recent Accounting Pronouncements

New Accounting Pronouncements – Issued But Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (ASU 2023-07), which requires issuers to make additional disclosures with respect to segment expenses, including required disclosure on an annual and interim basis for significant segment expenses and other segment items. ASU 2023-07 also permits the disclosure of more than one measure of a segment's profit or loss. ASU 2023-07 is effective for the Company as of January 1, 2024 for annual periods and as of January 1, 2025 for interim periods. We are evaluating the impact of this ASU on our consolidated financial statements.

In December 2023, the Financial Standards Accounting Board (FASB) issued Accounting Standards Update (ASU) 2023-09, Income Taxes (ASU 2023-09), which requires issuers to make additional discloses on an annual basis related to specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold on an annual basis, disclose additional information about income taxes paid as well as other disaggregated disclosures. ASU 2023-09 is effective for the Company as of January 1, 2025 for annual periods. We are evaluating the impact of this ASU on our consolidated financial statements.

New Accounting Pronouncements – Issued and Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. Subsequent to issuing ASU 2016-13, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses*, or ASU 2018-19, for the purpose of clarifying certain aspects of ASU 2016-13. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief*, or ASU 2019-05, to provide entities with more flexibility in applying the fair value option on adoption of the credit impairment standard. In November 2019, the FASB issued ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses*, which expands the scope of the practical expedient that allows entities to exclude the accrued interest component of amortized cost from various disclosure. Entities that elect to apply the practical expedient must disclose the total amount of accrued interest that they exclude from their disclosures of amortized cost. ASU 2018-19, ASU 2019-05 and ASU 2019-11 have the same effective date and transition requirements as ASU 2016-13. ASU 2016-13 became effective for fiscal years beginning after December 15, 2022, using a modified retrospective approach, for smaller reporting companies. Early adoption is permitted. We adopted ASU 2016-13 and related updates as of January 1, 2023. The adoption of this standard did not have a material impact on our financial statements.

Other recent accounting pronouncements issued by the FASB did not or are not believed by management to have a material impact on our financial statements.

2. FAIR VALUE MEASUREMENTS

Cash Equivalents and Marketable Securities

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2023 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 16,815	$ —	$ —	$ 16,815
	$ 16,815	$ —	$ —	$ 16,815
Restricted cash:				
Money market fund	$ 843	$ —	$ —	$ 843
Certificate of deposit	272	—	—	272
	$ 1,115	$ —	$ —	$ 1,115
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 26,752	$ 95	$ —	$ 26,847
U.S. Treasury securities (due in one to two years)	2,877	17	$ —	2,894
Government-sponsored enterprise securities (due in less than one year)	86,250	43	(92)	86,201
Government-sponsored enterprise securities (due in one to two years)	13,598	72	—	13,670
Commercial paper (due in less than one year)	102,270	31	(33)	102,268
Corporate notes (due in less than one year)	48,409	14	(63)	48,360
Corporate notes (due in one to two years)	26,628	130	(24)	26,734
	$ 306,784	$ 402	$ (212)	$ 306,974

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2022 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 39,771	$ —	$ —	$ 39,771
	$ 39,771	$ —	$ —	$ 39,771
Restricted cash:				
Money market fund	$ 93	$ —	$ —	$ 93
Certificate of deposit	271	—	—	271
	$ 364	$ —	$ —	$ 364
Marketable securities:				
U.S. Treasury securities (due in less than one year)	$ 12,983	$ —	$ (62)	$ 12,921
Municipal securities (due in one to two years)	3,000	—	(24)	2,976
Government-sponsored enterprise securities (due in less than one year)	9,860	—	(14)	9,846
Commercial paper (due in less than one year)	64,285	6	(92)	64,199
Corporate notes (due in less than one year)	26,014	—	(55)	25,959
	$ 116,142	$ 6	$ (247)	$ 115,901

Cash equivalents and marketable securities with unrealized losses that have been in a continuous unrealized loss position for less than 12 months and 12 months or longer at December 31, 2023 and 2022 were as follows:

	Less Than 12 Months		12 Months or Greater		Total	
(In thousands)	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
As of December 31, 2023:						
Government-sponsored enterprise securities (due in less than one year)	$ 69,377	$ (92)	$ —	$ —	$ 69,377	$ (92)
Commercial paper (due in less than one year)	58,622	(33)	—	—	58,622	(33)
Corporate notes (due in less than one year)	34,567	(63)	—	—	34,567	(63)
Corporate notes (due in one to two years)	3,952	(23)	—	—	3,952	(23)
	$ 166,518	$ (211)	$ —	$ —	$ 166,518	$ (211)
As of December 31, 2022:						
U.S. Treasury securities (due in less than one year)	$ 11,424	$ (57)	$ 1,497	$ (5)	$ 12,921	$ (62)
Municipal securities (due in less than a year)	—	—	2,976	(24)	2,976	(24)
Government-sponsored enterprise securities (due in less than one year)	9,845	(14)	—	—	9,845	(14)
Commercial paper (due in less than one year)	52,454	(92)	—	—	52,454	(92)
Corporate notes (due in less than one year)	1,998	(2)	23,962	(53)	25,960	(55)
	$ 75,721	$ (165)	$ 28,435	$ (82)	$ 104,156	$ (247)

The gross unrealized losses related to U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper and corporate notes as of December 31, 2023 and 2022 were due to changes in interest rates and not credit risk. We determined that the gross unrealized losses on our cash equivalents and marketable securities as of December 31, 2023 and 2022 were temporary in nature. Our exposure to unrealized losses may increase in the future due to the economic pressures or uncertainties associated with local or global economic recessions as a result of ongoing geopolitical events, such as the current military conflict between Ukraine and Russia, as well as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failure. We review our investments quarterly to identify and evaluate whether any investments have indications of possible other-than-temporary impairment. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. We currently do not intend to sell these securities before recovery of their amortized cost bases.

Fair Value on a Recurring Basis

We categorize financial instruments recorded at fair value on our consolidated balance sheets based upon the level of judgment associated with inputs used to measure their fair value. The categories are as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date. An active market for the asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2—Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3—Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Below is a description of the valuation methodologies used for financial instruments measured at fair value on our consolidated balance sheets, including the category for such financial instruments.

Money market funds and certificates of deposit are categorized as Level 1 within the fair value hierarchy as their fair values are based on quoted prices available in active markets. Commercial paper, U.S. Treasury securities, municipal securities, government-sponsored enterprise securities and corporate notes are categorized as Level 2 within the fair value hierarchy as their fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows.

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of December 31, 2023 and 2022 and indicates the fair value category assigned.

	Fair Value Measurements at Reporting Date Using			
(In thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
As of December 31, 2023:				
Money market funds[1][2]	$ 17,658	$ —	$ —	$ 17,658
Certificate of deposit[2]	272	—	—	272
U.S. Treasury securities[3][4]	—	29,742	—	29,742
Government-sponsored enterprise securities[3][4]	—	99,872	—	99,872
Commercial paper[3]	—	102,268	—	102,268
Corporate notes[3][4]	—	75,092	—	75,092
Total	$ 17,930	$ 306,974	$ —	$ 324,904
As of December 31, 2022:				
Money market funds[1][2]	$ 39,864	$ —	$ —	$ 39,864
Certificate of deposit[2]	271	—	—	271
U.S. Treasury securities[3]	—	12,921	—	12,921
Municipal securities[3]	—	2,976	—	2,976
Government-sponsored enterprise securities[3]	—	9,846	—	9,846
Commercial paper[3]	—	64,199	—	64,199
Corporate notes[3]	—	25,959	—	25,959
Total	$ 40,135	$ 115,901	$ —	$ 156,036

(1) Included in cash and cash equivalents on our consolidated balance sheets.

(2) Included in restricted cash on our consolidated balance sheets.

(3) Included in current portion of marketable securities on our consolidated balance sheets.

(4) Included in noncurrent portion of marketable securities on our consolidated balance sheets.

Equity Investment

In December 2007, we received 13,842,625 ordinary shares in Sienna Cancer Diagnostics Limited, or Sienna, in connection with a license we granted to them for our hTERT technology for use in human diagnostics. The shares, which represented less than 20% ownership, were recorded at a zero cost basis under the cost method of accounting, upon receipt. Since the adoption of ASU 2016-01 on January 1, 2018, we reassessed the fair value of our equity investment in Sienna at each reporting date and any resulting change in fair value was recognized on our consolidated statements of operations. In April 2020, Sienna announced its merger with BARD1 Life Sciences Limited, or BARD1, subject to approval by Sienna's shareholders. Effective August 3, 2020, the merger was complete, and we received 13 BARD1 shares for every five shares of Sienna ordinary shares, resulting in our ownership of 35,990,825 shares of BARD1.

During the first quarter of 2021, we sold all of our holdings in BARD1 and recognized a net gain of approximately $1,233,000 from the sales, including gains from foreign currency translation adjustments, which has been included in other income and expense on our consolidated statements of operations. As of March 31, 2021, no value remained for our equity investment in BARD1.

Credit Risk

We currently place our cash, restricted cash, cash equivalents and marketable securities with multiple institutions in the United States. Generally, these deposits may be redeemed upon demand and therefore, bear minimal risk. Deposits with banks may exceed the amount of insurance provided on such deposits. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and marketable securities. Cash equivalents and marketable securities currently consist of money market funds, government-sponsored enterprise securities, U.S. Treasury securities, municipal securities, commercial paper and corporate notes. Our investment policy, approved by the audit committee of our board of directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. However, we are exposed to credit risk in the event of default by the financial institutions holding our cash and cash equivalents to the extent recorded in our consolidated balance sheets. We have not experienced any losses in such accounts and we believe that we are not exposed to significant credit risk of our financial position at the depository institutions in which those deposits are held.

3. PROPERTY AND EQUIPMENT

Property and equipment, stated at cost, is comprised of the following:

	December 31,	
(In thousands)	2023	2022
Furniture and computer equipment	$ 2,273	$ 1,554
Leasehold improvements	135	135
	2,408	1,689
Less accumulated depreciation and amortization	(1,231)	(896)
	$ 1,177	$ 793

4. LICENSE AGREEMENT

Janssen Pharmaceuticals, Inc. License Agreement

On September 15, 2016, we entered into the License Agreement with Janssen Pharmaceuticals whereby we granted to Janssen Pharmaceuticals an exclusive worldwide license, or the Exclusive License, under our proprietary patents for the research, development and commercialization of products based on specialized oligonucleotide backbone chemistry and novel amidates for ribonucleic acid interference. In addition to the Exclusive License, we granted to Janssen Pharmaceuticals a non-exclusive worldwide license, or the Non-Exclusive License, under our patents covering the synthesis of monomers. This agreement was terminated effective April 2021.

5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

	December 31,	
(In thousands)	2023	2022
CRO and clinical trial costs	$ 23,541	$ 17,040
Manufacturing activities	14,629	5,321
Professional legal and accounting fees	556	9,668
Interest payable	768	561
Other	814	510
	$ 40,308	$ 33,100

6. COMMITMENTS AND CONTINGENCIES

Purported Securities Lawsuits

In 2020, three securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, were consolidated by the court. In September 2022, the parties agreed to a settlement and entered into a Stipulation and Agreement of Settlement, which was subject to court approval. The court granted final approval of the settlement on September 28, 2023 and final judgment was entered on October 3, 2023.

Under the terms of the Stipulation, in exchange for the release and dismissal with prejudice of all claims against the defendants in the consolidated class action complaint, we agreed to pay and/or to cause our insurance carriers to pay a total of $24,000,000, comprised of $17,000,000 in cash, which was paid into an escrow account under our available D&O insurance coverage and, $7,000,000 in cash which was paid after final approval of the settlement by the court. The settlement does not constitute an admission of fault or wrongdoing by Geron or any of our officers. As of December 31, 2022, our portion of the settlement amount of $7,000,000 had been included in accrued liabilities on our consolidated balance sheets and recognized as general and administrative expense on our consolidated statements of operations for the year ended December 31, 2022. Our portion of the settlement amount was paid in the fourth quarter of 2023. There is no liability outstanding as of December 31, 2023 as the matter was fully settled during the year ended December 31, 2023.

In 2020 and 2021, seven shareholder derivative actions were filed in a number of courts, naming as defendants certain of our then current officers and certain of our then current and former members of our board. On December 21, 2022, the parties to the shareholder derivative action filed in the Delaware Court of Chancery entered into a stipulation of settlement, or the Derivative Stipulation, and on May 17, 2023, the Delaware Court of Chancery approved the Derivative Stipulation, and the case was dismissed with prejudice. Subsequently, each of the remaining derivative cases were dismissed with prejudice.

Under the terms of the Derivative Stipulation, in exchange for the release and dismissal with prejudice of all claims against the defendants in the consolidated shareholder derivative actions filed in the Northern District, we agreed to pay and/or to cause our insurance carriers to pay a total of $1,350,000, comprised of $525,000 in cash, which was payable under our available D&O insurance coverage and $825,000 in cash payable by us. The settlement does not constitute an admission of fault or wrongdoing by any of our officers or members of our board. As of December 31, 2022, we had recorded the total settlement amount of $1,350,000 as accrued liabilities and $525,000 as interest and other receivables on our consolidated balance sheets. For the year ended December 31, 2022, we had recognized our portion of the settlement of $825,000 as general and administrative expense on our consolidated statements of operations. In the second quarter of 2023, our insurance carriers paid $525,000 in cash,

and we paid $825,000 in cash, for an aggregate total payment of $1,350,000. Accordingly, there are no outstanding amount to settle against this as of December 31, 2023.

While we have settled these lawsuits, it is possible that additional lawsuits might be filed, or allegations might be received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Such 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 such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of any additional lawsuits, and we may not prevail. In addition, we have and may continue to incur substantial legal fees and costs in connection with such lawsuits. Monitoring, initiating and defending against legal actions is time-consuming for our management, is likely to be expensive, and may detract from our ability to fully focus our internal resources on our business activities. We could be forced to expend significant resources in any potential future lawsuits, and we may not prevail in such lawsuits. Additionally, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage. Expenses associated with any potential future lawsuits could be material to our consolidated financial statements if we do not prevail in the defense of such lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to any potential future lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

Indemnifications to Officers and Directors

Our corporate bylaws require that we indemnify our directors, as well as those who act as directors and officers of other entities at our request, against expenses, judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceedings arising out of their services to Geron. In addition, we have entered into separate indemnification agreements with each of our directors and officers which provide for indemnification of these directors and officers under similar circumstances and under additional circumstances. The indemnification obligations are more fully described in our bylaws and the indemnification agreements. We purchase standard insurance to cover claims or a portion of the claims made against our directors and officers. Since a maximum obligation is not explicitly stated in our bylaws or in our indemnification agreements and will depend on the facts and circumstances that arise out of any future claims, the overall maximum amount of the obligations cannot be reasonably estimated.

Severance Plan

We have adopted two severance plans that apply to all of our employees who are not subject to performance improvement plans, one plan covering employees above the Vice President level, i.e., executives, and all other employees hired before January 1, 2022, and the other plan covering all non-executive employees hired on or after January 1, 2022. The severance plans provide for, among other benefits: (i) a severance payment upon a Change of Control Triggering Event and Separation from Service and (ii) a severance payment for each non-executive employee upon a Non-Change of Control Triggering Event and Separation from Service. As defined in the severance plans, a Change of Control Triggering Event and Separation from Service requires a “double trigger” where: (i) an employee is terminated by us without cause in connection with a change of control or within 12 months following a change of control provided, however, that if an employee is terminated by us in connection with a change of control but immediately accepts employment with our successor or acquirer, the employee will not be eligible for the benefits outlined in the plans, (ii) an employee resigns because in connection with a change of control, the offered terms of employment (new or continuing) by us or our successor or acquirer within 30 days after the change of control results in a material change in the terms of employment, or (iii) after accepting (or continuing) employment with us after a change of control, an employee resigns within 12 months following a change of control due to a material change in the terms of employment. Under the severance plans, a Non-Change of Control Triggering Event and Separation from Service is defined as an event where an employee is terminated by us without cause. Severance payments range from three to 18 months of base salary in connection with a Change of Control Triggering Event or from six weeks to 12 months of base salary in connection with a Non-Change of Control Triggering Event, as well as a pro-rata portion of the employee’s annual target bonus, depending on the employee’s position with us, payable in a lump sum payment, and monthly COBRA payments for the severance period. The severance plans also provide that they shall not supersede the provisions of any individual employment agreements entered into between us and our employees, and that the employees with such agreements will be entitled to whichever benefits are greater under the severance plan or their employment agreement. A copy of the severance plan covering our executive officers is filed as an exhibit to our annual report on Form 10-K. As of December 31,

2023, all our executive officers have employment agreements with severance provisions and will receive the greater severance benefits of their agreements or those in the severance plan applicable to them.

7. OPERATING LEASES

New Jersey Office Space Lease

In April 2019, we entered into an operating lease agreement for office space located at 3 Sylvan Way, Parsippany, New Jersey, or the New Jersey Lease. The initial term of the New Jersey Lease is 11 years with an option to extend for an additional five years and a one-time option to terminate the New Jersey Lease without cause as of the 103rd month anniversary of the commencement date of the lease. The New Jersey Lease commenced on October 1, 2019, upon our control of the office space on that date. Based on the initial term of the New Jersey Lease of 11 years, the right-of-use asset and corresponding operating lease liability was approximately $2,356,000, which represented the present value of lease payments over the initial lease term, net of a seven-month rent abatement period, using an incremental borrowing rate of 8% based on information available as of October 1, 2019. Under the New Jersey Lease, we are also obligated to pay certain variable expenses separately from the base rent, including electricity and common area maintenance. Such costs are being expensed in the period they are incurred. As of December 31, 2023, the remaining lease term for the New Jersey Lease is 6.8 years.

Foster City Office Space Lease

In October 2019, we entered into an operating lease agreement for office space located at 919 East Hillsdale Boulevard, Foster City, California, or the Foster City Lease. The initial term of the Foster City Lease is 87 months with an option to extend for an additional five years.

The Foster City Lease commenced on March 10, 2020, upon the substantial completion of all tenant improvements. As of the lease commencement date, the right-of-use asset and corresponding operating lease liability was approximately $1,868,000, which represented the present value of remaining lease payments using an incremental borrowing rate of 7% over the initial lease term of 87 months, net of a three-month rent abatement period. Under the Foster City Lease, we are also obligated to pay certain variable expenses separately from the base rent, including taxes and common area maintenance. Such costs are considered non-lease components and have been excluded from the calculation of the right-of-use asset and corresponding operating lease liability and are being expensed in the period they are incurred. As of December 31, 2023, the remaining lease term for the Foster City Lease is 3.5 years.

The components of lease costs included in operating expenses on our consolidated statements of operations for the New Jersey Lease, the Foster City Lease and a lease from a former location in Menlo Park, California, were as follows:

	Year Ended December 31,		
(In thousands)	2023	2022	2021
Operating lease costs	$ 962	$ 944	$ 946
Variable lease costs (1)	344	310	252
Total lease costs	$ 1,306	$ 1,254	$ 1,198

(1) Variable lease costs represent non-lease components, such as common area maintenance charges.

The undiscounted future non-cancellable lease payments under the New Jersey Lease and the Foster City Lease as of December 31, 2023 were as follows (in thousands):

2024	$ 987
2025	1,014
2026	1,040
2027	716
2028	376
Thereafter	675
Total lease payments	4,808
Less: imputed interest	(853)
Total	$ 3,955

8. DEBT

On September 30, 2020, or the Closing Date, we, Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, or SVB, entered into a term loan facility, or the Term Loan, up to $75.0 million, which was amended in August 2021, or the Original Loan Agreement. On June 30, 2022, we entered into a second amendment to the Original Loan Agreement. Under the second amendment, the aggregate principal amount available to us increased from $75,000,000 to $125,000,000, with such principal being available in a series of tranches, subject to certain terms and conditions. On December 14, 2023, we entered into a third amendment to the Original Loan Agreement, or as amended, the Loan Agreement. As of December 31, 2023, a total of $80.0 million has been drawn under the Loan Agreement.

On the effective date of the second amendment, we paid $100,000 as a facility charge that we recognized as a debt discount and are amortizing such cost to interest expense over the life of the loan using the effective interest rate method. Additional facility charges applied to future draw downs will be treated similarly. We also incurred legal fees in connection with the second amendment, which we recognized as debt issuance costs and are amortizing such cost to interest expense over the life of the loan using the effective interest rate method.

Under the third amendment, the aggregate principal amount drawn down and remaining available to us under the Term Loan remains at $125.0 million, with such principal being available in a series of tranches, subject to certain terms and conditions. The third amendment also provides that (i) the fourth tranche of the Term Loan was increased from $10.0 million to $30.0 million, (ii) the commitment period for the fifth tranche of the Term Loan of $20.0 million, which is available subject to achievement of a regulatory milestone and satisfaction of certain capitalization requirements, was extended through December 15, 2024, (iii) the variable annual interest rate on the outstanding loans has been decreased to the greater of: (x) 9.0%, or (y) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0%; and (iv) the interest only period of the Term Loan has been extended through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. In connection with the third amendment, on the third amendment effective date, we borrowed and received the entire fourth tranche of the Term Loan in the amount of $30.0 million. After giving effect to such borrowing, the outstanding principal amount under the Loan Agreement is $80.0 million. On the effective date of the third amendment, we paid $300,000 as a facility charge that we recognized as a debt discount and are amortizing such cost to interest expense over the life of the loan using the effective interest rate method. Additional facility charges applied to future draw downs will be treated similarly. We also incurred legal fees in connection with the third amendment, which we recognize as debt issuance costs and amortize such cost to interest expense over the life of the loan using the effective interest rate method. The third amendment of the Loan Agreement is not substantially different as compared to the Original Loan Agreement, and accordingly, we treated the amendment as a modification of the debt in accordance with ASC 470. On September 15, 2023, the third tranche of $20.0 million of the Term Loan expired and is no longer available for us, but was added to the fourth tranche as part of the third amendment to the Loan Agreement.

Under the Term Loan as amended, the Term Loan matures on April 1, 2025, or the Loan Maturity Date, and may be extended up to an additional six months upon the achievement of certain regulatory and financial milestones. The Term Loan bears interest at a floating rate per annum equal to the greater of either (i) 9.0% or (ii) the sum of (A) the Prime Rate (as reported in The Wall Street Journal) minus 4.5%, plus (B) 9.0% (8.5% as of December 31, 2023). The interest only period of the Term Loan is through June 30, 2024, and is further extendable to December 31, 2024 upon achievement of a regulatory and financial milestone and satisfaction of certain capitalization requirements. Following the expiration of the interest-only period, we are required to repay the Term Loan in equal monthly amortization payments of principal and interest until the Loan Maturity Date. Upon full repayment of the

Term Loan, we are also obligated to pay an end of term charge in an amount equal to 6.55% of the amount of the Term Loans actually borrowed. Such end of term charge is being accrued to interest expense over the term of the Term Loan using the effective interest rate method. At our option, upon at least five business days' prior written notice to Hercules, we may prepay all or any portion greater than or equal to $5.0 million of the outstanding loan by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest. There is no prepayment charge for prepayments of drawdowns under Tranche 1 or Tranche 2. Prepayments of drawdowns under Tranche 3, Tranche 4, Tranche 5 or Tranche 6 are subject to a prepayment charge of 1.5% of the prepayment amount, if the prepayment is made prior to June 30, 2025. Thereafter, any prepayment of Tranche 3, Tranche 4, Tranche 5 or Tranche 6 is not subject to a prepayment charge.

The Term Loan is secured by substantially all of Geron's assets, except our intellectual property, which is the subject of a negative pledge. The Term Loan contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. We are in compliance with the covenants under the Term Loan as of December 31, 2023.

In the event of default (subject, in certain instances, to specified grace periods), the principal, interest and any other monetary obligations on all then outstanding amounts under the Term Loan may become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding principal balance, and Hercules, as the administrative agent, may declare all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Term Loan. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Term Loan would automatically become due and payable.

Embedded Derivatives and Debt Discounts

The conditional exercisable call option related to the event of default is considered to be an embedded derivative which is required to be bifurcated and accounted for as a separate financial instrument. In the periods presented, the value of the embedded derivative is not material and therefore, no amount has been recognized. If an event of default becomes more probable than is currently estimated, then the embedded derivative could become material in future periods and would be recognized as a separate financial instrument at that time.

As of December 31, 2023, the net carrying value of the Term Loan was $81.9 million, which includes the principal amount of $80.0 million less the net unamortized discounts and debt issuance costs of $605,000 plus an accrued end of term charge of $2,691,000. The carrying value of the debt approximates the fair value as of December 31, 2023. The debt discounts and debt issuance costs are being amortized to interest expense over the life of loan amounts under Term Loan using the effective interest rate method.

Future Minimum Payments

The following table presents future minimum payments, including interest and the end of term charge, under the Term Loan as of December 31, 2023 (in thousands):

2024	$	56,066
2025		39,262
Total		95,328
Less: amount representing interest		(10,088)
Less: unamortized debt discount and issuance costs		(605)
Less: unamortized end of term charge		(2,691)
Less: current portion of debt		(46,893)
Noncurrent portion of debt	$	35,051

9. STOCKHOLDERS' EQUITY

Authorized Common Stock

In May 2023 our stockholders approved an amendment to our Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 675,000,000 to 1,350,000,000 shares.

Public Offering

On April 1, 2022, we completed an underwritten public offering of 53,333,334 shares of our common stock and a pre-funded warrant to purchase 18,095,238 shares of our common stock, or the 2022 pre-funded warrant, together with accompanying warrants to purchase 35,714,286 shares of our common stock, also known as the 2022 stock purchase warrants. The shares of common stock and the 2022 pre-funded warrant were immediately separable from the 2022 stock purchase warrants. All of the securities were issued separately. The combined public offering price of the common stock and accompanying 2022 stock purchase warrants was $1.05 per share. The 2022 stock purchase warrants have an exercise price of $1.45 per share and are exercisable immediately. The term of the 2022 stock purchase warrants expired in the third quarter of 2023, pursuant to the terms of the warrant agreement.. The combined public offering price of the 2022 pre-funded warrant and accompanying 2022 stock purchase warrant was $1.049 per share. The 2022 pre-funded warrant has an exercise price of $0.001 per share and may be exercised at any time until the 2022 pre-funded warrant is exercised in full. As of December 31, 2023, none of the 2022 pre-funded warrant and all of the 2022 stock purchase warrants have been exercised. The net cash proceeds from this offering were $69,916,000, after deducting the underwriting discount and other offering expenses paid by us, and exclude any future proceeds from the exercise of the 2022 pre-funded warrant and 2022 stock purchase warrants.

Upon the issuance of the 2022 pre-funded warrant and 2022 stock purchase warrants, we evaluated the terms of each warrant to determine the appropriate accounting and classification pursuant to FASB Accounting Standards Codification Topic 480, *Distinguishing Liabilities from Equity*, and FASB Accounting Standards Codification Topic 815, *Derivatives and Hedging*. Warrants are classified as liabilities when the warrant terms allow settlement of the warrant exercise in cash and classified as equity when the warrant terms only allow settlement in shares of common stock. The terms of the 2022 pre-funded warrant and the 2022 stock purchase warrants include certain provisions related to fundamental transactions and a cashless exercise provision in the event registered shares are not available, and do not include any mandatory redemption provisions. Based on our evaluation, we concluded the 2022 pre-funded warrant and the 2022 stock purchase warrants should be classified as equity with no subsequent remeasurement as long as such warrants continue to be classified as equity.

On January 10, 2023 we completed an underwritten public offering consisting of 68,007,741 shares of our common stock and the 2023 pre-funded warrant. All of the securities were issued separately. The public offering price of the common stock was $2.45 per share. The public offering price of the 2023 pre-funded warrant was $2.449 per share. The 2023 pre-funded warrant has an exercise price of $0.001 per share and may be exercised at any time until the 2023 pre-funded warrant is exercised in full. As of December 31, 2023, none of the 2023 pre-funded warrant has been exercised. The net cash proceeds from this offering were $213,337,000, after deducting the underwriting discount and other offering expenses paid by us, and exclude any future proceeds from the exercise of the 2023 pre-funded warrant.

Upon the issuance of the 2023 pre-funded warrant, we evaluated the warrant terms to determine the appropriate accounting and classification pursuant to FASB Accounting Standards Codification Topic 480, Distinguishing Liabilities from Equity, and FASB Accounting Standards Codification Topic 815, Derivatives and Hedging. Warrants are classified as liabilities when the warrant terms allow settlement of the warrant exercise in cash and classified as equity when the warrant terms only allow settlement in shares of common stock. The terms of the 2023 pre-funded warrant include certain provisions related to fundamental transactions and a cashless exercise provision in the event registered shares are not available, and do not include any mandatory redemption provisions. Based on our evaluation, we concluded the 2023 pre-funded warrant should be classified as equity with no subsequent remeasurement as long as such warrant continue to be classified as equity.

Warrant Exercises

For the year ended December 31, 2023, warrants to purchase 77,349,859 shares of our common stock were exercised for net cash proceeds of approximately $105,912,000. The warrants were issued in connection with underwritten public offerings of common stock and pre-funded warrants, together with accompanying stock

purchase warrants in May 2020, April 2022, and January 2023. As of December 31, 2023, the following warrants remained outstanding:

- pre-funded warrants with an exercise price of $0.001 per share to purchase 51,430,477 shares of our common stock, which have no expiration date; and
- stock purchase warrants with an exercise price of $1.30 per share to purchase 2,474,503 shares of our common stock related to the public offering of our common stock in May 2020, which expire on December 31, 2025.

For the year ended December 31, 2022, warrants to purchase 11,663,387 shares of our common stock were exercised for net cash proceeds of approximately $15,163,000. The warrants were issued in connection with an underwritten public offering of common stock and a pre-funded warrant, together with accompanying stock purchase warrants in May 2020. As of December 31, 2022, the pre-funded warrant to purchase 8,335,239 shares of our common stock was outstanding and stock purchase warrants to purchase 44,110,079 shares of our common stock associated with the May 2020 public offering remained outstanding.

Sales Agreement

On September 4, 2020, we entered into an At Market Issuance Sales Agreement, or the 2020 Sales Agreement, with B. Riley Securities, Inc., or B. Riley, pursuant to which we were able to elect to issue and sell shares of our common stock having an aggregate offering price of up to $100 million in such quantities and on such minimum price terms as we set from time to time through B. Riley as our sales agent. We agreed to pay B. Riley an aggregate commission rate equal to up to 3.0% of the gross proceeds of the sales price per share for common stock sold through B. Riley under the 2020 Sales Agreement. In connection with the 2020 Sales Agreement, we terminated the 2018 Sales Agreement. The 2020 Sales Agreement expired on September 4, 2023.

On November 1, 2023, we entered into an At Market Issuance Sales Agreement, or the 2023 Sales Agreement with B. Riley, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $100 million from time to time through B. Riley as the sales agent. We have agreed to pay B. Riley an aggregate commission rate equal to up to 3.0% of the gross proceeds of the sales price per share for common stock sold through B. Riley under the 2023 Sales Agreement. The 2023 Sales Agreement will automatically terminate upon the earlier of (i) the sale of all common stock subject to the 2023 Sales Agreement, or (ii) termination of the 2023 Sales Agreement in accordance with its terms.

For the year ended December 31, 2021, we sold an aggregate of 10,571,556 shares of our common stock pursuant to the 2020 Sales Agreement, resulting in net cash proceeds to us of approximately $20.4 million after deducting sales commissions and other offering expenses paid by us. No shares of our common stock were sold pursuant to the 2020 Sales Agreement or the 2023 Sales Agreement during the year ended December 31, 2023.

Equity Plans

2011 Incentive Award Plan

In May 2011, our stockholders approved the adoption of the 2011 Incentive Award Plan, or 2011 Plan. The 2011 Plan provided for grants of either incentive stock options or nonstatutory stock options and stock purchase rights to employees (including officers and employee directors) and consultants (including non-employee directors). Upon the adoption of the 2018 Equity Incentive Plan in May 2018 (see below), no further grants of stock options or stock purchase rights were made under the 2011 Plan. Stock options granted under the 2011 Plan expire no later than ten years from the date of grant. Stock option exercise prices were equal to the fair market value of the underlying common stock on the date of grant.

Service-based stock options under the 2011 Plan generally vested over a period of four years from the date of grant. Other stock awards (restricted stock awards and restricted stock units) had variable vesting schedules which were determined by our board of directors on the date of grant. All outstanding awards granted under the 2011 Plan remain subject to the terms of the 2011 Plan and the individual award agreements thereunder.

2018 Equity Incentive Plan

On May 15, 2018, our stockholders approved the adoption of the 2018 Equity Incentive Plan, or 2018 Plan, as the successor to the 2011 Plan. The 2018 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and

performance awards that may be settled in cash, stock, or other property. Eligible participants under the 2018 Plan include our employees, consultants and non-employee directors. The number of shares reserved for issuance under the 2018 Plan (subject to adjustment for certain changes in capitalization) is equal to the sum of (i) the unallocated shares of common stock remaining available for grant under the 2011 Plan as of May 15, 2018, (ii) 10,000,000 newly reserved shares of common stock and (iii) the number of shares subject to awards granted under the 2002 Equity Incentive Plan, and the 2011 Plan as such shares become available from time to time, referred to as the Prior Plans' Returning Shares. Such Prior Plans' Returning Shares become available for issuance under the 2018 Plan if outstanding stock awards granted under the 2002 Equity Incentive Plan and the 2011 Plan, after May 15, 2018, expire or terminate for any reason prior to exercise or settlement or are forfeited, cancelled or otherwise returned to us because of the failure to meet a contingency or condition required for the vesting of such shares, or, subject to certain exceptions, are reacquired or withheld (or not issued) by us to satisfy a tax withholding obligation in connection with a stock award. In May 2023, May 2022 and May 2021, our stockholders approved amendments to our 2018 Equity Incentive Plan to increase the total number of shares issuable under such plan by 43,360,000, 11,000,000, and 12,500,000 shares of our common stock, respectively.

Stock options granted under the 2018 Plan expire no later than ten years from the date of grant. Stock option exercise prices shall be equal to the fair market value of the underlying common stock on the date of grant. If, at the time we grant a stock option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of our stock, the stock option exercise price shall be at least 110% of the fair market value of the underlying common stock and shall not be exercisable more than five years after the date of grant.

We grant service-based and performance-based stock options to employees under the 2018 Plan. Service-based stock options generally vest over a period of four years from the date of the stock option grant. Performance-based stock options vest upon the achievement of specified milestones. Other stock awards (restricted stock awards and restricted stock units) have variable vesting schedules as determined by our board of directors on the date of grant.

Under certain circumstances, stock options may be exercised prior to vesting, subject to our right to repurchase the shares underlying such stock option at the exercise price paid per share. Our repurchase rights would generally terminate on a vesting schedule identical to the vesting schedule of the exercised stock option. During 2023 and 2022, we did not repurchase any shares under the 2018 Plan. As of December 31, 2023, we have no shares outstanding subject to repurchase under the 2018 Plan.

As of December 31, 2023, our Non-Employee Director Compensation Policy adopted by our board of directors in March 2014, as amended and restated in February and March 2022, provides for the automatic grant to non-employee directors of the following types of equity awards under the 2018 Plan:

First Director Option. Each person who becomes a non-employee director, whether by election by our stockholders or by appointment by our board of directors to fill a vacancy, will automatically be granted a stock option to purchase 200,000 shares of common stock, or First Director Option, on the date such person first becomes a non-employee director. The First Director Option vests annually over three years upon each anniversary date of appointment to our board of directors.

Subsequent Director Option. Each non-employee director (other than any director receiving a First Director Option on the date of the annual meeting) will automatically be granted a subsequent stock option to purchase 125,000 shares of common stock, a Subsequent Director Option, on the date of the annual meeting of stockholders in each year during such director's service on our board of directors. The Subsequent Director Option vests in full on the earlier of: (i) the date of the next annual meeting of our stockholders or (ii) the first anniversary of the date of grant.

2006 Directors' Stock Option Plan

The 2006 Directors' Stock Option Plan, or 2006 Directors Plan, was terminated by our board of directors and replaced by the 2011 Plan in March 2014. No further grants of stock options were made from the 2006 Directors Plan upon the 2006 Directors Plan's termination. All outstanding awards granted under the 2006 Directors Plan remain subject to the terms of the 2006 Directors Plan and the individual award agreements thereunder.

The stock options granted to non-employee directors under the 2006 Directors Plan were nonstatutory stock options, and they expire no later than ten years from the date of grant. The option exercise price was equal to the fair market value of the underlying common stock on the date of grant. The first director option granted to non-employee directors under the 2006 Directors Plan vested annually over three years upon each anniversary date of appointment to the board of directors. The subsequent director option granted to non-employee directors on the date of the annual meeting of stockholders in each year during such director's service on our board of directors under the 2006 Directors Plan vested one year from the date of grant.

2018 Inducement Award Plan

In December 2018, our board of directors approved the adoption of the 2018 Inducement Award Plan, or the Inducement Plan, pursuant to which we reserved 3,000,000 shares of our common stock to be used exclusively for grants of inducement awards to individuals who were not previously Geron employees or non-employee directors, other than following a bona fide period of non-employment. In May 2023, the compensation committee of our board of directors approved amendments to our 2018 Inducement Award Plan to increase the total number of shares issuable under such plan by 13,900,000, shares of our common stock. As of December 31, 2023, an aggregate total of 32,306,638 shares of common stock have been reserved under the Inducement Plan, with 11,616,841 available for grant.

The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock awards, and all awards under the Inducement Plan are intended to meet the standards under Rule 5635(c)(4) of the Nasdaq Listing Rules. The terms and conditions of the Inducement Plan and the inducement awards to be granted thereunder are substantially similar to our stockholder-approved 2018 Plan.

Directors' Market Value Stock Purchase Plan

In October 2018, our board of directors adopted a Directors' Market Value Stock Purchase Plan, or the Directors Market Plan. A total of 1,000,000 shares of our common stock have been reserved for the Directors Market Plan. Under the Directors Market Plan, non-employee directors may purchase shares of our common stock at the prevailing market price on the purchase date with cash compensation payable to them for their services as a board member. As stated in Geron's Non-Employee Director Compensation Policy, each non-employee director receives annual cash compensation, payable quarterly in arrears, for their services on the board and various committees of the board. As provided in the Non-Employee Director Compensation Policy, a non-employee director may elect to receive fully vested shares of common stock in lieu of cash and such shares shall be issuable from the Directors Market Plan.

For the years ended December 31, 2023, 2022 and 2021, we issued 36,864, 15,962 and 20,783 shares of common stock, respectively, under the Directors Market Plan. The weighted average grant date fair value of stock granted during the years ended December 31, 2023, 2022 and 2021 was $2.37, $1.92 and $1.38 per share, respectively. The total fair value of vested stock grants during 2023, 2022 and 2021 was $85,400, $29,000 and $29,000, respectively.

Aggregate stock option and award activity for the 2011 Plan, 2018 Plan, 2006 Directors Plan, Inducement Plan and Directors Market Plan is as follows:

	Shares Available For Grant	Outstanding Stock Options			
		Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value
Balance at December 31, 2022	18,370,729	65,902,400	$ 1.87		
Additional shares authorized	56,368,058	—	$ —		
Stock options granted	(20,855,230)	20,855,230	$ 2.72		
Awards granted	(36,864)	—	$ —		
Stock options exercised	—	(8,869,302)	$ 1.39		
Stock options cancelled/forfeited/expired	4,903,977	(4,903,977)	$ 2.15		
Balance at December 31, 2023	58,750,670	72,984,351 (1)	$ 2.16	6.70	$ 25,391,643
Stock options exercisable at December 31, 2023		39,995,642	$ 2.16	5.28	$ 15,557,976
Stock options fully vested and expected to vest at December 31, 2023		71,983,176	$ 2.15	6.67	$ 25,169,074

(1) Includes 7,936,030 performance-based stock options granted that have not achieved the specified performance milestones.

The aggregate intrinsic value in the preceding table represents the total intrinsic value, based on Geron's closing stock price of $2.11 per share as of December 31, 2023, which would have been received by the option holders had all the option holders exercised their stock options as of that date.

We have not granted any stock options with an exercise price below or greater than the fair market value of our common stock on the date of grant in 2023, 2022, and 2021. As of December 31, 2023, 2022 and 2021, there were 39,995,642, 36,085,389 and 30,459,136 exercisable stock options outstanding at weighted average exercise prices per share of $2.16, $2.17 and $2.35, respectively.

The total pretax intrinsic value of stock options exercised during 2023, 2022, and 2021 was $11,986,000 $787,000 and $93,000, respectively. Cash received from the exercise of stock options in 2023, 2022, and 2021 totaled approximately $12,356,000, $1,799,000 and $556,000, respectively.

Employee Stock Purchase Plan

In March 2014, our board of directors adopted the 2014 Employee Stock Purchase Plan, or 2014 Purchase Plan. The 2014 Purchase Plan was approved by our stockholders in May 2014. The 2014 Purchase Plan replaced the 1996 Employee Stock Purchase Plan, or 1996 Purchase Plan, which was terminated effective as of the date the 2014 Purchase Plan was approved by our stockholders. In May 2022, our stockholders approved an amendment to our 2014 Purchase Plan to increase the total number of shares issuable under such plan by 1,000,000 shares of our common stock, for an aggregate total reserve of 2,000,000 shares. As of December 31, 2023, an aggregate of 1,254,162 shares of our common stock have been issued under the 2014 Purchase Plan since its adoption.

The 2014 Purchase Plan is comprised of a series of offering periods, each with a maximum duration (not to exceed 12 months) with new offering periods commencing on January 1st and July 1st of each year. The date an employee enters the offering period will be designated as the entry date for purposes of that offering period. An employee may participate only in one offering period at a time. Each offering period consists of two consecutive purchase periods of six months' duration, with the last day of such period designated a purchase date.

Under the terms of the 2014 Purchase Plan, employees can choose to have up to 10% of their annual salary withheld to purchase our common stock, up to a limit of $25,000 per year. An employee may not make additional payments into such account or increase the withholding percentage during the offering period.

The purchase price per share at which common stock is purchased by the employee on each purchase date within the offering period is equal to 85% of the lower of (i) the fair market value per share of our common stock on the employee's entry date into that offering period or (ii) the fair market value per share of our common stock on the purchase date. If the fair market value per share of our common stock on the purchase date is less than the fair

market value at the beginning of the offering period, a new 12 month offering period will automatically begin on the first business day following the purchase date with a new fair market value.

Stock-Based Compensation for Employees and Directors

We measure and recognize compensation expense for all share-based payment awards made to employees and directors, including employee stock options, restricted stock awards and employee stock purchases, based on grant-date fair values for these instruments. We use the Black-Scholes option-pricing model to estimate the grant-date fair value of our service-based and performance-based stock options and employee stock purchases. The fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant.

As stock-based compensation expense recognized on the consolidated statements of operations for the years ended December 31, 2023, 2022 and 2021 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures, but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. Forfeitures have been estimated at the time of grant based on historical data and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

In 2023, 2022 and 2021, our board of directors awarded 832,790, 2,741,750 and 550,000 performance-based stock options, respectively, to certain employees. These performance-based stock options are included in the outstanding stock options table above. Performance-based stock options vest only upon achievement of discrete milestones. Stock-based compensation expense for performance-based stock options is recognized over the period from the date the performance condition is determined to be probable of occurring through the date the applicable condition is expected to be met and is reduced for estimated forfeitures, as applicable. If the performance condition is not considered probable of being achieved, no stock-based compensation expense is recognized until such time as the performance condition is considered probable of being achieved, if ever.

We recognize stock-based compensation expense for service-based stock options on a straight-line basis over the requisite service period, which is generally the vesting period. We recognized $3,167,000 of stock-based compensation expense for performance-based stock options on our consolidated statements of operations for the year ended December 31, 2023. We did not recognize any stock-based compensation expense for performance-based stock options on our consolidated statements of operations for the years ended December 31, 2022 and 2021, as the achievement of the specified milestones was not considered probable during that time. The following table summarizes the stock-based compensation expense related to service-based stock options and employee stock purchases for the years ended December 31, 2023, 2022 and 2021, which was allocated as follows:

	Year Ended December 31,		
(In thousands)	2023	2022	2021
Research and development	$ 7,426	$ 3,720	$ 3,597
General and administrative	11,099	4,281	4,483
Stock-based compensation expense included in operating expenses	$ 18,525	$ 8,001	$ 8,080

The fair value of stock options granted in 2023, 2022, and 2021 has been estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2023	2022	2021
Dividend yield	0%	0%	0%
Expected volatility range	0.815 to 0.827	0.772 to 0.817	0.775 to 0.783
Risk-free interest rate range	3.42% to 4.94%	1.69% to 4.57%	0.51% to 1.30%
Expected term range	6.0 yrs	5.5 yrs	5.5 yrs

The fair value of employee stock purchases in 2023, 2022, and 2021 has been estimated using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2023	2022	2021
Dividend yield	0%	0%	0%
Expected volatility range	0.791 to 0.832	0.614 to 0.865	0.507 to 0.707
Risk-free interest rate range	4.73% to 5.4%	0.40% to 2.79%	0.09% to 0.16%
Expected term range	6 - 12 mos	6 - 12 mos	6 - 12 mos

Dividend yield is based on historical cash dividend payments and we have paid no cash dividends to date. The expected volatility range is based on historical volatilities of our stock, since traded options on our common stock do not correspond to option terms and the trading volume of options is limited. The risk-free interest rate range is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term in effect on the date of grant for an award. The expected term of stock options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that stock options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Based on the Black-Scholes option-pricing model, the weighted-average estimated fair value of stock options granted during the years ended December 31, 2023, 2022 and 2021 was $1.95, $0.92 and $1.17 per share, respectively. The weighted average estimated fair value of employees' purchase rights for the years ended December 31, 2023, 2022 and 2021 was $1.10, $0.48 and $0.56 per share, respectively. As of December 31, 2023, total compensation cost related to unvested share-based payment awards not yet recognized, net of estimated forfeitures and assuming no probability of achievement for outstanding performance-based stock options, was $37,628,000, which is expected to be recognized over the next 26 months on a weighted-average basis.

Stock-Based Compensation to Service Providers

We grant stock options to consultants from time to time in exchange for services performed for us. In general, the stock options vest over the contractual period of the consulting arrangement. The fair value of stock options held by consultants is recorded as operating expenses over the vesting term of the respective equity awards. With the adoption of Accounting Standards Update 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, in the first quarter of 2019, the measurement date of stock options granted to consultants was fixed at the grant date. We recorded stock-based compensation expense of $742,000, $235,000 and $62,000 for the vested portion of the fair value of stock options held by consultants in 2023, 2022, and 2021, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2023 is as follows:

Outstanding stock options	72,984,351
Stock options and awards available for grant	58,750,670
Employee stock purchase plan	745,838
Warrants outstanding	53,904,980
Total	186,385,839

10. INCOME TAXES

The following table reconciles the federal statutory tax rate to the effective income tax rate from continuing operations:

	2023	2022	2021
Tax at statutory rate	21.0 %	21.0 %	21.0 %
State income tax, net of federal benefit	6.6	6.8	9.0
Federal and state tax credits	4.1	4.9	5.7
Stock-based compensation	(0.7)	(0.8)	(1.2)
Net operating loss not benefitted	(5.7)	(4.3)	(5.4)
Other	(0.5)	(0.1)	(0.2)
Change in valuation allowance	(24.8)	(27.5)	(28.9)
Effective tax rate	0.0 %	0.0 %	0.0 %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows:

	December 31,	
	2023	2022
	(In thousands)	
Net operating loss carryforwards	$ 272,300	$ 254,500
Federal and state tax credits	64,700	56,700
Capitalized research and development	43,300	21,800
Stock-based compensation	11,200	10,800
Operating lease liabilities	1,100	1,300
Other	3,600	5,600
Total deferred tax assets	396,200	350,700
Less: valuation allowance	(395,200)	(349,600)
Net deferred tax assets	1,000	1,100
Operating leases, right-of-use assets	(1,000)	(1,100)
Total deferred tax liabilities	(1,000)	(1,100)
Total net deferred tax assets	$ —	$ —

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial performance. Forming a conclusion that a valuation allowance is not required is difficult when there is negative evidence such as cumulative losses in recent years. Because of our history of losses, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $45.6 million and $38.9 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, we had domestic federal net operating loss carryforwards of approximately $1.0 billion. Of this, $635.6 million will expire at various dates beginning in 2024 through 2037 and the remaining will carryforward indefinitely under the new tax laws, but is subject to an 80% taxable income limitation for tax years beginning after 2020. As of December 31, 2023, we had state net operating loss carryforwards of approximately $841.2 million expiring at various dates beginning in 2028 through 2043, if not utilized. We also had federal tax credit carryforwards of approximately $72.7 million expiring at various dates beginning in 2024 through 2043, if not utilized. Our state tax credit carryforwards of approximately $21.4 million carry forward indefinitely.

Utilization of net operating loss and tax credit carryforwards may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized. The impact of any limitations that may be imposed due to such ownership changes has not yet been determined. Due to the Company's stock issuance in January 2023, the utilization of the Company's net operating loss and tax credit carryforwards are subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. The annual limitation may result in the expiration of the net operating loss and tax credit carryforwards before some or call of such amounts have been utilized. The final amount of the limitations imposed due to such ownership changes has not yet been determined.

In March and December 2020, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, and the Consolidated Appropriations Act, 2021 were passed into law and provide additional economic stimulus to address the impact of the COVID-19 pandemic, including among other items, several U.S. income tax provisions related to, among other things, net operating loss carrybacks, alternative minimum tax credits, modifications to interest expense limitations, and an option to defer payroll tax payments for a limited period. In 2021, we assessed our eligibility to claim a refund of employer taxes available under the Employee Retention Credit provisions of the CARES Act. For the years ended December 31, 2022 and 2021, we calculated eligible credits of approximately $483,000 and $1.1 million, respectively, provided by the CARES Act, which have been recognized as offsets to salaries costs in operating expenses in 2022 and 2021, respectively. As of December 31, 2022, the aggregate eligible credit amount has been accrued as a receivable on our consolidated balance sheets. We received the Employee Retention Credit from the IRS, and there are no outstanding receivables as of December 31, 2023.

We adopted the provision of the standard for accounting for uncertainties in income taxes on January 1, 2007. Upon adoption, we recognized no material adjustment in the liability for unrecognized tax benefits. At December 31, 2023, we had approximately $26.3 million of unrecognized tax benefits, none of which would currently affect our effective tax rate if recognized due to our net deferred tax assets being fully offset by a valuation allowance.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows (in thousands):

Balance as of December 31, 2022	$ 23,700
Increase related to prior year tax positions	—
Increase related to current year tax positions	2,600
Balance as of December 31, 2023	$ 26,300

If applicable, we would classify interest and penalties related to uncertain tax positions in income tax expense. Through December 31, 2023, there has been no interest expense or penalties related to unrecognized tax benefits.

We do not currently expect any significant changes to unrecognized tax benefits during the fiscal year ended December 31, 2023. In certain cases, our uncertain tax positions are related to tax years that remain subject to examination by the relevant tax authorities. Tax years for which we have carryforward net operating loss and credit attributes remain subject to examination by federal and most state tax authorities.

11. CONSOLIDATED STATEMENTS OF CASH FLOWS DATA

	Year Ended December 31,		
	2023	2022	2021
	(In thousands)		
Supplemental operating and investing activities:			
Net unrealized loss on marketable securities	$ (431)	$ (68)	$ (251)
Reclassification between prepaid and other current assets and deposits and other assets	—	(5)	—
Interest paid	$ (7,017)	$ 5,154	$ 2,704

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(I) Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation under the supervision and with the participation of management, including our Chief Executive Officer and our Chief Financial Officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

In designing and evaluating disclosure controls and procedures, our management recognizes that any system of controls, however well designed and operated, can provide only reasonable assurance, and not absolute assurance, that the desired control objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals in all future circumstances. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and our Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this annual report on Form 10-K, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

(II) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(III) Management's Report on Internal Control over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Management is responsible for establishing and maintaining an adequate internal control over financial reporting for us. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our evaluation under the framework set forth in "Internal Control—Integrated Framework," our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

(IV) Report of Independent Registered Public Accounting Firm

This annual report on Form 10-K includes an attestation report of our independent registered public accounting firm. It is set forth in Item 8 above.

ITEM 9B. OTHER INFORMATION

Trading Arrangements

During our last fiscal quarter, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of our securities set forth in the table below.

			Character of Trading Arrangement			
Name and Title	**Action**	**Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares to be Sold**	**Expiration Date**
Faye Feller, M.D., Executive Vice President and Chief Medical Officer	Termination[1]	October 25, 2023	X		30,000	January 12, 2024
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.						
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.						

[1] Represents the termination of a written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), as then in effect when adopted on January 13, 2023.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Certain information required by Part III is omitted from this annual report on Form 10-K because we will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for Geron's Annual Meeting of Stockholders expected to be held in May 2024, or the Proxy Statement, not later than 120 days after the end of the fiscal year covered by this annual report on Form 10-K, and certain information included therein is incorporated herein by reference, or an amendment to this annual report on Form 10-K under cover of Form 10-K/A containing the information required by this Part III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors and Nominees for Director

The information required by this item concerning our directors and nominees for director is incorporated by reference from the section captioned "Proposal 1: Election of Directors" contained in our Proxy Statement.

Identification of Executive Officers

The information required by this item concerning our executive officers is set forth in Part I, Item 1 of this annual report on Form 10-K.

Code of Ethics

We have adopted a Code of Conduct with which every person who works for Geron, including our board of directors, is expected to comply. The Code of Conduct is publicly available on our website under the Investors & Media section at www.geron.com. This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this annual report on Form 10-K. If any substantive amendments are made to the Code of Conduct or any waiver granted, including any implicit waiver, from a provision of the Code of Conduct to our Chief Executive Officer, Chief Financial Officer or Corporate Controller, we will disclose the nature of such amendment or waiver on that website or in a report on Form 8-K.

Copies of the Code of Conduct will be furnished without charge to any person who submits a written request directed to the attention of our Corporate Secretary, at our offices located at 919 East Hillsdale Boulevard, Suite 250, Foster City, California, 94404.

Certain Corporate Governance Matters

The information required by this item concerning our audit committee, audit committee financial expert and procedures by which stockholders may recommend nominees to our board of directors, may be found under the sections captioned "Board Leadership and Governance" and "Other Matters" contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the sections captioned "Summary Compensation Table and Narrative Disclosure to Summary Compensation Table," and "Compensation of Directors" contained in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the sections captioned "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" contained in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the sections captioned "Proposal 1: Election of Directors" and "Certain Transactions" contained in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the section captioned "Principal Accountant Fees and Services" contained in the Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

Included in Part II, Item 8 of this Report:

(2) Financial Statement Schedules

Financial statement schedules are omitted because they are not required or the information is disclosed in the financial statements listed in Item 15(a)(1) above.

(3) Exhibits

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
3.1	Restated Certificate of Incorporation	3.3	8-K	May 18, 2012	000-20859
3.2	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	May 18, 2012	000-20859
3.3	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	June 7, 2019	000-20859
3.4	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	May 13, 2021	000-20859
3.5	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	June 2, 2023	000-20859
3.6	Amended and Restated Bylaws of Registrant	3.1	8-K	December 15, 2023	000-20859
4.1	Description of Capital Stock	4.1			
4.2	Form of Common Stock Certificate	4.1	10-K	March 15, 2013	000-20859
4.3	Form of Pre-Funded Warrant to Purchase Common Stock	4.1	8-K	May 26, 2020	000-20859
4.4	Form of Warrant to Purchase Common Stock	4.2	8-K	May 26, 2020	000-20859
4.5	Form of Pre-Funded Warrant to Purchase Common Stock	4.1	8-K	March 30, 2022	000-20859
4.6	Form of Warrant to Purchase Common Stock	4.2	8-K	March 30, 2022	000-20859
4.7	Form of Pre-Funded Warrant to Purchase Common Stock	4.1	8-K	January 6, 2023	000-20859
10.1	Form of Indemnification Agreement	10.1	10-K	March 7, 2012	000-20859
10.2	Amended and Restated 2006 Directors' Stock Option Plan*	10.5	10-Q	November 7, 2013	000-20859
10.3	2011 Incentive Award Plan*	10.1	8-K	May 16, 2011	000-20859
10.4	Form of Stock Option Agreement under 2011 Incentive Award Plan*	10.11	10-K	March 15, 2013	000-20859
10.5	Form of Restricted Stock Award Agreement under 2011 Incentive Award Plan*	10.12	10-K	March 15, 2013	000-20859
10.6	Form of Non-Employee Director Stock Option Agreement under 2011 Incentive Award Plan*	10.2	10-Q	May 7, 2015	000-20859
10.7	2018 Equity Incentive Plan, as amended*	10.1	8-K	June 2, 2023	000-20859
10.8	UK Sub-Plan to 2018 Equity Incentive Plan*	10.1	10-Q	November 7, 2022	000-20859
10.9	Form of 2018 Equity Incentive Plan Option Agreement (Time Based)*	10.2	10-Q	November 7, 2022	000-20859
10.10	Form of 2018 Equity Incentive Plan Option Agreement (Performance Based)*	10.3	10-Q	November 7, 2022	000-20859
10.11	Form of Non-Employee Director Stock Option Agreement under 2018 Equity Incentive Plan*	10.4	8-K	May 18, 2018	000-20859
10.12	Form of Non-Employee Director Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.13	10-K	March 7, 2019	000-20859
10.13	Form of Performance-Vesting Stock Option Agreement under 2018 Equity Incentive Plan*	10.14	10-K	March 7, 2019	000-20859
10.14	Form of Performance-Vesting Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.15	10-K	March 7, 2019	000-20859
10.15	2018 Inducement Award Plan, as amended*	10.2	10-Q	August 3, 2023	000-20859
10.16	UK Sub-Plan to 2018 Inducement Award Plan*	10.5	10-Q	November 7, 2022	000-20859
10.17	Form of Stock Option Agreement under 2018 Inducement Award Plan*	10.2	8-K	December 14, 2018	000-20859
10.18	Form of Stock Option Agreement under 2018 Inducement Award Plan, as amended*	10.19	10-K	March 7, 2019	000-20859
10.19	Form of Performance-Vesting Stock Option Agreement under 2018 Inducement Award Plan*	10.20	10-K	March 7, 2019	000-20859
10.20	2014 Employee Stock Purchase Plan, as amended*	10.2	8-K	May 13, 2022	000-20859

10.21	Form of 2018 Inducement Award Plan Option Agreement (Time Based)*	10.6	10-Q	November 7, 2022	000-20859
10.22	Form of 2018 Inducement Award Plan Option Agreement (Performance Based)*	10.7	10-Q	November 7, 2022	000-20859
10.23	Non-Employee Director Compensation Policy, as amended February 16, 2022, March 7, 2022 and February 14, 2024*				
10.24	Directors' Market Value Stock Purchase Plan, effective October 1, 2018*	10.1	10-Q	November 1, 2018	000-20859
10.25	Amended and Restated Severance Plan, effective as of January 1, 2022*	10.22	10-K	March 10, 2022	000-20859
10.26	Amended and Restated Employment Agreement between the Registrant and John A. Scarlett, M.D., effective as of January 31, 2019*	10.29	10-K	March 7, 2019	000-20859
10.27	Amended and Restated Employment Agreement between the Registrant and Andrew J. Grethlein, effective as of January 31, 2019*	10.31	10-K	March 7, 2019	000-20859
10.28	Amended and Restated Employment Agreement between the Registrant and Olivia K. Bloom, effective as of January 31, 2019*	10.32	10-K	March 7, 2019	000-20859
10.29	Employment Agreement between the Registrant and Anil Kapur, effective as of December 2, 2019*	10.33	10-K	March 12, 2020	000-20859
10.30	Employment Agreement by and between the Registrant and Faye Feller, effective as of July 9, 2022*				
10.31	Employment Agreement by and between the Registrant and Scott A. Samuels, effective as of August 1, 2023*	10.1	10-Q	November 2, 2023	000-20859
10.32	Employment Agreement by and between the Registrant and Michelle Robertson, effective as of September 25, 2023*	10.2	10-Q	November 2, 2023	000-20859
10.33	Office Lease Agreement by and between Registrant and 3 Sylvan Realty LLC, effective as of April 30, 2019	10.18	10-Q	May 2, 2019	000-20859
10.34	Office Lease Agreement by and between Registrant and Hudson Metro Center LLC, effective as of October 9, 2019	10.1	8-K	October 15, 2019	000-20859
10.35	At Market Issuance Sales Agreement, dated November 1, 2023, by and between Registrant and B. Riley Securities, Inc.	10.1	8-K	November 2, 2023	000-20859
10.36	Loan and Security Agreement, dated September 30, 2020, amongst Registrant, Hercules Capital, Inc., and Silicon Valley Bank^	10.1	10-Q	November 5, 2020	000-20859
10.37	Amendment to Loan and Security Agreement, dated August 12, 2021, amongst Registrant, Hercules Capital, Inc., and Silicon Valley Bank^	10.1	10-Q	August 16, 2021	000-20859
10.38	Second Amendment to Loan and Security Agreement, dated June 30, 2022 amongst Registrant, Hercules Capital, Inc., and Silicon Valley Bank^	10.4	10-Q	August 11, 2022	000-20859
10.39	Third Amendment to Loan and Security Agreement, dated December 14, 2023 amongst Registrant, Hercules Capital, Inc., and Silicon Valley Bank^				
21.1	List of Subsidiaries				
23.1	Consent of Independent Registered Public Accounting Firm				
24.1	Power of Attorney (see signature page)				
31.1	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to				

	Section 302(a) of the Sarbanes-Oxley Act of 2002, dated February 28, 2024				
31.2	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated February 28, 2024				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated February 28, 2024**				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated February 28, 2024**				
97.1	Incentive Compensation Recoupment Policy, effective October 2, 2023*				
101	The following materials from the Registrant's annual report on Form 10-K for the year ended December 31, 2023, formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Consolidated Balance Sheets as of December 31, 2023 and 2022, (ii) Consolidated Statements of Operations, Consolidated Comprehensive Loss, Stockholders' Equity and Cash Flows for each of the three years in the period ended December 31, 2023, and (iii) Notes to Consolidated Financial Statements				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

^ Certain portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information is of the type that the Registrant customarily and actually treats as private or confidential.

* Management contract or compensation plan or arrangement.

** The certifications attached as Exhibits 32.1 and 32.2 that accompany this annual report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this annual report on Form 10-K), irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GERON CORPORATION

Date: February 28, 2024

By: /s/ Michelle Robertson
MICHELLE ROBERTSON
Executive Vice President, Finance, Chief Financial Officer and Treasurer

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, John A. Scarlett, M.D., and Michelle Robertson, and each one of them, attorneys-in-fact for the undersigned, each with the power of substitution, for the undersigned in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitutes, may do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his/her name.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JOHN A. SCARLETT JOHN A. SCARLETT	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	February 28, 2024
/s/ MICHELLE ROBERTSON MICHELLE ROBERTSON	Executive Vice President, Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 28, 2024
/s/ GAURAV AGGARWAL GAURAV AGGARWAL	Director	February 28, 2024
/s/ DAWN C. BIR DAWN C. BIR	Director	February 28, 2024
/s/ V. BRYAN LAWLIS V. BRYAN LAWLIS	Director	February 28, 2024
/s/ JOHN MCDONALD JOHN F. McDONALD	Director	February 28, 2024
/s/ SUSAN MOLINEAUX SUSAN M. MOLINEAUX	Director	February 28, 2024
/s/ ELIZABETH G. O'FARRELL ELIZABETH G. O'FARRELL	Director	February 28, 2024
/s/ ROBERT J. SPIEGEL ROBERT J. SPIEGEL	Director	February 28, 2024

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1) Registration Statements (Form S-3 Nos. 333-225184, 333-238595, 333-248637 and 333-269111) and in the related prospectuses and prospectus supplements,
2) Registration Statements (Form S-8 Nos. 333-239324, 333-258864, and 333-273669) pertaining to the 2018 Inducement Award Plan and the 2018 Equity Incentive Plan,
3) Registration Statement (Form S-8 No. 333-230171) pertaining to the 2018 Inducement Award Plan,
4) Registration Statement (Form S-8 No. 333-228147) pertaining to the Directors' Market Value Stock Purchase Plan,
5) Registration Statement (Form S-8 No. 333-225190) pertaining to the 2018 Equity Incentive Plan,
6) Registration Statement (Form S-8 No. 333-196677) pertaining to the 2014 Employee Stock Purchase Plan,
7) Registration Statement (Form S-8 No. 333-174350) pertaining to the 2011 Incentive Award Plan, the 2002 Equity Incentive Plan, the 1996 Directors' Stock Option Plan and the 1992 Stock Option Plan,
8) Registration Statement (Form S-8 No. 333-136330) pertaining to the 2002 Equity Incentive Plan and the 2006 Directors' Stock Option Plan, and
9) Registration Statement (Form S-8 No. 333-266795) pertaining to the 2018 Equity Incentive Plan, the 2018 Inducement Award Plan and the 2014 Employee Stock Purchase Plan.

of our reports dated February 28, 2024, with respect to the consolidated financial statements and the effectiveness of internal control over financial reporting of Geron Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Jose, California
February 28, 2024

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
FORM OF RULE 13A-14(A)
AS ADOPTED PURSUANT TO
SECTION 302(A) OF THE SARBANES-OXLEY ACT OF 2002

I, John A. Scarlett, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Geron Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2024

/s/ John A. Scarlett

JOHN A. SCARLETT, M.D.
President, Chief Executive Officer and Chairman of the Board

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
FORM OF RULE 13A-14(A)
AS ADOPTED PURSUANT TO
SECTION 302(A) OF THE SARBANES-OXLEY ACT OF 2002

I, Michelle Robertson, certify that:

1. I have reviewed this annual report on Form 10-K of Geron Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2024

/s/ Michelle Robertson

MICHELLE ROBERTSON
Executive Vice President, Finance,
Chief Financial Officer and Treasurer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Geron Corporation (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying annual report on Form 10-K of the Company for the year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 28, 2024

/s/ JOHN A. SCARLETT
JOHN A. SCARLETT, M.D.
President, Chief Executive Officer and Chairman of the Board

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Geron Corporation (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying annual report on Form 10-K of the Company for the year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 28, 2024

/s/ Michelle Robertson

MICHELLE ROBERTSON
Executive Vice President, Finance,
Chief Financial Officer and Treasurer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.