

# geron

2020  
ANNUAL REPORT

Letter to Stockholders

Proxy

10-K



## Dear Geron Stockholder,

In my letter to you in the Spring of last year, I commented on the extraordinary times we were experiencing during those early days of the pandemic. COVID-19 cases and deaths were increasing exponentially worldwide, and anxiety ran high. No one seemed to have a clear plan on how to defeat the pandemic. Lockdowns and sheltering in place orders caused widespread economic hardship and disrupted work schedules, school activities and home routines. Many experienced fear of financial ruin, as well as isolation and loneliness. A few months later, as COVID-19 case numbers declined and vaccine trials were underway, prospects for controlling the pandemic seemed achievable. Unfortunately, the winter months saw another surge, with case numbers and deaths even higher than last Spring. Health care facilities were at maximum capacity, and an end to the pandemic did not appear possible.

Today, front-line healthcare workers are safer and have developed better protocols for treating sick COVID patients. Vaccine distribution has begun, and the number of available vaccines is increasing. Case numbers have declined, and there's starting to be a return to some schools and non-essential businesses. However, troubling uncertainties remain as variants of the virus appear, and the number of cases seem to be plateauing at unacceptable levels.

For Geron, like many other biotech companies, the fluid and dynamic nature of the pandemic continues to create variability and unpredictability on our clinical trial activities, causing delays in clinical site openings, patient screening and enrollment for both our Phase 3 clinical trials – IMerge Phase 3 in lower risk myelodysplastic syndromes (MDS) and IMpactMF in refractory myelofibrosis (MF). As a result of these factors, site personnel resources have been constrained at many of our clinical sites, causing delays. Although we expanded the number of countries and sites to conduct our two trials, the pace of enrollment in both has been slower than we hoped or planned. We currently expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 could be available during the time period from the end of 2022 to the first half of 2023. For IMpactMF, we currently expect the interim analysis to occur in 2024 and the final analysis to occur in 2025. Because the analyses for IMpactMF are event-driven, the interim and final results may be available at different times than currently expected.

Despite the unpredictable impact of COVID-19 on our clinical trial activities, we remain committed to our vision of becoming a leader in the treatment of hematologic malignancies by changing the course of these diseases and improving and extending the lives of patients. In 2020, we made important progress toward realizing that vision through enrolling MDS patients in IMerge Phase 3; starting IMpactMF; progress in scaling up and establishing our imetelstat supply chain to ensure uninterrupted drug supply for both current and future clinical trials; presenting new data and analyses that provide strong evidence of imetelstat's disease-modifying potential that differentiates imetelstat from other treatments today; and raising new capital to support our development activities.

Importantly in 2020, the new data and analyses from our prior Phase 2 trials, IMerge Phase 2 in MDS and IMbark in MF, demonstrated that imetelstat targets telomerase, thus inhibiting the uncontrolled proliferation of malignant stem and progenitor cells in hematologic myeloid malignancies resulting in malignant cell apoptosis. In addition, these data showed a significant depletion of cytogenetic abnormalities and reductions in key driver mutations of the underlying diseases in both lower risk MDS and MF patients, as well as improvement in bone marrow fibrosis in MF patients, all of which

we believe provide strong evidence of disease-modifying activity. These molecular and histology data have also been correlated with the clinical benefits of transfusion independence in lower risk MDS and improved overall survival (OS) in relapsed/refractory MF.

We believe the clinical benefits, molecular observations and correlations from IMerge Phase 2 and IMbark highlight the magnitude of imetelstat's unique mechanism of action of telomerase inhibition, and provide strong evidence that imetelstat alters the course of MDS and MF. We also believe this disease-modifying activity has the potential to differentiate imetelstat from other currently approved and investigational treatments for MDS and MF. Furthermore, these data and analyses provide us with confidence in planning for the potential success of IMerge Phase 3 and IMpactMF.

In continuing to execute on our vision, our planned strategic priorities for the next three years include achieving top-line results in IMerge Phase 3, gaining regulatory approval of imetelstat in lower risk MDS and launching commercial sales in that indication. In 2021, we plan to complete enrollment in IMerge Phase 3; advance clinical site initiation and patient enrollment in IMpactMF; and present new data and analyses from IMerge Phase 2 at medical conferences. In addition, we have begun preparedness activities for Geron's first NDA submission and potential commercial launch.

We expect a highly differentiated profile for imetelstat at launch in the lower risk MDS market. In the target patient population of our Phase 2 trial, we have seen meaningful responses with 42% of patients achieving 8-week transfusion independence, as well as durable responses with 29% of patients being transfusion free for over one year. In addition, we have seen broad responses with transfusion independence across multiple MDS subtypes, including both ringed sideroblast positive, as well as ringed sideroblast negative patients, low and high transfusion burdened patients and patients with low and high erythropoietin levels. Because of this differentiated and advantageous profile, we continue to expect imetelstat to play a significant role in this market.

In closing, I would like to acknowledge the patients, investigators and study staff who have participated, are participating and will participate in the future in our imetelstat clinical trials. Their involvement enables us to advance the development of imetelstat to address the unmet medical needs in lower risk MDS and refractory MF. I also want to recognize our Geron employees, who are dedicated to serving patients and have persevered through the pandemic and resulting complications. Despite being unable to work in either our California or New Jersey offices, the remarkable dedication of our employees working remotely was instrumental for us to achieve our 2020 goals.

I wish all of you a healthy remainder of the year and thank you for your continued support.

Sincerely,



John A. Scarlett, M.D.  
Chairman and Chief Executive Officer

March 22, 2021

For important information regarding the use of forward-looking statements in this letter to stockholders, please refer to the inside back cover of this annual report.

## Use of Forward-Looking Statements

Except for the historical information contained herein, the letter to stockholders contains forward-looking statements made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such statements, include, without limitation, those regarding: (i) that imetelstat has potential disease-modifying activity; (ii) that Geron expects for IMerge Phase 3 to be fully enrolled in the second half of 2021; (iii) that Geron expects top-line results for IMerge Phase 3 to be available from the end of 2022 to the first half of 2023; (iv) that for IMPactMF, Geron expects the interim analysis to occur in 2024 and the final analysis to occur in 2025; (v) that Geron believes: (x) the clinical benefits, molecular observations and correlations from IMerge Phase 2 and IMbark highlight the magnitude of imetelstat’s unique mechanism of action of telomerase inhibition, and provide strong evidence that imetelstat alters the course of MDS and MF; (y) that this disease-modifying activity has the potential to differentiate imetelstat from other currently approved and investigational treatments for MDS and MF; and (z) these data and analyses provide Geron with confidence in planning for the potential success of IMerge Phase 3 and IMPactMF; (vi) that Geron expects to present new data and analyses from IMerge Phase 2 at medical conferences in 2021; (vii) that Geron’s planned strategic priorities for the next three years include achieving top-line results in IMerge Phase 3, gaining regulatory approval of imetelstat in lower risk MDS and launching commercial sales in that indication; and (viii) other statements that are not historical facts, constitute forward-looking statements. These forward-looking statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. These risks and uncertainties, include, without limitation, risks and uncertainties related to: (a) whether the current or evolving effects of the COVID-19 pandemic and resulting global economic and financial disruptions will materially and adversely impact Geron’s business and business prospects, its financial condition and the future of imetelstat; (b) whether Geron overcomes all of the potential delays and other adverse impacts caused by the current or evolving effects of the COVID-19 pandemic, and overcomes all the enrollment, clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges in order to meet the expected timelines and planned milestones in (ii), (iii), (iv) and (vii) above; (c) whether regulatory authorities permit the further development of imetelstat on a timely basis, or at all, without any clinical holds; (d) whether imetelstat is demonstrated to be safe and efficacious in IMerge Phase 3 and IMPactMF trials to enable regulatory approval and commercialization; (e) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (f) whether imetelstat actually demonstrates disease-modifying activity in patients; (g) that Geron will need to raise substantial capital in order to complete the development and commercialization of imetelstat, including to meet all of the expected timelines and planned milestones above; (h) whether regulatory authorities require an additional clinical trial for approval even if IMerge Phase 3 or IMPactMF meet their respective primary endpoint(s); (i) whether there are failures or delays in manufacturing or supplying sufficient quantities of imetelstat or other clinical trial materials in a timely manner, whether due to the current or evolving effects of the COVID-19 pandemic or otherwise; (j) whether imetelstat is able to maintain patent protection and have freedom to operate; (k) whether Geron can accurately project the timing of, or attain complete enrollment in IMerge Phase 3 or IMPactMF, whether due to the current or evolving effects of the COVID-19 pandemic or otherwise; and (l) whether Geron is able to enroll IMPactMF at a pace that would enable an interim analysis in 2024 and a final analysis in 2025. Additional information on the above risks and uncertainties and additional risks, uncertainties and factors that could cause actual results to differ materially from those in the forward-looking statements are contained in Geron’s filings and periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors” and elsewhere in such filings and reports, including Geron’s annual report on Form 10-K for the year ended December 31, 2020 and future filings and reports by Geron. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Geron disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

# Corporate Information

## BOARD OF DIRECTORS

**John A. Scarlett, M.D.**

Chairman of the Board

**Dawn C. Bir**

**Karin Eastham**

Lead Independent Director

**V. Bryan Lawlis, Ph.D.**

**Susan M. Molineaux, Ph.D.**

**Elizabeth G. O'Farrell**

**Robert J. Spiegel, M.D., FACP**

## OFFICERS

**John A. Scarlett, M.D.**

Chairman of the Board,  
President and Chief Executive Officer

**Olivia K. Bloom**

Executive Vice President, Finance,  
Chief Financial Officer and Treasurer

**Melissa A. Kelly Behrs**

Executive Vice President,  
Chief Business Officer

**Andrew J. Grethlein, Ph.D.**

Executive Vice President,  
Chief Operating Officer

**Anil Kapur**

Executive Vice President, Corporate  
Strategy and Chief Commercial Officer

**Aleksandra Rizo, M.D., Ph.D.**

Executive Vice President,  
Chief Medical Officer

**Stephen N. Rosenfield, J.D.**

Executive Vice President, Chief Legal  
Officer and Corporate Secretary

## INVESTOR RELATIONS

investor@geron.com

## TRANSFER AGENT & REGISTRAR

**Computershare Investor Services**

P.O. Box 505005  
Louisville, KY 40233-5005  
(800) 962-4284 - tel

## INDEPENDENT AUDITORS

**Ernst & Young LLP**

275 Shoreline Drive  
Suite 600  
Redwood City, CA 94065

## LEGAL COUNSEL

**Cooley LLP**

3175 Hanover Street  
Palo Alto, CA 94304

## STOCK LISTING

**Geron Corporation**

common stock trades on the Nasdaq  
Global Select Market under the ticker  
symbol GERN



**Geron Corporation**

919 E. Hillsdale Blvd.  
Foster City, CA 94404

(650) 473-7700 - tel

(650) 473-7750 - fax

info@geron.com - email

www.geron.com

**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, 2020

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: 0-20859

**GERON CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

919 East Hillsdale Blvd., Suite 250, Foster City, CA  
(Address of principal executive offices)

75-2287752  
(I.R.S. Employer  
Identification No.)

94404  
(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.

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 \$516,434,000 based upon the closing price of the registrant's common stock on June 30, 2020 on the Nasdaq Global Select Market. The calculation of the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant excludes shares of common stock held by each officer, director and stockholder that the registrant concluded were affiliates on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2021, there were 318,527,540 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

**Document**

**Form 10-K  
Parts**

Portions of the Registrant's definitive proxy statement for the 2021 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2020

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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.

## 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 related to uncertainty of non-clinical and clinical trial results or regulatory approvals or clearances, the future development of imetelstat, including any future efficacy or safety results that may cause the benefit-risk profile of imetelstat to become unacceptable, our need for additional capital to support the development and commercialization of imetelstat and to otherwise grow our business, establishing and maintaining imetelstat manufacture and supply, enforcement of our patent and proprietary rights, managing our business growth, litigation risks, the effects of the COVID-19 pandemic, potential competition and other risks that are described herein and that are otherwise described from time to time in our Securities and Exchange Commission reports including, but not limited to, the factors described in “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 section 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. 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. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. 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*

- We are wholly dependent on the success of our sole product candidate, imetelstat, a telomerase inhibitor, for the treatment of hematologic malignancies.
- Any suspension of or delays in the enrollment, conduct or completion of, our current Phase 3 clinical trials, IMerge Phase 3, our Phase 3 clinical trial in Low or Intermediate-1 risk myelodysplastic syndromes, or lower risk MDS, or IMpactMF, our Phase 3 clinical trial in Intermediate-2 or High-risk myelofibrosis, or refractory MF, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Any termination of either IMerge Phase 3 or IMpactMF would have a material adverse effect on our business that might cause us to cease operations.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier stage clinical trials and non-clinical studies may not be predictive of future results.
- If IMerge Phase 3 or IMpactMF fail to demonstrate safety and effectiveness to the satisfaction of the United States Food and Drug Administration, or FDA, or similar regulatory authorities in other countries or do not otherwise produce positive results, we would incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of imetelstat, which would have a material adverse effect on our business that might cause us to cease operations.

- We rely on third parties to conduct our clinical trials and their failure to perform could have a material adverse effect on our business that might cause us to cease operations.

***Risks Related to COVID-19***

- The COVID-19 pandemic has affected and continues to affect our ability to conduct clinical trial activities, causing delays in clinical site initiations and patient screening and enrollment in our clinical trials, IMerge Phase 3 and IMpactMF, and may delay and disrupt regulatory activities and our manufacturing and supply chain and have other adverse effects on our business and operations.

***Risks Related to Our Financial Position and Indebtedness and Need For Additional Financing***

- We will need to obtain substantial additional funding to complete the current Phase 3 clinical trials, IMerge Phase 3 and IMpactMF, and any commercialization of imetelstat, if approved. If we are unable to raise this capital when needed, we would be forced to delay, reduce or eliminate our research and development activities and other operations or commercialization efforts which would have a material adverse effect on our business that might cause us to cease operations. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish certain rights to imetelstat.
- We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.
- 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 Regulatory Compliance Matters and Commercialization of Imetelstat***

- Our failure to obtain regulatory approval for imetelstat in the United States, or U.S., would have a material adverse effect on our business that would likely cause us to cease operations.
- If we are not successful in commercializing imetelstat, we will not be able to achieve our projections for future revenue, if any.
- If imetelstat is approved for marketing and commercialization and we are unable to establish sales, marketing and distribution capabilities, we will be unable to successfully commercialize imetelstat if and when it is approved.

***Risks Related to Protecting our Intellectual Property, Competition and Litigation***

- If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat for an adequate amount of time, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to imetelstat, and our ability to successfully commercialize imetelstat may be adversely affected.
- If 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; severely and adversely affect our financial results, business and business prospects and the future of imetelstat; and might cause us to cease operations.
- We and certain of our officers have been named as defendants in two pending putative securities class action lawsuits and four shareholder derivative lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome.

### ***Risks Related to Manufacturing Imetelstat***

- We rely on contractors to manufacture and supply imetelstat and may be unable to ensure that we have adequate quantities of imetelstat for current and potential future clinical trials and potential commercial uses.

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

- We are subject to government regulations and contractual obligations related to privacy and information security. Our actual or perceived failure to comply with such obligations could harm our business. Additionally, cyber-attacks or information security breaches that compromise our data or those of our partners or vendors could expose us to liability, affect our reputation and otherwise harm our business.
- Significant disruptions of information technology systems, including cloud-based systems, or breaches of data security could adversely affect our business.
- Changes in and failures to comply with United States federal and state as well as foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

### **Calculation of Aggregate Market Value of Non-Affiliate Shares**

For purposes of calculating the aggregate market value of shares of our common stock held by non-affiliates as set forth on the cover page of this annual report on Form 10-K, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and certain 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over Geron. These assumptions should not be deemed to constitute an admission that all executive officers, directors and certain 5% or greater stockholders 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

##### *Summary*

Geron is a late-stage clinical biopharmaceutical company that is focused on the development and potential commercialization of imetelstat, an innovative therapeutic for hematologic myeloid malignancies. Geron's vision is to be recognized as a leader in the treatment of hematologic malignancies. Geron is committed to improving and extending the lives of patients by changing the course of these diseases by targeting telomerase. We are currently focused on the development and potential commercialization of imetelstat, a first in class telomerase inhibitor, and are conducting two ongoing Phase 3 clinical trials that are intended to enable registration: (i) IMerge Phase 3 in Low or Intermediate-1 risk myelodysplastic syndromes, or lower risk MDS, and (ii) IMPactMF in Intermediate-2 or High-risk myelofibrosis, or refractory MF.

Like many other biopharmaceutical companies, we have experienced and continue to experience delays in clinical site initiations, as well as patient screening and enrollment in our clinical trials due to the COVID-19 pandemic. At the beginning of 2020, the pace of site opening and patient screening and enrollment was in line with our expectations. However, in the spring of 2020, the COVID-19 pandemic began to rapidly affect clinical trial sites around the world. Many of our clinical sites established self-imposed holds on site initiations and enrollment during this period out of concern for patient exposure to COVID-19 and due to lack of available staff. As a result, we experienced significant delays in site initiations, as well as patient screening and enrollment, in IMerge Phase 3. During the summer of 2020, as the number of COVID-19 cases declined due to public health safety measures, some clinical sites removed their self-imposed holds on site initiations and enrollment, which improved the momentum of patient enrollment. However, beginning in November 2020, another steep rise in COVID-19 cases in most of the countries where IMerge Phase 3 is being conducted again negatively impacted the pace of enrollment. The emergence of COVID-19 variants also began, causing further unpredictability and uncertainty about the pace at which patients and healthcare workers would be able to return to clinical sites.

Since vaccine distribution has commenced in many countries, and we have begun to see the number of COVID-19 cases declining, we currently believe our clinical trial operations may normalize in the next several months. However, the pace at which any normalization may occur remains uncertain and unpredictable. Taking into account these dynamic and evolving circumstances, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023. If full enrollment in IMerge Phase 3 completes after the third quarter of 2021, top-line results will not be available by the end of 2022.

For IMPactMF, COVID-19 has also negatively impacted clinical trial activities. In addition, in 2020 a number of competing trials were initiated in MF and other oncology indications in the countries where we planned to conduct IMPactMF. As a result of these factors, site personnel resources are constrained at many clinical sites, causing delays in site initiation activities. Although we have expanded the number of countries and sites where we plan to conduct the trial, we now expect IMPactMF to be fully enrolled in 2024. Given these challenges, under current planning assumptions, we expect the interim analysis for IMPactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, the results may be available at different times than currently expected. All plans and timing expectations are subject to risks and uncertainties described in "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K, including the effects of the COVID-19 pandemic, as described below.

We believe that data from two prior Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in hematologic myeloid malignancies, potentially resulting in meaningful clinical benefits for patients. Data reported from our Phase 2 clinical trial in lower risk MDS provide evidence that imetelstat may achieve meaningful and durable transfusion independence and increase in hemoglobin levels, suggesting potential recovery of normal blood cells. Similarly, data reported from our Phase 2 clinical trial in myelofibrosis, or MF, suggest imetelstat potentially improves overall survival, or OS, for MF patients who have relapsed after or are refractory to prior treatment with a janus kinase, or JAK, inhibitor, or relapsed/refractory MF. Additionally, from these Phase 2 clinical trials, we have observed depletion of cytogenetic abnormalities and reductions in key driver mutations of the underlying diseases in both

lower risk MDS and MF patients, as well as improvement in bone marrow fibrosis in MF patients, all of which we believe provides evidence of disease-modifying activity. Furthermore, these molecular and histology data have been correlated with the clinical benefits of transfusion independence in lower risk MDS and improved OS in relapsed/refractory MF. We believe the clinical benefits, molecular observations and correlations from these two Phase 2 trials highlight the magnitude of imetelstat's unique mechanism of action of telomerase inhibition, and provide strong evidence that imetelstat may alter the course of MDS and MF. We believe this disease-modifying activity has the potential to differentiate imetelstat from other currently approved and investigational treatments for MDS and MF.

Imetelstat has been granted Fast Track designations by the United States Food and Drug Administration, or FDA, for the treatment of 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, and for the treatment of patients with relapsed/refractory MF. Imetelstat has also been granted orphan drug designations by the FDA in the United States and by the European Commission for the European Medicines Agency, or EMA, in the European Union, or EU, for the treatment of MDS and also for the treatment of MF.

In 2021, we have begun preparations for the future submissions of a New Drug Application, or NDA, in the United States, and a Marketing Authorization Application, or MAA, in Europe, for imetelstat in lower risk MDS, both of which we plan to submit in 2023, assuming enrollment in IMerge Phase 3 is completed by end of 2021, and top-line results from IMerge Phase 3 are available in 2023 supporting such submissions. We intend to discuss with the FDA options for a rolling submission process, as allowed under imetelstat's Fast Track designation in lower risk MDS. Under either a six-month priority review or a standard ten-month review process, upon potential approval by the FDA, we expect that commercial launch of imetelstat in lower risk MDS in the United States could occur in 2024. In Europe, we anticipate review of the MAA by the European Medicines Agency, or EMA, could take approximately 12 months and commercial launch of imetelstat in lower risk MDS in Europe could occur in 2024.

If imetelstat is approved for marketing by regulatory authorities, we plan to commercialize imetelstat independently in the United States and may seek potential commercialization partners for territories outside of the United States. In 2021, we plan to conduct preliminary commercial preparations, such as building the internal infrastructure to support a commercial launch, conducting market research and hiring commercial leadership in medical affairs, pricing and market access and market analytics.

### ***Impact of COVID-19 on Our Business***

The COVID-19 pandemic has resulted, and is expected to continue to result, in significant economic disruption, and has adversely affected and will likely continue to adversely affect our business. As of the date of this filing, significant uncertainty exists concerning the ultimate duration and severity of the COVID-19 pandemic. We are actively monitoring the situation and have taken and intend to take those actions that may be required by federal, state or local authorities or that we determine are in the best interests of our patients, investigators, employees and stockholders. For example, we have restricted access to our offices in California and New Jersey to essential activities for the health and safety of our employees and in compliance with local "shelter-in place" orders and suspended non-essential travel worldwide. Our employees have been able to work remotely without significant disruption to our business.

As discussed above, like many other biopharmaceutical companies, we have experienced and continue to experience delays in clinical site initiations and patient screening and enrollment in our clinical trials, IMerge Phase 3 and IMPactMF, due to the COVID-19 pandemic. We continue to monitor each clinical site through our contract research organizations, or CROs, as well as to conduct direct outreach to investigators and study staff. Due to the recent decline in COVID-19 cases and the commencement of vaccine distribution, we currently believe our clinical trial operations may normalize in the next several months. However, the pace at which any normalization may occur remains uncertain and unpredictable. Taking into account these dynamic and evolving circumstances, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023.

For IMPactMF, in addition to the negative impact of COVID-19, in 2020 a number of competing trials in MF and other oncology indications were initiated in the countries where we planned to conduct IMPactMF. As a result

of these factors, site personnel resources are constrained at many clinical sites, causing delays in site initiation activities. Although we have expanded the number of countries and sites where we plan to conduct the trial, we now expect IMpactMF to be fully enrolled in 2024. Given these challenges, under current planning assumptions, we expect the interim analysis for IMpactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, the results may be available at different times than currently expected.

The fluidity and dynamic nature of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect COVID-19 will have on our clinical trials, our operations and our business, all of which are highly reliant on the continued worldwide progress toward managing this health crisis. All plans and timing expectations will be delayed or interrupted if COVID-19 pandemic conditions continue unabated, or worsen, creating further limitations on our clinical trial activities.

In alignment with recent guidance from the FDA on clinical trials, “FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards,” together with other national and regional guidelines outside the United States, we have taken steps designed to address unavoidable protocol deviations caused by COVID-19 illness and/or COVID-19 control measures. In addition, we issued an Urgent Safety Measure together with a Dear Investigator Letter to all of our clinical sites involved with IMerge Phase 3 to apply certain measures to protect patient safety that include enhanced ongoing monitoring for signs and symptoms of or exposure to COVID-19 as well as guidance for withholding treatment to patients who have tested positive, who show signs and/or symptoms of COVID-19, or who have potential exposure to COVID-19. Similar guidance has been provided in our clinical trial protocol for IMpactMF.

### ***Imetelstat – A Unique Drug Candidate Directed at a Novel Target Designed to Result in Disease-Modifying Activity***

Telomerase is an enzyme that is upregulated in many malignant stem and progenitor cells and allows them to proliferate without limitation, thereby driving tumor growth and progression. Imetelstat, our proprietary telomerase inhibitor, was designed to directly inhibit telomerase in malignant cells with continuously upregulated telomerase. We have global rights to imetelstat, which was discovered and first developed at Geron.

Data from our Phase 2 imetelstat clinical trials in lower risk MDS and relapsed/refractory MF showed dose- and exposure-dependent reductions of previously known pharmacodynamic markers, or biomarkers, of telomerase inhibition, such as telomerase activity, telomere length and expression of human telomerase reverse transcriptase, or hTERT, thereby indicating the on-target mechanism of action of imetelstat. Furthermore, these reductions in telomerase biomarkers correlated to better clinical outcomes for patients with higher telomerase activity, higher hTERT level and shorter telomere length. These biomarker data and the evidence of reductions in key driver mutations for MDS and MF, as well as cytogenetically abnormal clones, have been correlated to the clinical benefits observed in our Phase 2 clinical trials. In addition, these molecular data indicate by targeting telomerase, imetelstat inhibits the uncontrolled proliferation of malignant stem and progenitor cells resulting in apoptosis of malignant cells. We believe that the totality of these data provide strong evidence of disease-modifying activity of imetelstat treatment, which we believe has the potential to differentiate imetelstat from other currently approved and investigational treatments for MDS and MF.

### ***Compelling and Differentiating Phase 2 Data Support Phase 3 Development***

In lower risk MDS, we reported more mature data from 38 patients in the Phase 2 portion of the IMerge clinical trial, or IMerge Phase 2, in June 2020. As reported previously, 42% (16/38) of patients achieved the primary endpoint of 8-week transfusion independence, and 75% (12/16) of these patients showed a hemoglobin rise of at least 3 grams per deciliter during the transfusion free interval when compared to pretreatment level. An important observation from the more mature data set was the longer durability of transfusion independence, including 29% (11/38) of patients being transfusion-free for more than one year, and a median duration of transfusion independence of 20 months. Such durability provides significant and meaningful clinical benefit to lower risk MDS patients, given their chronic anemia and the debilitating impact of serial blood transfusions, and further supports the disease-modifying potential of imetelstat treatment. Additional information about this more mature data is described below, including safety data, which remained consistent with safety data from prior clinical trials of imetelstat in hematologic malignancies.

In relapsed/refractory MF, we previously reported efficacy and safety data 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 13 – 16 months in medical literature. In IMbark, patients also experienced other clinical benefits, including symptom improvement, spleen reduction and bone marrow fibrosis improvement. We reported recent correlation analyses from IMbark in June 2020 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. Given the shortened survival for refractory MF patients, extended median OS would provide substantial clinical benefit. Additional information about the correlation analyses is described below under “Recently Reported Analyses of IMbark Phase 2 Data Provide Evidence of Improvement in OS and Disease-Modifying Potential of Imetelstat.”

### ***Ongoing Phase 3 Development***

IMerge Phase 3 is a double-blind, randomized, placebo-controlled clinical trial that, based on discussions with U.S. and European regulatory authorities, we believe may support, if successful, the registration of imetelstat in lower risk MDS. The trial is designed to enroll approximately 170 patients with lower risk transfusion dependent MDS relapsed/refractory to ESA, who have not received prior treatment with either a hypomethylating agent, or HMA, or lenalidomide and are non-del(5q). IMerge Phase 3 is being conducted at over 100 medical centers globally, including North America, Europe, Middle East and Asia. In December 2020, we achieved 50% of the planned patient enrollment and in March 2021, we attained 65% of the planned patient enrollment. Taking into account the dynamic and evolving circumstances of COVID-19 on our clinical trial activities, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available in the time period from the end of 2022 to the first half of 2023.

IMPactMF is designed to be an open label 2:1 randomized, Phase 3 clinical trial to evaluate imetelstat versus best available therapy, or BAT, in approximately 320 patients with Intermediate-2 or High-risk MF who are refractory to prior treatment with a JAK inhibitor, or refractory MF. Based on our discussions with the FDA, we believe the current design of IMPactMF may support, if the trial is successful, the registration of imetelstat in refractory MF. Currently, we expect to engage over 180 sites to participate in IMPactMF across North America, South America, Europe, Australia and Asia. In December 2020, we opened the first three trial sites to patient enrollment.

Given the challenges caused by COVID-19 on our clinical trial activities, under current planning assumptions, we expect the interim analysis for IMPactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, the results may be available at different times than currently expected. At the interim analysis, if the pre-specified statistical OS criterion is met, we expect such data may support the registration of imetelstat in 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 after the interim analysis.

### ***Plan for Potential Commercialization of Imetelstat***

In 2021, we have begun preparations for the future submissions of an NDA for imetelstat in the United States, and an MAA in Europe, for imetelstat in lower risk MDS, both of which we plan to submit in 2023, assuming enrollment in IMerge Phase 3 is completed by end of 2021, and top-line results from IMerge Phase 3 are available in 2023 supporting such submissions. We intend to discuss with the FDA options for a rolling submission process, as allowed under imetelstat’s Fast Track designation in lower risk MDS. Under either a six-month priority review or a standard ten-month review process, upon potential approval by the FDA, we expect that commercial launch of imetelstat in lower risk MDS could occur in the United States in 2024. In Europe, we anticipate review of the MAA by the EMA could take approximately 12 months and commercial launch of imetelstat in lower risk MDS in Europe could occur in 2024.

If imetelstat is approved for marketing by regulatory authorities, we plan to commercialize imetelstat ourselves in the United States and may seek potential commercialization partners for territories outside of the United States. Given these plans, we have developed a potential commercial launch plan, which includes potential financing plans that are driven by the achievement of certain clinical milestones, such as top-line results. In 2021, we plan to conduct preliminary commercial preparations, such as building the internal infrastructure to support a commercial

launch, conducting market research and hiring commercial leadership in medical affairs, pricing and market access and market analytics.

### ***Potential Patent Term Extensions and Market Exclusivity***

We have issued U.S. and European patents pertaining to treatment of MF and MDS with imetelstat that extend patent coverage into 2033.

We also hold issued patents covering imetelstat composition of matter. In the United States, our composition of matter patent coverage extends through 2025. In Europe, our composition of matter patent coverage expires in 2024, and includes patent rights in Germany, France, the United Kingdom, and other member countries of the European Patent Convention. Potential patent term extensions may be available to extend our imetelstat composition of matter patent terms in the United States up to 2030 through provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (as amended), or the Hatch-Waxman Act, and in Europe up to 2029 under a Supplementary Protection Certificate, or SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation. In the United States and in Europe, the scope of protection under such a patent term extension, if any were granted, would be defined by the description of the imetelstat product as approved for marketing. An additional six-month extension of the protection under any SPC granted may be available in Europe pursuant to European Regulation (EC) No. 1901/2006 (Pediatric Regulation), or the European Pediatric Regulation. However, such pediatric extension of SPC protection is not available if a one-year extension of marketing exclusivity has already been granted in respect of a new pediatric indication.

Upon drug product approval, there are additional extensions of regulatory exclusivity which we may receive. We have orphan drug designations for both MDS and MF in the United States and in Europe. In the United States, under the Orphan Drug Act of 1983, orphan drug designation allows for market exclusivity for seven years following drug product approval for the orphan disease indication. In Europe, under the European Union Orphan drug regulation (EC) No. 141/2000, orphan drug designation allows for market exclusivity for ten years following drug product approval for each of the orphan disease indications, with the potential for extension of market exclusivity for two years pursuant to the European Pediatric Regulation. If we are unable to maintain orphan drug designation, upon drug product approval:

- In the United States, we may have five years of new chemical entity, or NCE exclusivity, which includes data and market exclusivity, under the Hatch-Waxman Act; and
- In European countries, we may have eight years of data exclusivity plus two years of market exclusivity through provisions of the European Union Data exclusivity Directive 2004/27/EC, with the potential for extension of market exclusivity for one year for a new pediatric indication being authorized.

In addition, a six month pediatric extension may be available in the United States pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, to the longest extension or exclusivity period available under a patent term extension, the NCE exclusivity period or the orphan drug exclusivity period.

### ***Financial Resources***

As of December 31, 2020, we had approximately \$260 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities, which we believe is sufficient for our operations until the end of 2022. Taking into account the dynamic and evolving circumstances of COVID-19 on our clinical trial activities, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023. If top-line results are available after the end of 2022, we will require additional capital to reach top-line results. In any event, we will require substantial additional funding to further advance the imetelstat program, including through IMerge Phase 3 and IMpactMF and conducting the clinical, regulatory and potential commercialization activities necessary to bring imetelstat to market in lower risk MDS and refractory MF.

## **Telomerase: Scientific Rationale**

### ***Telomeres and Telomerase in Normal Development***

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

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

### ***Telomeres and Telomerase in Cancer***

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

## **Telomerase Inhibition and Hematologic Malignancies: Inducing Cancer Cell Death**

We believe that inhibiting telomerase may be an attractive approach to treating cancer because it may limit the proliferative capacity of malignant 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 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 hematologic myeloid malignancy is a cancer that occurs in the hematopoietic myeloid 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 acute myeloid leukemia, or 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 hematologic myeloid 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 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 elicit its effect through an antisense inhibition 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 IC<sub>50</sub>, or half maximal inhibitory concentration, is 0.5 – 10 nM in cell free assays. Single-dose kinetics 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.

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.

### ***Proof-of-Concept of Imetelstat's Disease-Modifying Potential***

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, suggest 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*.

Reported adverse events, or AEs, and laboratory investigations associated with imetelstat in the ET Trial and the Pilot Study included cytopenias, gastrointestinal symptoms, constitutional symptoms, and hepatic biochemistry abnormalities. Dose-limiting toxicities, such as profound and prolonged thrombocytopenia and neutropenia, and other safety issues, including death, were observed in the ET Trial and the Pilot Study. In those trials, such myelosuppression was managed by dose holds and modification rules.

### **Lead Indication in Phase 3 Clinical Development: Lower Risk MDS**

#### ***Unmet Medical Need in 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 United States living with the disease and approximately 16,000 reported new cases of MDS in the United States every year. 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 erythropoiesis stimulating agents, or 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 April 2020, a new drug, Reblozyl (luspatercept) was approved for use in lower risk MDS patients 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. 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. No drug therapy has been shown prospectively to alter or delay the course of the disease.

### ***IMerge: Ongoing Phase 2/3 Clinical Trial in Lower Risk MDS***

#### Trial Design

IMerge is a two-part Phase 2/3 clinical trial evaluating imetelstat in transfusion dependent lower risk MDS patients who are relapsed after or refractory to prior treatment with an ESA. To be eligible for IMerge, patients are 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. Part 1 of IMerge was designed as a Phase 2, open label, single-arm trial to assess the efficacy and safety of a 7.5 mg/kg dose of imetelstat administered as an intravenous infusion every four weeks.

IMerge Phase 3 is a double-blind, randomized, placebo-controlled clinical trial that, based on discussions with U.S. and European regulatory authorities, we expect will support, if successful, the registration of imetelstat in lower risk MDS. The trial is designed to enroll approximately 170 patients with lower risk transfusion dependent MDS who are relapsed or refractory to an ESA, have not received prior treatment with either an HMA or lenalidomide and are non-del(5q). IMerge Phase 3 is being conducted at over 100 medical centers globally, including North America, Europe, Middle East and Asia. Further information on IMerge Phase 3, including the trial design, patient eligibility criteria and locations of clinical sites, is posted on [clinicaltrials.gov](http://clinicaltrials.gov).

The primary efficacy endpoint of IMerge is the rate of RBC-TI lasting at least eight weeks, defined as the proportion of patients without any RBC transfusion during any consecutive eight weeks since entry to the trial, or 8-week RBC-TI rate. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, and the rate of hematologic improvement-erythroid, or HI-E, defined as 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 efficacy endpoints include 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.

#### More Mature Clinical Data from IMerge Phase 2 Continue to Differentiate Imetelstat in Lower Risk MDS

IMerge Phase 2 is an open label, single arm trial to assess the safety and efficacy of imetelstat in transfusion dependent lower risk MDS patients relapsed or refractory to ESAs. The primary and secondary endpoints in IMerge Phase 2 are identical to IMerge Phase 3.

Thirty-two patients were initially enrolled in IMerge Phase 2, of which a cohort of 13 patients had not received prior treatment with either an HMA or lenalidomide and were non-del(5q). Preliminary data from IMerge Phase 2 showed that the 13-patient initial cohort exhibited an increased rate and durability of transfusion independence compared to the overall trial population (8-week RBC-TI rate: 54% vs. 34%).

To increase the clinical experience and confirm the benefit-risk profile of imetelstat from the 13-patient initial cohort, new patient enrollment in IMerge Phase 2, was expanded and 25 additional patients were enrolled in an

expansion cohort. The combined initial cohort of 13 patients and the expansion cohort of 25 patients (n=38) represent a target patient population of transfusion dependent, non-del(5q) lower risk MDS patients who were relapsed/refractory to ESAs and naïve to HMA and lenalidomide treatment. These patients depend on serial RBC transfusions to manage anemia and fatigue. Moreover, dependency on RBC transfusions is associated with iron overload leading to secondary organ complications which results in poor survival. Therefore, the ultimate goal for most clinical trials in lower risk MDS is to enable patients to become transfusion independent for as long as possible.

In June 2020, an oral presentation of more mature data from IMerge Phase 2, was made at the 2020 European Hematology Association, or EHA, Annual Congress. The presentation reported long-term efficacy and safety data from 38 patients in IMerge Phase 2, based on a February 4, 2020 cut-off date. The median follow-up was 24.0 months (range: 5.6-45.5) and the median treatment duration was 8.5 months (range: 0.02-38.7). The median number of treatment cycles was 9.0 (range: 1-40).

The baseline characteristics of the 38 patients highlight the high transfusion burden of these patients, with a median baseline transfusion burden of 8 units per 8 weeks, and with the majority of the patients having received more than 4 units per 8 weeks prior to study entry.

<b>Patient Baseline Characteristics</b>	<b>n=38</b>
Median age (range), years	71.5 (46-83)
Male, n (%)	25 (66%)
Eastern Cooperative Oncology Group (ECOG) Performance Standard 0-1, n (%)	34 (89%)
International Prognostic Scoring System risk, n (%)	
Low	24 (63%)
Intermediate-1	14 (37%)
RBC transfusion burden, units/8 weeks, median (range)	8 (4-14)
4-5 units/8 weeks at baseline, n (%)	6 (16%)
≥6 units/8 weeks at baseline, n (%)	32 (84%)
World Health Organization 2001 category, n (%)	
Refractory Anemia with Ringed Sideroblasts (RARS) or Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts (RCMD-RS)	27 (71%)
Refractory Anemia (RA), Refractory Cytopenia with Multilineage Dysplasia (RCMD) or Refractory Cytopenia with Multilineage Dysplasia and Excess of Blasts (RAEB-1)	11 (29%)
Prior ESA use, n (%)	34 (89%)
Serum erythropoietin (sEPO) >500 mU/mL, n (%)	12 <sup>a</sup> (32%)

<sup>a</sup> Of the 37 patients with sEPO levels reported.

Key efficacy data reported in the June 2020 EHA presentation are summarized in the table below:

<b>Key Efficacy Outcomes</b>	<b>n=38</b>
8-week RBC-TI, n (%)	16 (42%)
Time to onset of 8-week RBC-TI, weeks, median (range)	8.3 (0.1-40.7)
Duration of TI, weeks, median (95% CI) <sup>a</sup>	88 (23.1-140.9*)
Cumulative duration of TI ≥8 weeks <sup>b</sup> , median (95% CI) <sup>a</sup>	92.3 (42.9-140.9)
Hemoglobin (Hb) rise ≥3.0 g/dL during TI <sup>c</sup> , n (%)	12 (32%)
24-week RBC-TI, n (%)	12 (32%)
Hb rise ≥3.0 g/dL during TI <sup>c</sup> , n (%)	11 (29%)
1-year RBC-TI, n (%)	11 (29%)
HI-E per International Working Group 2006, n (%)	26 (68%)
≥1.5 g/dL increase in Hb lasting >8 weeks <sup>d</sup> , n (%)	13 (34%)
Transfusion reduction by ≥4 units/8 weeks, n (%)	26 (68%)
Duration of HI-E, weeks, median (95% CI) <sup>a</sup>	92.7 (37.1-149.4)

\* Longest TI >2.7 years

<sup>a</sup> Kaplan Meier method

<sup>b</sup> Cumulative Duration of TI  $\geq$ 8 weeks is defined as the sum of all periods of TI  $\geq$ 8 weeks during treatment

<sup>c</sup> Maximum Hb rise of  $>$ 3g/dL from pretreatment level (pretreatment level defined as mean Hb/8 weeks)

<sup>d</sup> All patients also achieved 8-week RBC-TI

In addition to the above results, HI-E responses were observed across different patient subgroups, including by ringed sideroblast, or RS, sub-type, baseline transfusion burden and serum EPO levels. Also, reductions in variant allele frequency, or VAF, of SF3B1 mutation correlated with shorter time to RBC-TI and longer duration of RBC-TI. We believe that these results, together with the one-year durable transfusion independence and the  $\geq$ 3g/dL rise in hemoglobin from pretreatment levels for 75% of RBC-TI responders, indicate potential disease-modifying activity of imetelstat treatment, which we believe differentiates imetelstat from other currently approved and investigational treatments in lower risk MDS.

As summarized in the table below, the safety profile was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. Reversible and manageable Grade 3/4 thrombocytopenias and neutropenias were reported in 61% and 55% of the patients, respectively, without significant clinical consequences. 2/38 patients (5%) had Grade 3 febrile neutropenia. 3/38 patients (8%) had Grade 3/4 bleeding. Furthermore, 90% of the observed Grade 3/4 neutropenias and 87% of the observed Grade 3/4 thrombocytopenias resolved to Grade 2 or lower by laboratory assessment within four weeks. Grade 3/4 anemia was reported in 21% of the patients, however only one was assessed as related to imetelstat.

<b>Adverse Events (AE)</b>	<b>All Grades n=38 (n, %)</b>	<b>Grade 3/4 n=38 (n, %)</b>
Thrombocytopenia	25 (66%)	23 (61%)
Neutropenia	22 (58%)	21 (55%)
Anemia	10 (26%)	8 (21%)

The most frequent non-hematologic toxicities are listed in the table below. Grade 3 liver function test, or LFT, elevations reported in the trial were reversible, with no cases of liver test elevations consistent with Hy's law.

<b>Treatment Emergent Adverse Events (TEAE)</b>	<b>All Grades n=38 (n, %)</b>	<b>Grade 3/4 n=38 (n, %)</b>
Back Pain	9 (24%)	2 (5%)
Pyrexia	8 (21%)	0
Diarrhea	7 (18%)	0
Nasopharyngitis	7 (18%)	0
Alanine Aminotransferase (ALT) increased	7 (18%)	2 (5%)*
Aspartate Aminotransferase (AST) increased	6 (16%)	3 (8%)*
Bronchitis	6 (16%)	3 (8%)
Asthenia	6 (16%)	1 (3%)
Headache	6 (16%)	1 (3%)
Urinary tract infection	6 (16%)	1 (3%)
Constipation	6 (16%)	0
Edema peripheral	6 (16%)	0
Fatigue	6 (16%)	0

\* Grade  $\geq$ 3 AST and ALT were reversible

These data were published in the Journal of Clinical Oncology in October 2020. They were also reported in an oral presentation at the American Society of Hematology, or ASH, Annual Meeting in December 2020.

## Current Status of IMerge Phase 2

IMerge Phase 2 is closed to new patient enrollment, and patients remaining in the treatment phase are eligible to continue to receive imetelstat treatment, per investigator discretion. We expect more mature data, including treatment and follow-up, from the patients remaining in IMerge Phase 2 to be available in 2021 and plan to present such data at a future medical conference in 2021.

## Current Status of IMerge Phase 3

IMerge Phase 3 opened for patient screening and enrollment in August 2019, and the first patient was dosed in October 2019. In December 2020, we achieved 50% of the planned patient enrollment and in March 2021, we attained 65% of the planned patient enrollment. Taking into account the dynamic and evolving circumstances of COVID-19 on our clinical trial activities, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available in the time period from the end of 2022 to the first half of 2023. The timing and achievement of enrollment completion and top-line results depend on numerous factors, including further delays or interruptions related to the effects of the COVID-19 pandemic. In addition, our ability to conduct and complete IMerge Phase 3 depends on whether we can maintain the relevant clearances from regulatory authorities and other institutions to conduct and complete the trial, and our ability to raise additional capital to reach top-line results in the trial if such results are not available by the end of 2022.

## **Second Indication in Phase 3 Clinical Development: Myelofibrosis**

### ***Unmet Medical Need in Myelofibrosis***

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 red blood cells, 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 United States and approximately 3,000 reported new cases each year. Up to 20% of patients with MF develop AML.

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. The only drug therapies approved by the FDA and other regulatory authorities for treating these MF patients are JAK inhibitors, ruxolitinib and fedratinib. 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 Refractory MF***

IMPactMF, our Phase 3 clinical trial in refractory MF, is designed to be an open label 2:1 randomized, controlled clinical trial to evaluate imetelstat (9.4 mg/kg administered by intravenous infusion over two hours every three weeks) in approximately 320 patients with Intermediate-2 or High-risk disease who are refractory to prior treatment with a JAK inhibitor. Patients 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 BAT control arm excludes 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. Existing data also suggest that lowering the dose would not result in a clinically meaningful reduction in toxicity, and 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. The primary efficacy endpoint for the trial is OS. Key secondary endpoints include symptom response, spleen response, progression free survival, complete response, partial response, clinical improvement, duration of

response, safety, pharmacokinetics, and patient reported outcomes. Currently, we expect to engage over 180 sites to participate in IMPactMF across North America, South America, Europe, Australia and Asia. Further information on IMPactMF, including the trial design, patient eligibility criteria and locations of clinical sites, is posted on [clinicaltrials.gov](http://clinicaltrials.gov).

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 (each death referred to herein as an “event”). An interim analysis of OS is planned to be conducted after approximately 70% of the total projected number of events for the final analysis have occurred. Both the planned interim and final analyses are event driven and could occur on different timelines than we currently expect.

### Current Status of IMPactMF

In December 2020, we opened IMPactMF for patient screening and enrollment. COVID-19 has also negatively impacted clinical trial activities in IMPactMF. In addition, in 2020 a number of competing trials were initiated in MF and other oncology indications in the countries where we planned to conduct IMPactMF. As a result of these factors, site personnel resources are constrained at many clinical sites, causing delays in site initiation. Although we have expanded the number of countries and sites where we plan to conduct the trial, we now expect IMPactMF to be fully enrolled in 2024. Given these challenges, under current planning assumptions, we expect the interim analysis for IMPactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, 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 support the registration of imetelstat in 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, including delays or interruptions related to the effects of the COVID-19 pandemic. In addition, our ability to conduct and complete IMPactMF depends on whether we can obtain and maintain the relevant clearances from regulatory authorities and other institutions to conduct and complete the trial, and our ability to raise additional capital in order to complete the trial.

### ***IMbark: Completed Phase 2 Clinical Trial in Relapsed/Refractory MF***

#### Trial Design

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 Intermediate-2 or High-risk MF who have relapsed after or are refractory to prior treatment with a JAK inhibitor. 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.

At the December 2018 ASH Annual Meeting, with a clinical cut-off date of October 22, 2018 and a median follow-up of 27.4 months (range: 0.2-33.0), we reported a median OS for the 9.4 mg/kg dosing arm of 29.9 months. In May 2019 with a clinical cut-off date of April 30, 2019, we reported a median OS in the 9.4 mg/kg dosing arm of 28.1 months. Our data compare favorably to the median OS of 14 – 16 months reported in medical literature for patients previously treated with JAK inhibitors.

#### Current Status of IMbark

In February 2020, we closed IMbark since we believe we had obtained sufficient data from the trial to support potential late-stage development in MF. As of the end of February 2020, no further follow-up of remaining patients is being conducted.

## Recently Reported Analyses of IMbark Phase 2 Data Provide Evidence of Improvement in OS and Disease-Modifying Potential of Imetelstat

In 2020, new data and analyses from IMbark were reported through three poster presentations at the EHA Annual Congress in June and through an oral presentation and two poster presentations at the ASH Annual Meeting in December. Information in these presentations highlighted the following:

- Dose-related improvement in OS and correlation with other clinical benefits observed in IMbark, such as symptom response and spleen volume reduction as well as fibrosis improvement.
- Improvements in OS in a patient subpopulation of triple negative MF patients, a particularly poor prognosis patient population due to the absence of the three primary driver mutations in MF.
- Dose-dependent inhibition of telomerase with imetelstat, resulting in on-target activity that correlates with improvement in OS and dose-dependent reduction in variant allele frequency of driver mutations, indicating imetelstat targets the underlying malignant clone.

Taken together, we believe these presentations support the OS outcome observed in IMbark. Furthermore, the reductions in the variant allele frequency of key driver mutations in MF, and the improvement in bone marrow fibrosis which have also been correlated to the improvement in OS, provide further evidence of imetelstat's disease-modifying potential, which we believe differentiates imetelstat from currently approved and investigational treatments in MF.

### **Intellectual Property**

Intellectual property, including patent protection, is very important to our business. We file patent applications in the United States and other jurisdictions, and we also rely on trade secret protection and contractual arrangements to protect aspects of our business. An enforceable patent with appropriate claim coverage can provide an advantage over competitors who may seek to employ similar approaches to develop therapeutics, and so the future commercial success of imetelstat, and therefore our future success, will be in part dependent on our intellectual property strategy. The information provided in this section should be reviewed in the context of the section entitled "Risks Related to Protecting Our Intellectual Property" described in "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K.

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 administration methods. 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, 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.

We endeavor to monitor worldwide patent filings by third parties that are relevant to our business. Based on this monitoring, we may determine that an action is appropriate to protect our business interests. Such actions may include negotiating patent licenses where appropriate, filing oppositions 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.

### ***Imetelstat***

We own issued patents related to imetelstat in the United States, 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 United States. 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 U.S. and European patents pertaining to treatment of MF and MDS with imetelstat that extend patent coverage into 2033.

In addition, we hold issued patents covering imetelstat composition of matter. In the United States, our composition of matter patent coverage extends through 2025. In Europe, our composition of matter patent coverage expires in 2024, and includes patent rights in Germany, France, the United Kingdom, and other member countries of the European Patent Convention. Potential patent term extensions may be available to extend our imetelstat composition of matter patent terms in the United States up to 2030 through provisions of the Hatch-Waxman Act, and in Europe up to 2029 under a Supplementary Protection Certificate, or SPC, as permitted under the European SPC Regulation. In the United States and in Europe, the scope of protection under such a patent term extension, if any were granted, would be defined by the description of the imetelstat product as approved for marketing. An additional six-month extension of the protection under any SPC granted may be available in Europe pursuant to European Regulation (EC) No. 1901/2006 (Pediatric Regulation), or the European Pediatric Regulation. However, such pediatric extension of SPC protection is not available if a one-year extension of marketing exclusivity has already been granted in respect of a new pediatric indication.

Our patent rights relating to imetelstat include those covering composition claims to the drug molecule and related nucleic acid telomerase inhibiting molecules, as well as 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 such 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 United States, 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, 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 2025. If we do not receive marketing approval and submit a request for patent term extension for our European composition of matter patents for imetelstat before our patents expire in 2024, our European composition of matter patents will expire in 2024. 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 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 Collaboration Agreement, we have an exclusive worldwide license for intellectual property developed under the 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 Collaboration Agreement. We now are responsible for the costs for maintaining, prosecuting and litigating all imetelstat intellectual property that we own.

## **Licensing**

### ***Former Collaboration and License Agreement with Janssen***

On November 13, 2014, we entered into a license and collaboration agreement with Janssen, or the Collaboration Agreement, pursuant to which we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all human therapeutic uses, including hematologic myeloid malignancies. Janssen terminated the Collaboration Agreement effective September 28, 2018. As of the end of September 2019, the imetelstat program was fully transferred from Janssen to us.

Since September 28, 2018, we have been responsible for 100% of the development costs for the imetelstat program. We will not receive any milestone payments or royalties from Janssen for the development or commercialization of imetelstat, and Janssen has no obligations to us or any third parties, such as clinical sites or vendors, to fund any of the ongoing or any potential future imetelstat clinical trials.

For a further discussion of the Collaboration Agreement, see Note 4 on License Agreements in Notes to Financial Statements of this Form 10-K.

### ***Other License Agreements***

In September 2016, we granted a license to Janssen Pharmaceuticals, Inc., or Janssen Pharmaceuticals, an affiliate of Janssen, for the research, development and commercialization of products based on specialized oligonucleotide backbone chemistry and novel amidates for disorders, excluding cancers originating from the blood or bone marrow. In connection with this license, we also granted to Janssen Pharmaceuticals a non-exclusive worldwide license under our patent rights covering the synthesis of monomers, which are the building blocks of oligonucleotides. Janssen Pharmaceuticals has terminated the license, and termination will be effective as of April 12, 2021. Upon the effective date of termination, all patent rights originally conveyed under the license will revert to Geron.

We previously granted patent licenses to a number of other organizations to utilize aspects of our technologies to develop and commercialize products outside of the imetelstat program; however, all of our patent license agreements related to our telomerase technology have now expired or been terminated, and we expect no further revenue under such agreements in the future.

See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Revenues” included in Part II, Item 7, of this annual report on Form 10-K for a further discussion of revenues from our license agreements.

### **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 assuming full responsibility for the imetelstat program, we have engaged third-party contractors 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. Many of these contractors previously had relationships with Geron related to the manufacture and/or supply of imetelstat.

We do not have direct control over third-party personnel or operations. These third-party contractors, and/or any other contractors 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 contractors, and/or any other contractors 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 contractors for imetelstat. The information provided in this section should be reviewed in the context of the section entitled “Risks Related to Manufacturing” 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 hematologic myeloid malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and 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 erythropoiesis stimulating agents, or 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, data from IMerge Phase 2 suggest 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, a Bristol-Myers Squibb Corporation, or Celgene; 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.; and Reblozyl (luspatercept), a TGF-beta inhibitor, by Acceleron Pharma, Inc., or Acceleron, in collaboration with Celgene.

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.; and APR-246, an activator of p53 protein, by Aprea Therapeutics, Inc.

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

### ***Competition in 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 – 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 and Inrebic (fedratinib) by Celgene. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cell counts; 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, some of which may obtain regulatory approval earlier than imetelstat include pacritinib, a JAK inhibitor, by CTI Biopharma; momelotinib, a JAK inhibitor, by Sierra Oncology; pelabresib, a BET inhibitor, by Constellation Pharmaceuticals, Inc.; navitoclax, a BCLXL, BCL-2 and BCLW inhibitor, by AbbVie, Inc.; and parsaclisib, a PI3K delta inhibitor, by Incyte Corporation. Other approaches for MF currently under investigation that could compete with imetelstat in the future include luspatercept, a TGF-beta inhibitor, by Acceleron, in collaboration with Celgene; PRM-151, an anti-fibrosis antibody, by Promedior, Inc.;

LCL 161, an inhibitor of apoptosis protein (IAP), by Novartis; KRT-232, an inhibitor of MDM2, by Kartos Therapeutics, Inc.; GB2064, a LOXL2 inhibitor from Galecto Biotech; ING-41, a selective GSK-3b inhibitor, by Actuate Therapeutics, Inc.; XPOVIO (Selinexor), a nuclear export inhibitor, by Karyopharm Therapeutics, Inc.; TL-895, a tyrosine kinase inhibitor, by Telios Pharma, Inc.; IMG7289, a LSD1 inhibitor, by Imago Biosciences, Inc.; and APG-1252, a dual BCL-2/BCL-XL inhibitor, by Ascentage Pharma.

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.

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 United States and other countries is a significant factor in the development, manufacture and marketing of imetelstat. Imetelstat will require regulatory approval by governmental agencies prior to commercialization. In particular, potential human therapeutic products, such as imetelstat, are subject to rigorous preclinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in European and other countries. Various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage, import, export, distribution 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 Compliance Matters 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. For example, we have two active INDs for our imetelstat program. 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 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 a New Drug Application, or 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 and Other Regulatory Approval Process***

Prior to initiating clinical trials in a region outside of the United States, a clinical trial application must be submitted and reviewed by the appropriate regulatory authority regulating the country in which the trial will be conducted. Whether or not FDA clearance or approval has been obtained, approval of a product by comparable regulatory authorities in Europe and other countries is necessary prior to commencement of marketing the product in such countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant an approval, or may require additional data before granting it, even though the relevant product has been cleared or approved by the FDA or another authority. As with the FDA, the regulatory authorities in the European Union, or EU, and other developed countries have lengthy approval processes for pharmaceutical products. The process for gaining approval in particular countries varies, but generally follows a similar sequence to that described for FDA approval. In Europe, the European Medicine Agency, or EMA, and the European Committee for Proprietary Medicinal Products 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.

### ***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 United States or, if the disease or condition affects more than 200,000 individuals annually in the United States, if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. 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.

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 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.

### ***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 Low or Intermediate-1 risk MDS who are non-del(5q) 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.

### ***Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations***

We may also be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These additional healthcare 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 anti-kickback, fraud and abuse, false claims, privacy and security, and healthcare professionals payment sunshine 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 or Medicaid. 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 of federal healthcare covered business, 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) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives.

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 laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. Further, we may be subject to state laws that require drug manufacturers 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 and local laws that require the registration of pharmaceutical sales representatives; state 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 General Data Protection Regulation, or GDPR, from the European Union, or EU, many of which differ from each other in significant ways, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements will comply with applicable healthcare, privacy and data security laws and regulations will involve substantial costs. For example, the GDPR, which became effective on May 25, 2018, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. European data protection laws, such as the GDPR, also impose strict rules on the transfer of personal data out of the European Economic Area, Switzerland and United Kingdom. Further, the GDPR provides and authorizes the imposition of 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. The GDPR has increased our responsibility and potential liability in relation to personal data that we process or control compared to prior EU law, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. Likewise, we expect that there will continue to be

new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018, or CCPA, which has been characterized as the first “GDPR-like” privacy statute to be enacted in the United States, that went into effect on January 1, 2020. Although the CCPA exempts certain 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 information we maintain about California residents. In any event, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare, information security or privacy laws, such as the GDPR, in light of the lack of applicable precedent and regulations. Federal, state and foreign enforcement bodies have increased their scrutiny of biotechnology companies and interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, fines, penalties and settlements in the industry.

If our operations are found to be in violation of any of these or any other healthcare, information security and privacy-related 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.

### ***Reimbursement and Healthcare Reform***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate that receives regulatory approval. In the United States 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 United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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 cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump Administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration’s proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

Further, 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 United States. 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.

The United States 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 remain judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA. 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.

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 2030 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation suspended these reductions from May 1, 2020 through March 31, 2021. 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 United States to control the rising cost of healthcare.

## Information About Our Officers

The following table sets forth certain information with respect to our executive officers as of January 31, 2021:

Name	Age	Position
John A. Scarlett, M.D. ....	69	President, Chief Executive Officer and Chairman of the Board
Olivia K. Bloom .....	52	Executive Vice President, Finance, Chief Financial Officer and Treasurer
Anil Kapur .....	51	Executive Vice President, Corporate Strategy and Chief Commercial Officer
Melissa A. Kelly Behrs.....	57	Executive Vice President, Chief Business Officer
Andrew J. Grethlein, Ph.D. ....	56	Executive Vice President, Chief Operating Officer
Aleksandra Rizo, M.D., Ph.D....	46	Executive Vice President, Chief Medical Officer
Stephen N. Rosenfield, J.D.....	71	Executive Vice President, Chief Legal Officer and Corporate Secretary

**John A. Scarlett, M.D.**, has served as our Chief Executive Officer and a director since September 2011 and President since January 2012 and was appointed to Chairman of the Board in December 2018. Dr. Scarlett has served as a director for Chiasma, Inc., a biopharmaceutical company focused on transforming injectable drugs into oral medications, since February 2015 and CytomX Therapeutics, Inc., a biopharmaceutical company focused on developing antibody therapeutics for the treatment of cancer, since June 2016. Prior to joining Geron, Dr. Scarlett served as President, Chief Executive Officer and a member of the board of directors of Proteolix, Inc., a privately held, oncology-oriented biopharmaceutical company, from February 2009 until its acquisition by Onyx Pharmaceuticals, Inc., an oncology-oriented biopharmaceutical company, in November 2009. From February 2002 until its acquisition by Ipsen, S.A. in October 2008, Dr. Scarlett served as the Chief Executive Officer and a member of the board of directors of Tercica, Inc., an endocrinology-oriented biopharmaceutical company, and also as its President from February 2002 through February 2007. From March 1993 to May 2001, Dr. Scarlett served as President and Chief Executive Officer of Sensus Drug Development Corporation. In 1995, he co-founded Covance Biotechnology Services, Inc., a contract biopharmaceutical manufacturing operation, and served as a member of its board of directors from inception to 2000. From 1991 to 1993, Dr. Scarlett headed the North American Clinical Development Center and served as Senior Vice President of Medical and Scientific Affairs at Novo Nordisk Pharmaceuticals, Inc., a wholly owned subsidiary of Novo Nordisk A/S. Dr. Scarlett received his B.A. degree in chemistry from Earlham College and his M.D. from the University of Chicago, Pritzker School of Medicine.

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

**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 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.

**Melissa A. Kelly Behrs** has served as our Executive Vice President, Chief Business Officer since January 2019. Previously, she was our 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.

**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 nonprofit technology research and business development corporation. Dr. Grethlein received his A.A. degree in liberal arts from Simon's Rock Early College, his B.S. in biology from Bates College, and his M.S. and Ph.D. in chemical engineering from Michigan State University.

**Aleksandra Rizo, M.D., Ph.D.**, has served as our Executive Vice President, Chief Medical Officer since January 2019. Prior to joining Geron, Dr. Rizo was Executive Director, Strategy and Clinical Lead at Celgene Corporation, a biopharmaceutical company, from March 2018 to January 2019, where she led submission activities and participated in strategic and business development initiatives. From October 2008 to March 2018, Dr. Rizo served in a number of oncology drug development functions at Janssen Research and Development, LLC, a pharmaceutical company, including Senior Director, Compound Development Team Leader for all Phase 1 myeloid assets, and Global Clinical Leader for all late-stage myeloid assets, including imetelstat from November 2014 to March 2018, as well as Global Clinical Leader for the ibrutinib mantle cell lymphoma program. In these roles, she had oversight and leadership responsibilities for overall clinical development strategy, study designs, execution and data interpretation. In addition, Dr. Rizo was a core member of Janssen's Hematology Strategy Team where she participated and led diligence projects in hematology. During her initial tenure with Janssen, Dr. Rizo also worked on a variety of Velcade clinical trials in lymphoma and multiple myeloma. Dr. Rizo holds an M.D. from the University Ss Cyril and Methodius, Skopje, Macedonia, where she also completed a residency in internal medicine/hematology. She also has a Ph.D. in human leukemic stem cell biology from the University of Groningen, Groningen, Netherlands, and a Ph.D. in mouse stem cell biology from the University of Tokyo, Tokyo, Japan.

**Stephen N. Rosenfield, J.D.**, has served as our Executive Vice President, Chief Legal Officer and Corporate Secretary since January 2019. Previously, he served as our Executive Vice President, General Counsel and Corporate Secretary from February 2012 to January 2019, General Counsel and Secretary since January 2012 and Secretary since October 2011. Mr. Rosenfield received a B.S. from Hofstra University and a J.D. from Northeastern University School of Law.

## **Employees**

As of December 31, 2020, we had 53 full-time employees and 2 part-time employees. Five of our employees hold Ph.D. degrees and 21 hold other advanced degrees. Of this current total workforce, 31 employees were engaged in, or directly supported, our research and development activities, and 24 employees were engaged in business development, legal, finance and administration. None of our employees are covered by a collective bargaining agreement; nor have we experienced work stoppages. We consider relations with our employees to be good. In order to enable us to further develop and potentially commercialize imetelstat, we will need to maintain and continue to hire additional experienced personnel in clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing, regulatory affairs, medical affairs and sales and marketing.

The success of our business is fundamentally connected to the well-being of our employees. We provide robust compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, broad-based equity awards, a 401(k) plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others. These benefits provide our employees choices where possible so they can customize their benefits to meet their needs and the needs of their families, as well as access to tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors to improve their physical and mental health.

In response to the COVID-19 pandemic and “shelter in place” and similar orders issued by state and local governments, we have temporarily restricted access to our offices in California and New Jersey, as well as suspended any non-essential business travel. Our employees are conducting their work remotely, and they otherwise have minimal presence in our offices for essential activities. The safety, health and well-being of our employees is paramount. As such, we will consider ongoing government regulations and local health conditions before lifting any restrictions on travel or allowing any gatherings at our offices.

## **Consultants**

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. We retain each consultant according to the terms of a consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, we have in the past and may again in the future grant options to purchase our common stock to consultants, subject to the vesting requirements contained in the consulting agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer, or may have other consulting or advisory agreements that may limit their availability to us.

## **Corporate Information**

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

## **Available Information**

Our internet address is [www.geron.com](http://www.geron.com). Information included on our website is not part of this annual report on Form 10-K. We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the United States Securities and Exchange Commission, or the SEC. In addition, copies of our annual reports are available free of charge upon written request.

## 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 imetelstat on a timely basis, or at all.***

Imetelstat is our sole product candidate, upon whose success we are wholly dependent. We do not have any other products or product candidates. Our ability to develop imetelstat to and through regulatory approval and potential commercial launch is subject to significant risks and uncertainties, including, among other things, our ability to:

- obtain sufficient safety and efficacy data from IMerge Phase 3 and IMPactMF to support any application for regulatory approval, without clinically meaningful safety issues, side effects or dose-limiting toxicities related to imetelstat that may negatively impact its benefit-risk profile, whether or not in the same indications or therapeutic areas;
- obtain substantial additional capital in order to enable us to conduct our operations and to advance the imetelstat program through IMerge Phase 3 and IMPactMF and to complete the clinical, regulatory and potential commercialization activities necessary to bring imetelstat to market in lower risk MDS and refractory MF;
- 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;
- develop clinical plans for, and successfully commence, conduct and complete potential future clinical trials of imetelstat;
- generate sufficient safety and efficacy data from ongoing and potential future clinical trials of imetelstat that provide a positive benefit-risk profile to support the continued and future development of imetelstat;
- achieve full enrollment in IMerge Phase 3 in the second half of 2021, and top-line results from IMerge Phase 3 in the time period from the end of 2022 to the first half of 2023;
- obtain and maintain required regulatory clearances and approvals for imetelstat;
- enter into and maintain arrangements with third parties to provide services needed to further research and develop imetelstat, including maintaining the agreement with our CROs, or to manufacture imetelstat, in each case at commercially reasonable costs;
- enter into and maintain arrangements with third parties, or establish internal capabilities, to provide sales, marketing, distribution and other commercialization functions in compliance with applicable laws, and maintain sufficient commercial resources to launch imetelstat;
- achieve acceptance of imetelstat, if approved, by patients and the relevant medical communities;
- compete effectively with other approved treatments;
- obtain appropriate coverage and reimbursement levels for the cost of imetelstat from governmental authorities, private health insurers and other third-party payors;
- obtain, maintain and enforce adequate intellectual property and regulatory exclusivity for imetelstat both in the United States and globally; and

- recruit and retain personnel sufficient to support the development and potential commercialization of imetelstat, including to conduct and complete IMerge Phase 3 and IMpactMF, and potential future clinical trials of imetelstat.

If we are not able to successfully achieve the above-stated 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 of imetelstat, which would severely harm our business and prospects, and might cause us to cease operations.

***IMerge Phase 3 and IMpactMF, and potential future clinical trials of imetelstat, could be interrupted, delayed, terminated or abandoned for a variety of reasons, including due to the COVID-19 pandemic, which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.***

Currently, the active clinical trials of imetelstat are IMerge Phase 2, IMerge Phase 3 and IMpactMF. The fluidity and dynamic nature of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect COVID-19 will have on our clinical trials, our operations and our business all of which depend on the continued worldwide progress toward managing this health crisis. Although vaccine distribution has commenced in many countries, the emergence of COVID-19 variants causes further uncertainty and unpredictability on clinical trial activities, including clinical site initiations, patient screening and enrollment, as well as constraints on available sites and site personnel. As a result, we expect the pace of enrollment in IMerge Phase 3 and IMpactMF trials to be slower. Under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023. For IMpactMF, results are based on event-driven analyses. Under current assumptions, we expect that the interim analysis may occur in 2024 and the final analysis in 2025. In addition, the conduct and completion of IMerge Phase 3 and IMpactMF, and commencement and conduct of any potential future clinical trials of imetelstat, could be interrupted, delayed or abandoned for a variety of reasons, including as a result of failures or delays related to:

- overcoming enrollment challenges related to the effects of the COVID-19 pandemic in IMerge Phase 3, and successfully retaining patients in, and conducting and completing, IMerge Phase 3;
- overcoming enrollment and operational challenges related to opening new clinical sites and conducting and completing IMpactMF due to the effects of the COVID-19 pandemic, while also competing with clinical trials for other investigational drugs in the same patient population;
- obtaining and/or maintaining regulatory clearances in the United States or other countries to conduct clinical trials, such as obtaining or maintaining regulatory clearances to commence, conduct or modify current or potential future clinical trials of imetelstat, in a timely manner, or at all, which could, for example, prevent us from, or result in substantial delays in, conducting or completing IMerge Phase 3 and IMpactMF, or commencing potential future clinical trials of imetelstat;
- maintaining the INDs and equivalent submissions in other countries for imetelstat without such INDs and/or equivalent submissions in other countries being placed on full or partial clinical hold, suspended or subject to other requirements by the FDA or other regulatory authorities;
- contracting with a sufficient number of clinical trial sites to conduct current and potential future clinical trials, as well as identifying, recruiting and training suitable clinical investigators, especially given the constraints caused by the COVID-19 pandemic and other competing clinical trials;
- 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 by the data safety review committees of current clinical trials, and safety or futility findings by the data safety review committees of potential future clinical trials of imetelstat, based on emerging data occurring during such clinical trials, such as significant systemic or organ toxicities, including severe cytopenias, hepatotoxicity, fatal bleeding with or without any associated thrombocytopenia, patient injury or death, or other safety issues, resulting in an unacceptable benefit-risk profile;
- use of trial endpoints that inherently require prolonged periods of clinical observation or analysis of the resulting data to determine trial outcomes;

- manufacturing sufficient quantities of imetelstat, or other clinical trial materials, in a manner that meets the quality standards of the FDA and other regulatory authorities, and responding to any disruptions to drug supply, clinical trial materials or quality issues that may arise, including as a result of limitations in available manufacturing capacity due to obligations to manufacture and distribute vaccines to address the COVID-19 pandemic; temporary or permanent shut down of contract manufacturing facilities due to violations of good manufacturing practice, or GMP, regulations or other applicable requirements; or infections or cross-contaminations of product candidates in the manufacturing process or capacity limitations;
- ensuring the ability to manufacture and supply imetelstat at acceptable costs for potential future clinical trials of imetelstat;
- obtaining sufficient quantities of any study-related treatments, materials (including comparator products, placebo or combination therapies) or ancillary supplies, including in light of challenges and delays that may arise from the effects of the COVID-19 pandemic;
- obtaining acceptance by regulatory authorities of any manufacturing changes for imetelstat, as well as successfully implementing any such manufacturing changes;
- 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 United States or jurisdictions in other countries, including our CROs, laboratory service providers and clinical trial sites, on all aspects of clinical development and collaborating with them successfully, including with respect to challenges and delays that have arisen and may continue to arise from the effects of the COVID-19 pandemic;
- third-party clinical investigators or our CROs losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials according to our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or GCP, or regulatory requirements, or not performing data collection or analyses in a timely or accurate manner;
- third-party contractors becoming debarred, disqualified or suspended or otherwise penalized by the FDA or other similar international regulatory authorities for violations of applicable regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of any applications for regulatory approval;
- obtaining timely review and clearances by regulatory authorities for any clinical protocol amendments or modifications to our manufacturing process which may be sought for current and potential future clinical trials of imetelstat, including responding to questions or comments from these authorities in a timely and adequate manner, which could, for example, prevent us from conducting or completing IMerge Phase 3 and IMPactMF, or commencing other potential future clinical trials of imetelstat; and
- obtaining institutional review board or ethics committee approvals for clinical trial protocols or protocol amendments, including any future refinements to the trial design we may seek for IMerge Phase 3 and IMPactMF, or as a result of changes in regulatory requirements and policies, which could, for example, prevent us from conducting or completing IMerge Phase 3 or IMPactMF, and commencing potential future clinical trials of imetelstat.

We could also encounter delays if a clinical trial is suspended or terminated. Clinical trials may be suspended or terminated due to a number of factors, including: (a) failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; (b) inspection of the clinical trial operations or trial site by the FDA or similar regulatory authorities in other countries resulting in the imposition of a clinical hold; (c) safety issues or adverse side effects; (d) failure to demonstrate a benefit from using a drug; or (e) changes in governmental regulations or administrative actions.

Failures or delays with respect to any of the aforementioned events could adversely affect our ability to conduct or complete IMerge Phase 3 and IMPactMF, 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, and might cause us to cease operations.

***Further difficulties enrolling or retaining patients in IMerge Phase 3 and IMpactMF, whether as a result of the effects of the COVID-19 pandemic or for any other reasons, could further delay or otherwise adversely affect our clinical development and commercialization activities, which would cause our business and business prospects to be severely harmed, and we might cease operations.***

The timely completion of a clinical trial in accordance with its protocol depends, among other things, on the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. Further challenges in screening, enrolling and retaining patients in IMerge Phase 3 and IMpactMF, whether as a result of the effects of the COVID-19 pandemic or for any other reasons, may further delay our conduct of such trials, or cause them to be discontinued. If we experience difficulties in retaining patients in the treatment or follow-up phase of IMerge Phase 2, whether as a result of the effects of the COVID-19 pandemic or for any other reasons, our ability to continue to assess longer-term durability of RBC-TI responses would be adversely affected. The enrollment and retention of patients in IMerge Phase 3 and IMpactMF, depend on many factors, such as:

- our ability to identify and screen patients who meet the patient eligibility criteria specified in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoint;
- the proximity of patients to trial sites, and patients' willingness and ability to travel to trial sites for treatment or monitoring during the COVID-19 pandemic;
- the design of the trial, including potential patients' reluctance to participate in the trial due to the possibility of being assigned to a placebo control arm;
- our ability to recruit and retain clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions of the potential advantages of imetelstat, both in relation to other available therapies, including any new drugs that have been (e.g., Reblozyl® for lower risk MDS) or may be approved for the indications being investigated, and as a result of data reported from previous or current clinical trials of imetelstat, and their willingness to participate in clinical trials of imetelstat;
- reduced availability of patients due to the recent approval of Reblozyl® in lower risk MDS;
- monitoring patients adequately during and after treatment;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in any imetelstat clinical trial will drop out of the trial before completion due to lack of efficacy, adverse side effects, investigator decision, progressive disease, COVID-19 or COVID-19-related site activities and restrictions, alternate treatments being approved for the indication, or personal issues.

In addition, IMerge Phase 3 and IMpactMF, as well as potential future clinical trials of imetelstat, will compete with other clinical trials for product candidates that are in the same therapeutic areas with imetelstat, and such trials may also be conducted at the same clinical sites. This competition is reducing the number of clinical sites and hospital staff available to participate in IMpactMF, as well as the number and type of patients available to enroll or remain in current and potential future imetelstat clinical trials. Moreover, because imetelstat represents a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients into imetelstat clinical trials, or may decide not to enroll, or may not recommend enrollment, in IMerge Phase 3 or IMpactMF, based on efficacy and safety results reported to date and that may be reported in the future.

Delays caused by the effects of the COVID-19 pandemic or other factors in patient enrollment, or the inability to retain or treat patients, have resulted in and may in the future result in further increased costs due to extended timelines and other factors, and may lead to incomplete data sets, or adversely affect the timing or outcome of current and potential future clinical trials of imetelstat, such as IMerge Phase 3 or IMpactMF, which could delay or prevent the commencement, conduct or completion of these trials and adversely affect the clinical development and

potential commercialization of imetelstat. Such occurrences would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

***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, further 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, such as IMerge Phase 3 or IMpactMF. For example, 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, including one case of febrile neutropenia after prolonged myelosuppression with intracranial hemorrhage resulting in patient death, which the investigator assessed as possibly related to imetelstat, as well as reversible Grade 4 febrile neutropenia;
- bleeding events, with or without thrombocytopenia, including reversible Grade 3/4 bleeding events;
- hepatotoxicity, such as liver function test abnormalities, the clinical significance and long-term consequences of which are currently undetermined, and hepatic failure;
- gastrointestinal events;
- infections;
- muscular and joint pain;
- fatigue;
- headache; and
- infusion-related reactions.

If patients in any clinical trials of imetelstat, including IMerge Phase 2, IMerge Phase 3, IMpactMF or any potential future clinical trial of imetelstat, experience similar or more severe adverse events, or new or unusual adverse events, or if the FDA or other regulatory authorities determine that efficacy and safety data in current or potential future clinical trials of imetelstat do not support an adequate benefit-risk profile to justify continued treatment of patients, then the FDA or other regulatory authorities may again 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, such clinical trial or all the imetelstat clinical trials, which might cause us to cease operations.

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 IMerge Phase 2, IMerge Phase 3 and IMpactMF continue to receive imetelstat treatment, additional or more severe toxicities or safety issues, including additional serious adverse events and dose-limiting toxicities, may be observed as patient treatment continues and more data become available. In addition, because additional data are being generated from these trials, 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, and any other severe adverse effects that may be associated with life-threatening clinical outcomes. If such toxicities or other safety issues in any clinical trial of imetelstat are determined by us, the FDA or similar regulatory authorities in other countries 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 regulatory authorities in other countries and if any such information supplied by us, or by our former collaboration partner, is not deemed acceptable, current clinical trials of imetelstat could be suspended, terminated, or placed on clinical hold by the FDA or similar regulatory authorities in other countries;
- the ability to retain enrolled patients in 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; or

- additional, unexpected clinical trials or non-clinical studies may be required to be conducted.

The occurrence of any of the aforementioned events could interrupt, further delay, or halt, any development and potential commercialization of imetelstat by us, which would have a severe adverse effect on our results of operations, financial condition, 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.***

Success in non-clinical testing and early clinical trials, including Phase 2 clinical trials, such as IMerge Phase 2 and IMbark, does not ensure that later clinical trials will be successful, nor does it predict final clinical trial results. We cannot be certain that any of the prior, current or potential future clinical trials of imetelstat will generate sufficient, consistent or adequate efficacy and safety data demonstrating a positive benefit-risk profile, which would be necessary to obtain regulatory approval to market imetelstat in any indication. Imetelstat in later stages of clinical trials may fail to show the desired 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.

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 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 less reliable than trials with a larger number of patients. As a result, there may be less certainty that imetelstat would achieve a statistically significant effect in any future clinical trials. Moreover, 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 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 regulatory authorities in other countries, could result in the trial's failure, or could otherwise delay, limit or prevent marketing approval of imetelstat in refractory MF by the FDA or regulatory authorities in other countries.

In addition, in IMerge Phase 2, the initial data review for the 25-patient expansion cohort that was conducted by Janssen in the second quarter of 2018, which Janssen called a "data snapshot," exhibited an eight-week RBC-TI rate of 28%, while the 13-patient initial cohort exhibited an eight-week RBC-TI rate of 54%, resulting in an overall eight-week RBC-TI rate of 37% for the combined cohorts. Patients in both the initial and expansion cohorts were naïve to both HMA and lenalidomide and were non-del(5q). We believe the observed difference in eight-week RBC-TI rate between the 13-patient initial cohort and the 25-patient expansion cohort may be attributable to factors such as the maturity of the data at the time of the data snapshot, since the median follow-up time of the expansion cohort at the time of the data snapshot was less than half the length of time the 13-patient initial cohort had been followed when their data were first reported, or the higher overall baseline transfusion burden of the expansion cohort. Although the latest reported eight-week RBC-TI rate in June 2020 is higher than that reported in the data snapshot from the second quarter of 2018, we cannot assure you that the eight-week RBC-TI rate reported for the combined cohorts in IMerge Phase 2 will improve further with longer follow-up, or at all, or that the eight-week RBC-TI rate of patients enrolled in IMerge Phase 3 will be comparable to what has been reported in the 13-patient initial cohort, the 25-patient expansion cohort, or the combined cohorts in IMerge Phase 2. 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 IMerge Phase 2 and IMbark, and if this were to occur with IMerge Phase 3 or IMPactMF, this would adversely affect future development prospects of imetelstat and may cause us to cease operations.

In addition, 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, complete and partial remissions were observed in the pilot study of imetelstat conducted at Mayo Clinic, or the Pilot Study. However, similar activity was not observed in the MF patients enrolled in IMbark, as shown by the one partial remission observed in the IMbark primary analysis. We believe that differences in the IMbark study design when compared to the Pilot Study design, such as more restrictive patient enrollment criteria requiring either documented objective lack of response to a JAK inhibitor or evidence of progressive disease while on treatment with a JAK inhibitor, may have contributed to the data observed in IMbark differing significantly from data reported from the Pilot Study, but we cannot assure you that any future clinical trials of imetelstat in MF will yield results comparable to IMbark or the Pilot Study. In addition, the potential improvement in survival observed in the 9.4 mg/kg dosing arm in IMbark will need to be further assessed in IMPactMF, and similar results, including potential improvement in survival, if any, with respect to any patient population or patient population subgroup, may not be observed in IMPactMF. Likewise, although the statistical analyses comparing IMbark data to closely matched real-world data, or RWD, reported at the EHA Annual Congress meeting in June 2019 suggest favorable OS for imetelstat-treated relapsed/refractory MF patients 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. 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.

Failure to achieve positive results in current or potential future imetelstat clinical trials would interrupt, further delay, or halt, any development and potential commercialization of imetelstat by us, which would have a severe adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which might cause us to cease operations.

***Interim, “snapshot,” “top-line,” and preliminary data or statistical analyses from clinical trials that we announce or publish from time-to-time may change as more patient data become available, may be more positive than the final data, and are subject to audit and verification procedures that could result in material changes in the final data. Thus, such preliminary data should be considered carefully and with caution and not relied upon as indicative of future clinical results.***

From time-to-time, preliminary or interim safety and efficacy data from previous and current imetelstat clinical trials have been reported or announced by us, clinical investigators or our prior collaboration partner(s). For example, preliminary data from IMerge Phase 2 were reported at the ASH Annual Meetings in December 2017, December 2018 and December 2020, and at the EHA Annual Congress meetings in June 2018, June 2019 and June 2020. We expect similar reports or announcements of safety and efficacy data from us or clinical investigators as data continues to mature in our IMerge Phase 2. Preliminary or interim results may not be reproduced in any current or potential future clinical trials of imetelstat, and thus should be considered carefully and with caution, and not relied upon as indicative of future clinical results. Material adverse differences in final data, compared to preliminary or interim data, could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

Additional or updated safety and efficacy data from current or potential future imetelstat clinical trials may result in a benefit-risk profile that does not justify the continued development of imetelstat in a particular patient population, or at all. For example, because patients remaining in the treatment phase continue to receive imetelstat in IMerge Phase 2, efficacy and safety data continue to be generated from the trial and will continue to evolve until all

patients have ceased treatment. More mature data that may be reported in the future from IMerge Phase 2, and any data reported from IMerge Phase 3 or IMpactMF, may materially differ from and be less positive than data previously reported from IMerge Phase 2 and IMbark. Thus, the 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 enrollment, completion and potential success of IMerge Phase 3 or IMpactMF, or cause us to abandon further development of imetelstat entirely.

***The research and development of imetelstat is subject to numerous risks and uncertainties.***

The science and technology of telomere biology, telomerase and our proprietary oligonucleotide chemistry are relatively new. There is no precedent for the successful commercialization of a therapeutic product candidate based on these technologies. Significant research and development activities will be necessary to further develop imetelstat, our sole product candidate, and may take years to accomplish, if at all.

Because of the significant scientific, regulatory and commercial challenges that must be overcome to successfully research, develop and commercialize imetelstat, the development of imetelstat in hematologic myeloid malignancies, including MF and MDS, may be further delayed or abandoned, even after significant resources have been expended on it. Examples of such situations include:

- in September 2012, the discontinuation of our Phase 2 clinical trial of imetelstat in metastatic breast cancer;
- in April 2013, the discontinuation of our development of imetelstat in solid tumors with short telomeres;
- in March 2014, the full clinical hold placed by the FDA on imetelstat clinical trials;
- in the third quarter of 2016, closure of the 4.7 mg/kg dosing arm in IMbark to new patient enrollment and suspension of enrollment in the 9.4 mg/kg dosing arm in IMbark because an insufficient number of patients in the 9.4 mg/kg dosing arm met the protocol defined interim efficacy criteria at 12 weeks;
- in the third quarter of 2017, expansion of IMerge Phase 2 to enroll additional lower risk MDS patients in a target patient population; and
- in September 2018, Janssen's decision to terminate the Collaboration Agreement.

Further delay, suspension or abandonment of the development of imetelstat in hematologic myeloid malignancies, including resulting from our inability to successfully enroll, conduct and complete IMerge Phase 3 and IMpactMF, and to plan for, commence, conduct and complete potential future clinical trials of imetelstat, could have a material adverse effect on the future of imetelstat and our business prospects, and we might cease operations.

***We have limited experience as a company in conducting large-scale, late-stage clinical trials, such as IMerge Phase 3, IMpactMF, or potential future similar trials, and no prior experience as a company in those functional areas that would be required for the successful commercialization of our sole product candidate, imetelstat.***

Although we have hired individuals who have experience conducting Phase 3 clinical trials, as a company we have limited experience in conducting large-scale, late-stage clinical trials, such as IMerge Phase 3 or IMpactMF. We cannot be certain that we will be able to enroll, conduct or complete either trial, or any other potential future large-scale, late-stage clinical trial of imetelstat, in a timely fashion, or at all. These large-scale, late-stage clinical trials require internal development experience that we are beginning to develop; and therefore, we still rely heavily on third-party clinical investigators, CROs, service providers, vendors, suppliers and consultants. Relying on these third parties and establishing effective and collaborative relationships with them to conduct large-scale, late-stage clinical trials may cause delays that are outside of our control. Any such delays could have a material adverse effect on our business.

We do not have experience as a company with activities that would be required for the commercialization of imetelstat, should we receive future regulatory approval to do so. Developing an internal sales, marketing and distribution capability is an expensive and time-consuming process, and will require additional management expertise. We may not be able to negotiate and enter into third-party marketing and distribution agreements on terms

that are economically attractive, or at all. Even if we do enter into such agreements, third-party marketers and distributors may not successfully market or distribute our sole product candidate, imetelstat.

Our inability to successfully plan, commence, enroll, conduct and complete large-scale, late-stage clinical trials, such as IMerge Phase 3, IMpactMF or potential future similar trials, or to successfully establish commercialization capabilities for imetelstat if we receive future regulatory approval to do so, would severely and adversely affect our financial results, business and business prospects, and the future 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 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 whether due to the effects of the COVID-19 pandemic or otherwise, or disputes with our CROs about the quality of their performance or other matters, could prevent us from enrolling, conducting or completing IMerge Phase 3 or IMpactMF, or could otherwise further delay or halt our imetelstat clinical development activities including current or future imetelstat clinical trials. 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 any imetelstat clinical trials, including IMerge Phase 3 and IMpactMF, 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 regulatory authorities in other countries 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 regulatory authorities in other countries, may require us to perform additional clinical trials before approving any application for 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 product produced under applicable current Good Manufacturing Practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register imetelstat clinical trials that we sponsor and post the results of certain completed clinical trials on certain government-sponsored databases, such as ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Our ability to comply with these regulations and standards is 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, which would have a severe adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which might cause us to cease operations.

In addition, the execution of clinical trials and the subsequent compilation and analysis of the data produced, 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. If third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, our clinical trials may be extended, delayed or terminated, or may be unsuccessful or need to be repeated, which could have a material adverse effect on our business and might cause us to cease operations.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional costs and delays because of the time it takes to finalize a contract with a new CRO and their commencement of work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. The COVID-19 pandemic and public health safety measures taken in response have also had a significant impact on our CROs. Although we carefully manage our relationships with our CROs, investigators and other third parties, our CROs and we 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 interpretation 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.

#### **RISKS RELATED TO COVID-19**

***The effects of the ongoing COVID-19 global pandemic have negatively impacted, and will likely continue to negatively impact, our business and health care resources around the world, including a significant number of clinical sites involved with IMerge Phase 3 and planned clinical sites for IMpactMF.***

Our business and business prospects, our financial condition and the future of imetelstat generally could be materially and adversely affected by the effects of the ongoing global COVID-19 pandemic. The ongoing COVID-19 pandemic and public health safety measures taken in response to COVID-19 have had a significant impact, both direct and indirect, on businesses, as significant reductions in business-related activities have occurred, clinical development and regulatory activities have been curtailed, delayed or suspended and supply chains have been disrupted. In response to the COVID-19 pandemic and “shelter in place” and similar orders issued by state and local governments, we have temporarily restricted access to our offices in California and New Jersey. Many of our employees continue to conduct their work remotely, and they otherwise have minimal presence in our offices for essential activities. The effects of the “shelter in place” and similar orders, as well our own policies, may negatively impact productivity, disrupt our business and continue to delay our imetelstat development program and clinical trial timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, our increased reliance on personnel working remotely could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. These and similar, and perhaps more severe, disruptions in our operations could continue to negatively impact our business and business prospects, our financial condition and the future of imetelstat.

Due to the effects of the COVID-19 pandemic, we have had and expect to continue to have, or we may potentially have in the future, disruptions and/or delays in our imetelstat development program, including with respect to our ability to:

- open trial sites for screening and enrollment;
- screen, enroll and assess patients;
- retain enrolled patients in the clinical trial;

- ensure patient clinical and lab collection visits;
- conduct monitoring visits;
- manufacture and/or supply study drug;
- report trial results; or
- interact with regulators or other important agencies due to limitations in employee resources or otherwise.

For IMerge Phase 3, we have clinical trial sites in many countries that have had high incident rates of COVID-19. Restrictions on travel, availability of site personnel, and diversion of hospital staff and resources to COVID-19 patients, have disrupted our trial operations, as well as patient recruitment in many areas, resulting in a slowdown in patient enrollment and/or deviations from or disruptions in key clinical trial activities, such as opening, initiating and monitoring clinical trial sites. Although vaccine distribution has commenced in many countries, the emergence of COVID-19 variants causes further uncertainty and unpredictability on clinical trial activities, including clinical site initiations, patient screening and enrollment. As a result, we expect the pace of enrollment in IMerge Phase 3 to be slower. Under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023. Based on current planning assumptions, if full enrollment completes after the third quarter of 2021, top-line results will not be available by the end of 2022.

For IMpactMF, we plan to open multiple clinical trial sites to patient enrollment. Similar to IMerge Phase 3, many of these clinical trial sites are in countries that have had high incident rates of COVID-19. As such, we have experienced and expect to continue to experience disruption in clinical trial activities and delays in enrollment, as well as constraints on available sites and site personnel. Given these challenges, under current planning assumptions, we expect that the interim analysis may occur in 2024 and the final analysis in 2025. Because IMpactMF results are based on event-driven analyses, the results may be available at different times than currently expected.

If the effects of the COVID-19 pandemic continue and persist for an extended period of time and/or become more severe, we could experience further disruptions to our clinical development timelines, continued delays in enrollment and clinical trial site initiation in IMerge Phase 3 and IMpactMF, and other disruptions that could severely impact our business and the imetelstat development program, including those resulting from:

- new, continued or heightened difficulties in opening clinical trial sites for patient screening and enrollment and recruiting clinical site investigators and clinical site staff;
- continued or heightened delays or difficulties caused by missed patient clinical and lab collection visits, and uncertainty how the FDA will view these deviations from the protocol caused by the effects of the COVID-19 pandemic;
- potential refusal by the FDA to accept data, including from clinical trials in affected geographies or failure to comply with updated FDA guidance and expectations related to the conduct of clinical trials during the COVID-19 pandemic;
- continued or heightened delays or disruptions in clinical trial activities due to reduced availability of personnel at CROs and vendors;
- substantial reduction of health care resources available for the conduct of clinical trials, including the temporary postponement of clinical trial activities at certain hospitals serving as our clinical trial sites and diversion of hospital staff away from the conduct of our clinical trials, such as those experienced by us to date;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- loss of potential and recruited patients in clinical trials due to clinical site COVID-19 activities, desire of patients to avoid frequent visits to hospitals because of potential increased exposure to COVID-19, or loss of life of patients due to COVID-19;

- interruption of, or delays in receiving, supplies of imetelstat from our contract manufacturing organizations due to among other things, staffing shortages, production slowdowns or stoppages, shortages in raw materials or laboratory supplies because of ongoing efforts to address the pandemic, limitations in available capacity at contract manufacturing vendors or drug distribution service providers due to obligations to manufacture and distribute vaccines to address the spread of COVID-19, disruptions in supply chain and production systems and import/export complications;
- increased costs for clinical trial activities due to delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, whether as a result of the effects of the COVID-19 pandemic or for any other reasons, which would require further additional capital that may not be available; and
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, product development, manufacturing, and general company operations, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home, or mass transit disruptions.

These and other factors arising from the effects of the COVID-19 pandemic could further adversely impact our ability to enroll, conduct and complete IMerge Phase 3 and IMpactMF and any other potential future clinical trials of imetelstat, and could otherwise materially and adversely affect our business and business prospects, our financial condition and the future of imetelstat.

In addition, we rely on third-party CROs and other third parties to assist us with clinical trial activities. The COVID-19 pandemic has also had a significant impact on our CROs, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. Also, absenteeism by governmental employees or the focus of regulatory authorities' efforts and attention on the approval of other therapeutics or other activities related to COVID-19 could likewise impact the timeliness of regulatory authority responses and the processing of regulatory submissions for imetelstat. In any event, if the effects of the COVID-19 pandemic continue and persist for an extended period of time and/or become more severe, we may experience significant disruptions to our clinical development timelines, which would materially and adversely affect our business and business prospects, our financial condition and the future of imetelstat.

While at this time we believe that we have sufficient drug supply for IMerge Phase 3 and IMpactMF, we could experience disruptions to our supply chain, as well as delays or limitations in our ability to obtain sufficient materials for the manufacture of imetelstat for our current and potential future clinical trials. Such disruptions could adversely affect our ability to conduct ongoing and potential future clinical trials of imetelstat. For example, some of our suppliers of certain materials used in the production of imetelstat are located in countries that were or are heavily affected by the COVID-19 pandemic. In these countries, closures and other restrictions resulting from the COVID-19 outbreak in the region could disrupt our supply chain or limit our ability to obtain sufficient materials for the manufacture of imetelstat. In addition, we may experience limitations in available capacity at contract manufacturers or drug suppliers, or potential shortages of consumable manufacturing supplies, due to obligations to manufacture and distribute vaccines to address the spread of COVID-19. For example, we have experienced manufacturing schedule delays at one of our contract manufacturers due to government mandated manufacturing of high priority COVID-19 vaccines in connection with Operation Warp Speed, and we anticipate such delays, or potential shortages of consumable manufacturing supplies, may continue in 2021.

The effects of the COVID-19 have increased market volatility and could result in a significant long-term disruption of global financial markets, reducing or eliminating our ability to raise additional capital, which could negatively affect our liquidity and our ability to further advance the imetelstat program, including through IMerge Phase 3 and IMpactMF and conducting the clinical, regulatory and potential commercialization activities necessary to bring imetelstat to market in lower risk MDS and refractory MF. If top-line results from IMerge Phase 3 are available after the end of 2022, we will require additional capital to reach top-line results. In addition, the global economic slowdown caused by the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

The extent to which the COVID-19 pandemic impacts our business, our regulatory and clinical development activities, clinical supply chain and other business operations, as well as the value of and market for our common

stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration and severity of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our regulatory and clinical development activities, clinical supply chain and other business operations or the global economy as a whole. However, these effects could materially and adversely affect our business and business prospects, our financial condition and the future of imetelstat. In addition, to the extent the effects of the COVID-19 pandemic adversely affect our business and financial condition, they may also have the effect of heightening many of the other risks and uncertainties described elsewhere under the heading “Risk Factors”.

## **RISKS RELATED TO REGULATORY COMPLIANCE MATTERS AND COMMERCIALIZATION OF IMETELSTAT**

***Our inability to 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 United States 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 or halt our activities and plans for clinical development and commercialization;
- significantly harm the commercial potential of imetelstat;
- impose additional development costs;
- diminish any competitive advantages that may have been available to us; or
- further delay or preclude any revenue we may receive from the future commercialization of imetelstat, if any.

Before we can seek to obtain regulatory approval for the commercial sale of imetelstat, we need to demonstrate that imetelstat is safe and effective in IMerge Phase 3, IMpact MF or potential additional clinical trials of imetelstat. We will need to complete significant additional research, manufacturing activities and clinical testing as well as other assessments before we can submit any application with the FDA or similar regulatory authorities in other countries for regulatory approval of imetelstat, including confirming compliance with the agreed pediatric plans with EMA and FDA.

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 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 regulatory authorities in other countries, could result in the trial’s failure, or could otherwise delay, limit or prevent marketing approval of imetelstat for refractory MF by the FDA or regulatory authorities in other countries.

If imetelstat cannot be successfully developed in our current Phase 3 clinical trials, IMerge or IMpactMF, our business and business prospects would be severely and adversely affected, and we might cease operations. Even if we do successfully complete one or more of our Phase 3 clinical trials of imetelstat, the results will not necessarily be predictive of imetelstat activity in new indications and for future pivotal trials that may be needed to support any application to FDA or similar regulatory authorities for such new indications. We may therefore fail to further

develop or commercialize imetelstat, which would severely and adversely affect our business and business prospects, and might cause us to cease operations.

***Obtaining potential future regulatory clearances to market imetelstat in the United States and other countries is a costly and lengthy process, and we cannot predict when or if regulatory authorities will approve imetelstat for commercial sale.***

The process of obtaining marketing approvals, both in the United States and in other countries, is lengthy, expensive and uncertain. It may take many years, 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 or refractory MF, which would significantly harm our business, business prospects 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 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 United States and an MAA in the EU. As a company, we have not previously submitted an NDA or similar applications to comparable regulatory authorities in other countries for imetelstat.

Imetelstat must receive all relevant regulatory approvals before it may be marketed in the United States 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;
- unfavorable benefit-to-risk assessment, in the case of marginal efficacy and/or clinically relevant safety concerns;
- 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;
- errors or deficiencies in the conduct of the imetelstat program prior to its transition to us by our former collaborator, and/or in the transition of the imetelstat program to us by our former collaborator;
- unwillingness or inability by our former collaborator to provide information requested by the FDA or other regulatory authorities regarding the time period when our former collaborator was responsible for the imetelstat program;
- requirement to develop a risk evaluation and mitigation strategy, or REMS, including post-marketing studies, as a potential condition to approval;
- disagreement regarding the formulation, labeling and/or the specifications for imetelstat;
- deficiencies in the manufacturing processes or facilities of our third-party contract manufacturers; 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.

Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render imetelstat not commercially viable, which would harm imetelstat's future value and our business and business prospects. In addition, obtaining regulatory approval is a lengthy, expensive and uncertain process. For example, following the result of a referendum in 2016, the United Kingdom left the European Union on

January 31, 2020, commonly referred to as Brexit, and its withdrawal from the European Union was completed on December 31, 2020. Although the impact of the withdrawal of the United Kingdom from the European Union will not be known for some time, it has resulted in considerable uncertainty in relation to the regulatory process in Europe, which could result in a delay in the review of regulatory submissions made in Europe by biotechnology and pharmaceutical companies, including potentially by us in the future, and could also lead to less efficient, more expensive, and potentially lengthier regulatory review processes for companies like us, who may seek to obtain regulatory approval for drug products in the European Union or the United Kingdom. Such regulatory changes in the United Kingdom or elsewhere could adversely affect and/or delay our ability to obtain approval of, and market and sell, imetelstat in the United States or other countries.

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, 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. 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 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.

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, the price of our common stock, our business and business prospects, and the future of imetelstat, and might cause us to cease operations.

***Although orphan drug designation has been granted to imetelstat for the treatment of MF and MDS in the United States 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 Medicines Agency, or EMA, 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 if the FDA or EMA 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 in the EU at the time of submitting the MAA would lead to the loss of the additional two-year exclusivity period.

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 EMA can subsequently approve a different drug with the same active moiety for the same condition, if the FDA or EMA 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.

***A Fast Track designation by the FDA, such as the Fast Track designations received for imetelstat for MDS and MF, 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 anemia due to Low or Intermediate-1 risk MDS who are non-del(5q) 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 Intermediate-2 or High-risk MF whose disease has relapsed after or is refractory to JAK inhibitor treatment.

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;
- 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.

Failure to comply with regulatory requirements can result in severe civil and criminal penalties, including but not limited to:

- recall or seizure of products;
- injunctions against the import, manufacture, distribution, sales and/or marketing of products; and
- criminal prosecution.

The imposition of any of these penalties or other commercial limitations 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 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 further delay in or our inability to obtain regulatory approvals of imetelstat, and our business and business prospects could be severely harmed, and we could cease operations.***

Although we have purchased inventories of drug product, drug substance and raw materials from our former collaboration partner under a supply agreement that meet our specifications, some of this material will require further processing in order to be used in clinical trials, and/or may also require regulatory review and acceptance prior to use. In addition, while we have re-established our own manufacturing supply chain in order to further process such purchased materials as well as to be able to manufacture and supply additional quantities of imetelstat that meet applicable regulatory standards for current and potential future clinical trials and potential commercial uses, the process of manufacturing imetelstat is complex and remains subject to several risks, including:

- the ability to scale-up and attain sufficient production yields with appropriate quality control and quality assurance;
- reliance on third-party contract manufacturing organizations, or CMOs, 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 the COVID-19 pandemic;
- 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 supply chain capable of providing imetelstat for IMerge Phase 3, IMpactMF, and/or other potential future clinical trials of imetelstat, and potential future commercial uses, which would delay or result in a cessation of IMerge Phase 3, IMpactMF, or other potential future clinical trials of imetelstat. Occurrence of any such events would further delay or preclude any applications for regulatory approval and therefore further delay or preclude our ability to earn revenue from the commercialization, if any, of imetelstat, which would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

***If third parties that manufacture imetelstat fail to perform as needed, then 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 contractors 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 contractors to supply starting materials, drug substance and drug product. Failure by such third-party contractors to perform in a timely manner, 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. We may not be able to obtain imetelstat from third-party contractors on acceptable terms, or at all. We expect to rely on third-party contractors to produce and deliver sufficient quantities of imetelstat and other materials to support clinical trials 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:

- being unable to contract with suitable third-party manufacturers, because the number of potential manufacturers is limited;

- delays and disruptions experienced by third-party manufacturers due to the effects of the COVID-19 pandemic, which have adversely impacted and could continue to adversely impact the ability of such parties to fulfill their contractual obligations to us;
- limitations in available capacity at contract manufacturers or drug suppliers, or potential shortages of consumable manufacturing supplies, due to obligations to manufacture and distribute vaccines to address the spread of COVID-19; for example, we have experienced manufacturing schedule delays at one of our contract manufacturers due to government mandated manufacturing for high priority COVID-19 vaccines in connection with Operation Warp Speed, and we anticipate such delays, or potential shortages of consumable manufacturing supplies, may continue in 2021;
- requirements by regulatory authorities for significant activities to validate and qualify any replacement manufacturer, which could involve new testing and compliance inspections;
- the inability to execute timely contracts with additional third-party manufacturers and suppliers on acceptable terms, or at all;
- the inability of third-party manufacturers to timely formulate and manufacture imetelstat or to produce imetelstat in the quantities or of the quality required to meet clinical and commercial needs, whether due to the effects of the COVID-19 pandemic or any other reasons;
- 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 products;
- compliance by third-party manufacturers with cGMP standards mandated by the FDA and state agencies and other government regulations corresponding to similar regulatory authorities in other countries;
- breach or termination of manufacturing or supply contracts;
- inadequate storage or maintenance at contracted facilities resulting in theft or spoilage;
- capacity limitation and scheduling imetelstat manufacturing activities as a priority in contracted facilities; 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 drug supply necessary for non-clinical and clinical activities, and commercialization. For example, manufacturing delays could adversely impact the conduct or completion of imetelstat clinical trials, such as IMerge Phase 3, IMPactMF or commencement of other potential future clinical trials, or preclude or delay potential future commercial sales, which could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

In addition, third-party contractors and/or any other contractors 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 contractors 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.

***It may not be possible to manufacture imetelstat at costs or scales necessary to conduct clinical trials or potential future commercialization activities.***

Oligonucleotides are relatively large molecules produced using complex chemistry, and the cost of manufacturing an oligonucleotide like imetelstat is greater than the cost of making typical small molecule drugs. Therefore, imetelstat for clinical use is more expensive to manufacture than most other treatments currently available today or that may be available in the future. Similarly, the cost of manufacturing imetelstat for commercial use will need to be significantly lower than current costs in order for imetelstat to become a commercially successful

product. We may not be able to achieve sufficient scale increases or cost reductions necessary for successful commercial production of imetelstat. Failure to achieve necessary cost reductions could result in decreased sales, if any, for us, which would materially 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 OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING**

***Our failure to obtain substantial additional capital would force us to further delay, reduce or eliminate development of imetelstat, including IMerge Phase 3 and IMPactMF and any potential future clinical trials of imetelstat, and our potential future imetelstat commercialization efforts, 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. Currently, we believe we have sufficient funds for our operations until the end of 2022. Taking into account the dynamic and evolving circumstances of COVID-19 on our clinical trial activities, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023. Based on current planning assumptions, if full enrollment completes after the third quarter of 2021, top-line results will not be available by the end of 2022. If top-line results from IMerge Phase 3 are available after the end of 2022, we will require additional capital to reach top-line results. In any event, we will require substantial additional funding to further advance the imetelstat program, including through IMerge Phase 3 and IMPactMF and conducting the clinical, regulatory and potential commercialization activities necessary to bring imetelstat to market in lower risk MDS and refractory MF. In addition, our ability to commercialize imetelstat in the United States, if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities.

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, and 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 will be further delayed or interrupted if COVID-19 pandemic conditions continue unabated, or worsen, creating further limitations on our clinical trial activities. 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 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 regulatory authorities in other countries;
- the scope, progress, duration, results and costs of current and potential future clinical trials, including IMerge Phase 3, IMPactMF and other potential future clinical trials of imetelstat, as well as non-clinical studies and assessments, of imetelstat;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in IMerge Phase 3 or IMPactMF or any potential future clinical trials of imetelstat, whether as a result of the effects of the COVID-19 pandemic or for any other reasons;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, such as obtaining and maintaining regulatory clearances and approvals for IMPactMF in the United States and in other countries;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing imetelstat, including our ability to achieve any meaningful reduction in manufacturing costs;
- the costs of multiple third-party vendors and service providers, including our CROs and CMOs, to pursue the development, manufacturing and potential commercialization of imetelstat;

- our ability to establish, enforce and maintain collaborative or other strategic arrangements for research, development, clinical testing and manufacturing of imetelstat and potential future commercialization and marketing;
- our efforts to enhance operational, financial and management processes and systems that will be required for future development and commercialization of imetelstat, and our ability to successfully recruit and retain additional key personnel to support the development and potential future commercialization of imetelstat;
- our ability to successfully market and sell imetelstat, if imetelstat receives future regulatory approval or clearance, in the United States and other countries, and the associated costs;
- the costs and timing necessary to build a sales force in the United States to market and sell imetelstat, should it receive regulatory approval;
- the sales price for imetelstat;
- the availability of coverage and adequate third-party reimbursement for imetelstat;
- expenses associated with the pending putative securities class action lawsuits and derivative lawsuits, as well as any other potential litigation;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation;
- the costs of maintaining and operating facilities in California and New Jersey, telecommunications and administrative oversight, as well as higher expenses for travel when travel becomes possible in light of the COVID-19 pandemic; and
- the costs of enabling our personnel to telecommute as required by federal, state and local “shelter in place” or comparable orders, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

We do not have any committed external source of funds or other support for our development and commercialization efforts. 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 with any further delays in reporting results from IMerge Phase 3 or IMpactMF.

Additional financing through public or private debt or equity financings, including pursuant to the 2020 Sales Agreement with B. Riley Securities, Inc., or B. Riley Securities, the Loan Agreement with Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, or SVB, to the extent available, 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 caused by the effects of the COVID-19 pandemic, and may in the future be affected by other factors which are unpredictable and over which we have no control. In this regard, the effects of the COVID-19 pandemic 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. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development 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, your ownership interest 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 with Hercules and SVB 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, and potential future sales of our common stock, including under the 2020 Sales Agreement with B. Riley Securities or potential future drawdowns, if available, under our Loan Agreement with Hercules and SVB, will be sufficient to fund our operating plans. In any event, we will continue to need substantial additional funds to meet operational needs and capital requirements to advance the imetelstat program in clinical development, including through IMerge Phase 3 and IMpactMF and potential commercialization of imetelstat in lower risk MDS and refractory MF, 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, including completing IMerge Phase 3 and IMpactMF, or commencing, conducting or completing other potential future clinical trials of imetelstat, or pursuing potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

***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 current and 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, 2020, our accumulated deficit was approximately \$1.2 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 hTERT technology have expired or been terminated due to expiration of the underlying hTERT patents, and are not expected to generate any further revenues. We have no ongoing collaboration agreement related to imetelstat and have no current plans to enter into any corporate collaboration, partnership or license agreements that result in revenues.

We also expect to experience increased negative cash flow for the foreseeable future as we fund our operations and imetelstat clinical development activities advance. This will result in decreases in our working capital, total assets and stockholders' equity. Further, we may be unable to replenish our working capital by future financings. 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.

***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. Under the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, 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 in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

Under Sections 382 and 383 of the Code, 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 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. In addition, a portion of the carryforwards may expire before being available to reduce future income tax liabilities which could adversely impact our financial position. In addition, 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.

## **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.***

Under the Loan Agreement with Hercules and SVB, drawdowns are available in three tranches, or Tranches A, B and C, subject to certain terms and conditions, including, with respect to Tranche B and Tranche C, achievement of certain clinical, financial and regulatory milestones. Concurrently with the closing of the Loan Agreement, we borrowed \$25.0 million of Tranche A, and \$10.0 million of Tranche A remains available to be borrowed until June 15, 2021. If we do not achieve the specified clinical, financial and regulatory milestones, we will not be eligible to draw funds under Tranche B and Tranche C of the Loan Agreement, and we may need to obtain additional or alternative financing to advance our development of imetelstat. Such additional or alternative financing may not be available on attractive terms, if at all, and could be more costly for us to obtain. In addition, before we would consider drawing down the remainder of Tranche A and Tranches B and C of the Loan Agreement, if available, we must first satisfy ourselves that we will have access to future alternate sources of capital, such as from 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. As a result, our development of imetelstat could be significantly delayed, which would materially adversely affect our business, business prospects, financial condition and operating results.

All obligations under the Loan Agreement are secured by substantially all of our existing property and assets, excluding intellectual property, which is subject to a negative pledge. 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 borrow the remaining \$10.0 million available to us under Tranche A before June 15, 2021 or are able to drawdown any of the other Tranches, 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 its security interest in the assets securing such indebtedness.

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 requiring us to maintain a cash balance in an amount greater than or equal to \$25.0 million, commencing June 1, 2022, which balance minimum is reduced to \$20.0 million upon achievement of certain regulatory milestones. If we enter into certain licensing transactions, this cash covenant requirement would increase to \$30.0 million. 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 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 could result in an event of default. In addition, the Loan Agreement includes customary affirmative and negative covenants and other events of default, the occurrence and continuance of which provide the Hercules and SVB with the right to demand immediate repayment of all principal and unpaid interest 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;
- 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 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, 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 potential 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 management or development personnel, or to maintain our current management and personnel. If we are unable to successfully retain, motivate and incentivize our existing personnel, or to attract, assimilate and retain other highly qualified management and senior development personnel in the future on acceptable terms, our ability to further develop imetelstat will be impaired, and our business and the price of our common stock would be adversely impacted. As a result of “shelter in place” and similar orders related to COVID-19, as well our own policies, 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. Further, if members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to the effects of the COVID-19 pandemic, we may not be able to execute on our business strategy and/or our operations may be negatively impacted.

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. The expansion of our operations also could lead to significant costs and could delay the execution of our business plans or disrupt our current operations. Our ineffective performance in managing any such future growth would negatively impact our business prospects.

As our operations continue to expand, we expect that we will need to manage new and additional relationships with various service providers, vendors, suppliers and other third parties, as well as a workforce in multiple countries, jurisdictions and locations. We may not successfully manage our imetelstat commercialization and development efforts effectively, including our current and potential future imetelstat clinical trials. If we fail to achieve key development goals, our abilities to grow as a company, and to further develop and potentially commercialize imetelstat, could be prevented or hindered, and our business and business prospects would be severely harmed, which might cause us to cease operations.

***We expect imetelstat to remain our sole product candidate for the foreseeable future. If we are unable to successfully develop or commercialize imetelstat, our business and business prospects would be severely harmed, which might cause us to cease operations.***

Other than imetelstat, we do not currently have any other oncology products or product candidates. As a result, we are and will be wholly reliant upon the development of imetelstat, our sole product candidate, for the foreseeable future. If we are unable to successfully develop and commercialize imetelstat, our business and business prospects would be severely harmed, which might cause us to cease operations.

***If imetelstat is approved for marketing and commercialization and we are unable to establish sales, marketing and distribution capabilities, we will be unable to successfully commercialize imetelstat if and when it is approved.***

As a company, we have no sales, marketing or distribution capabilities or experience. To achieve commercial success for imetelstat, if approved, we must either develop a sales and marketing organization, which would be expensive and time consuming, outsource these functions to other third parties, or use a hybrid model incorporating both of these approaches.

There are risks involved with both establishing our own sales and marketing 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 force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which would be costly.

Factors that may inhibit our efforts to commercialize imetelstat on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians regarding the indications we are targeting and imetelstat, if approved;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe imetelstat;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability to price imetelstat at a sufficient price point to ensure an adequate and attractive level of profitability; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, 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 sell and market imetelstat or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution 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 sales and distribution capabilities or devote the necessary resources and attention to sell and market imetelstat effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing imetelstat.

***If we are unable to establish potential future collaborative arrangements for imetelstat, we 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 United States. We may seek another collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat, especially outside the United States, 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 the effects of the COVID-19 pandemic on our clinical trial activities and the resulting delays in reporting any results from IMerge Phase 3 and 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 negotiate 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.

In any event, we are unable to predict when, if ever, we will enter into any collaborative arrangements because of the numerous risks and uncertainties associated with establishing collaborative arrangements. Moreover, given the significant risks and uncertainties regarding the future imetelstat development program, potential collaborative partners may be reluctant to enter into new collaborative arrangements with us, or may only be willing to do so on terms that are not favorable to us. As a result, we may not be successful in finding a new collaborative partner or partners on favorable terms, if at all. 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 United States;
- 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 substantial additional capital than our current resources.

In order to advance the imetelstat program, including through IMerge Phase 3 and IMpactMF, or to commence, conduct and complete other potential future clinical trials of imetelstat, as well as undertaking potential commercialization activities for imetelstat in the United States, we will need to raise substantial additional capital. In addition, if we elect to increase our expenditures to fund imetelstat development or commercialization activities outside the United States, we will be required to substantially increase our personnel resources and we will need to obtain substantial further capital, which may not be available to us on acceptable terms, or at all. If we are unable to raise substantial additional capital, we will not be able to advance the imetelstat program, including through IMerge Phase 3 and IMpactMF or other potential future clinical trials of imetelstat, nor will we be able to bring imetelstat to market and generate product revenues. Establishing the infrastructure necessary to further develop, commercialize, market and sell imetelstat worldwide will require substantial resources and may divert the attention of our management and key personnel and negatively impact our imetelstat development or commercialization efforts in the United States.

***We currently have no products approved for commercial sale, and we have not yet demonstrated an ability to obtain marketing approvals for any product candidates, which makes it difficult to assess our future viability.***

We have never derived any revenue from the sales of any products. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking non-clinical studies and clinical trials of imetelstat and past product candidates that we have subsequently discontinued, and engaging in research and development under collaboration agreements. We have not yet demonstrated an ability to obtain regulatory approvals for commercialization activities, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, for these and other reasons discussed elsewhere in these risk factors, it is difficult to predict our future success and the viability of our business and the imetelstat program.

***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 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 and diagnostic products. We may become subject to product liability claims or claims related to clinical trial conduct, 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 clinical trial liability insurance, and we may not be able to maintain this type of insurance for any of our current Phase 3 clinical trials, IMerge or IMpactMF, or this type of insurance may become too expensive for us to afford because of the highly risky and uncertain nature of 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, including IMerge Phase 3 or ImpactMF. 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.

***We and certain of our officers have been named as defendants in two pending putative securities class action lawsuits and four shareholder derivative lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits 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 product development activities.

Between January 23 and March 5, 2020, three putative securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed on March 19, 2020. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, or the Northern District, were consolidated by the Court on May 14, 2020, and on August 20, 2020, the lead plaintiffs filed a consolidated class action complaint. The consolidated class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to IMbark during the period from March 19, 2018, to September 26, 2018. The consolidated complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose facts related to the alleged failure of IMbark to meet the two primary endpoints of the trial, spleen response rate and Total Symptom Score, and that our stock price dropped when such information was disclosed. The plaintiffs in the consolidated class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On October 22, 2020, lead plaintiffs filed an amended consolidated class action complaint. We filed a motion to dismiss the amended consolidated class action complaint on November 23, 2020. The hearing on the motion to dismiss was held on February 8, 2021.

Between April 23, 2020 and November 12, 2020, four shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former board members. Of these actions, or the Derivative Lawsuits, one was filed in the Northern District, one was filed in the Court of Chancery of the State of Delaware, and two were filed in the U.S. District Court for the District of Delaware, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and violations of Section 14 of the Exchange Act, based on the same underlying facts as the consolidated class action lawsuit described above. The plaintiffs seek damages, corporate governance reforms, equitable relief, restitution, and an award of reasonable costs, including attorneys' fees. All four Derivative Lawsuits have been deferred until 30 days after an order on our motion to dismiss the amended class action complaint in the consolidated class action lawsuit has been made.

It is possible that additional lawsuits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. 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 the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. 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 the settlement or defense

of the pending lawsuits and 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.

We have not established any reserve for any potential liability relating to the pending lawsuits or any potential future lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests in the pending lawsuits, or 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 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.

## **RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY**

***If we are unable to obtain and maintain sufficient intellectual property protection for imetelstat for an adequate amount of time, or if the scope of the intellectual property protection is not sufficiently broad, 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 United States 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 United States 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 our product 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 our product 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 related to imetelstat might further delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval, and therefore further delay or preclude any future development or commercialization of imetelstat by us. Further, 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 government 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 and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the Patent Office and various government patent agencies in other countries over the lifetime of our owned and licensed patents and/or patent applications and any patent rights we may own or license in the future. Maintaining such compliance may be impacted by the COVID-19 pandemic. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant 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, any of the foregoing could expose us to liability to the applicable patent 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 United States, 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 (e.g., patents claiming imetelstat and/or components thereof, methods of use, or methods of making) 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.

Under the Hatch-Waxman Act, a patent may be eligible for future patent term extension of up to five years under certain circumstances. Depending upon the timing, duration and specifics of any potential marketing approval of imetelstat, one or more of our owned or licensed U.S. patents may be eligible for patent term extension under the Hatch-Waxman Act. Similar extensions are also available in certain countries and territories outside the United States, such as in Japan and in Europe. 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. 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 including Europe, we will be unable to obtain any patent term extension of that expired patent, and the scope of our patent rights may be limited. In addition, should we seek such 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 United States, 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, 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 2025. If we do not receive marketing approval and submit a request for patent term extension for our European composition of matter patents for imetelstat before our patents expire in 2024, our European composition of matter patents will expire in 2024. Similarly, if we do not receive marketing approval in certain non-European countries before our composition of matter patents expire in 2024, our composition of matter

patents in such countries will expire in 2024. 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 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 new drug application 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 United States 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 United States 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 United States 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 that the persons or entities that we name as inventors 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 Janssen under the Collaboration Agreement 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.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. The impact of the withdrawal of the United Kingdom from the European Union will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain Supplementary Protection Certificates of imetelstat based on our United Kingdom patents and our ability to establish and maintain European trademarks in the United Kingdom. In 2012, the European Union Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unity Patent, or UP, and a new European Unified Patent Court, or UPC, for litigation of European patents. It is uncertain

that implementation of the EU Patent Package will occur. If the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to “opt out” of the UPC on a patent-by-patent basis, although the time permitted for this opt-out is not yet known. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could 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. 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.

***Challenges to our owned or licensed patent rights would result in costly and time-consuming legal proceedings that could prevent or limit development 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 of our U.S. patents and those we have licensed and may license from others, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in Patent Office proceedings compared to the evidentiary standard in U.S. federal court, a third-party could potentially provide evidence in a Patent Office proceeding sufficient for the Patent Office to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, 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, to challenge the validity of certain patents. As a result, entities associated with hedge funds have challenged valuable pharmaceutical patents through the IPR process. 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 United States 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.

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. For example, litigation may arise as a result of our decision to enforce

our patent rights against third parties. 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 not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, maintaining, defending and enforcing patents on imetelstat and our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. 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. There can be no assurance that we will obtain or maintain patent rights inside or outside the United States under any future license agreements. In addition, the laws of some countries outside the United States do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with imetelstat and our technologies and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions outside the United States. 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 United States have compulsory licensing laws under which a patent owner must grant licenses to third parties. Proceedings to enforce our patent rights, even if obtained, in jurisdictions outside the United States could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. While we intend to protect our intellectual property rights in major markets for imetelstat, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market imetelstat. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

***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.

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 licenses to those patents or other proprietary rights or develop or obtain alternative technologies. 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. If that were to occur, we might need 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. 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.

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. Any infringement claims against us would likely be expensive to resolve, and the cost of any unblocking license that we could be required to obtain is unpredictable and could be significant. 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 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, manufacture 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 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 were not able to protect our 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 without 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 COMPETITIVE FACTORS**

***If 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 indicating potential disease-modifying activity with imetelstat treatment; and knowledge and expertise around the development of potential treatments for hematologic myeloid malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and 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.

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, a Bristol-Myers Squibb Corporation, or Celgene; 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.; and Reblozyl (luspatercept), a TGF-beta inhibitor, by Acceleron Pharma, Inc., or Acceleron, in collaboration with Celgene.

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.; and APR-246, an activator of p53 protein, by Aprea Therapeutics, Inc.

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

If approved for commercial sale for the treatment of MF, imetelstat would compete against currently approved JAK inhibitors: Jakafi (ruxolitinib) by Incyte Corporation and Inrebic (fedratinib) by Celgene. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cell counts; 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, some of which may obtain regulatory approval earlier than imetelstat include pacritinib, a JAK inhibitor, by CTI Biopharma; momelotinib, a JAK inhibitor, by Sierra Oncology; pelabresib, a BET inhibitor, by Constellation Pharmaceuticals, Inc.; navitoclax, a BCLXL, BCL-2 and BCLW inhibitor, by AbbVie, Inc.; and piasclisib, a PI3K delta inhibitor, by Incyte Corporation. Other approaches for MF currently under investigation that could compete with imetelstat in the future include luspatercept, a TGF-beta inhibitor, by Acceleron, in collaboration with Celgene; PRM-151, an anti-fibrosis antibody, by Promedior, Inc.; 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 Galecko Biotech; ING-41, a selective GSK-3b inhibitor, by Actuate Therapeutics, Inc.; XPOVIO (Selinexor), a nuclear export inhibitor, by Karyopharm Therapeutics, Inc.; TL-895, a tyrosine kinase inhibitor by, Telios Pharma, Inc.; IMG7289, a LSD1 inhibitor, by Imago Biosciences, Inc.; and APG-1252, a dual BCL-2/BCL-XL inhibitor, by Ascentage Pharma.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We anticipate increased competition in the future as new companies explore treatments for hematologic myeloid malignancies, which may significantly impact the commercial viability of imetelstat. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to 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.

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 level of reimbursement;
- level of generic competition;
- price; and
- patent position, including potentially dominant patent positions of others.

As a result of the foregoing, competitors may develop more commercially desirable or affordable products 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.

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

If approved for marketing, imetelstat may not achieve market acceptance, or the potential worldwide or U.S. 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 country 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;
- the ability to establish in the medical community the potential advantages of imetelstat over alternative treatment methods, including with respect to efficacy, safety, cost or route of administration;
- 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 other 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;
- the effectiveness of sales, marketing and distribution support for imetelstat;
- the extent to which imetelstat is approved for inclusion on formularies in hospitals and managed care organizations;
- the pricing of imetelstat;
- 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.

The established use of conventional products competitive with imetelstat may limit or preclude the potential for imetelstat to receive market acceptance upon any commercialization. We may be unable to demonstrate any pharmacoeconomic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for hematologic myeloid malignancies. Third-party payors may decide that any potential improvement that imetelstat may provide to clinical outcomes in hematologic myeloid malignancies is not adequate to justify the costs of treatment with imetelstat. If the health care 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, and might cause us to cease operations.

***If acceptable prices or adequate reimbursement for imetelstat is not obtained, 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. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. 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 regulatory authorities in other countries. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which 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.

***The adoption of health policy changes and health care reform in the United States may adversely affect our business and financial results.***

In the United States and some jurisdictions outside the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could impact our business. For example, in response to the COVID-19 pandemic, the CARES Act was signed into law in March 2020. The CARES Act is aimed at providing emergency assistance and health care for individuals, families and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. Generally, there has been increasing legislative and enforcement interest in the United States 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. While a number of reform measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could affect pricing for imetelstat if it is approved. The effects of the COVID-19 pandemic may introduce temporary or permanent healthcare reform measures, which could have negative financial implications on our business.

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. For a discussion of health reform activity, see Item 1 “Business—Government Regulation—Reimbursement and Healthcare Reform” in this Annual Report on Form 10-K.

Cost control initiatives also could decrease the price that we may receive for imetelstat in the future. If imetelstat is not considered cost-effective or adequate third-party reimbursement for the users of imetelstat cannot be obtained, then we may be unable to maintain price levels sufficient to realize an appropriate return on our investment in imetelstat. Any of these events would severely and adversely affect our financial results, business and business prospects, and might cause us to cease 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; 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 any product of ours for which 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, Data Privacy and Security, and Transparency Laws and Regulations” in this Annual Report on Form 10-K. Additionally, efforts to ensure that our current and future business arrangements will comply with applicable healthcare, privacy and data security laws and regulations will involve substantial costs. For example, the GDPR, which became effective on May 25, 2018, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, provides an enforcement authority and authorizes the imposition of large penalties 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. The GDPR has increased our responsibility and potential liability in relation to personal data that we process or control compared to prior EU law, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management’s attention and increase our cost of doing business. Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the CCPA, which has been characterized as the first “GDPR-like” privacy statute enacted in the United States because it mirrors a number of the key provisions in the GDPR, became effective on January 1, 2020, and we cannot determine the impact such laws, regulations and standards will have on our business. In any event, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidances or case law involving applicable healthcare or privacy laws, including the GDPR, in light of the lack of applicable precedent and regulations.

Federal and state enforcement bodies have recently 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, 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.

***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, contract research organizations, 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 other 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 preclinical 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, 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, any of which could adversely affect our business, financial condition, results of operations or prospects.

## **RISKS RELATED TO OUR COMMON STOCK AND FINANCIAL REPORTING**

***Historically, our stock price has been extremely volatile.***

Historically, our stock price has been extremely volatile. Between January 1, 2011 and December 31, 2020, our stock has traded as high as \$7.79 per share and as low as \$0.75 per share. Between January 1, 2020 and December 31, 2020, the price has ranged between a high of \$2.40 per share and a low of \$0.75 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 research and development of imetelstat, or results of, further delays in the commencement, enrollment or conduct of, discontinuation of, or further modifications or refinements to any clinical trials of imetelstat, including IMerge Phase 3 or IMpactMF, for any reason, or our inability, for any reason, to successfully continue the development of imetelstat;
- having sufficient financial resources to reach top-line results in IMerge Phase 3;
- obtaining substantial additional capital, on commercially reasonable terms, necessary to advance the imetelstat program, including through IMerge Phase 3 and IMpactMF and conducting the clinical, regulatory and potential commercialization activities necessary to bring imetelstat to market in lower risk MDS and refractory MF;
- preliminary, interim or final clinical trial data reported with respect to current or potential future clinical trials of imetelstat, and investor perceptions thereof;
- not receiving timely regulatory clearances or approvals in any jurisdiction, whether within or outside of the United States, including, if we do not obtain regulatory clearance to commence, modify, conduct or continue clinical trials of imetelstat in MF, MDS or any additional hematologic myeloid malignancies in a timely manner or at all;

- announcements regarding the safety of imetelstat and partial or full clinical holds placed on the imetelstat INDs by the FDA or other regulatory authorities, or other regulatory developments related to imetelstat;
- the experimental nature of imetelstat;
- the terms and timing of any future collaboration agreements for the development and potential commercialization of imetelstat that we may establish;
- the demand in the market for our common stock;
- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, potential future collaborative partners or our competitors;
- fluctuations in our operating results;
- 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 the COVID-19 pandemic;
- perceptions of the biotechnology and pharmaceutical industry by the public, legislature, regulators and the investment community;
- announcements concerning imetelstat proprietary rights;
- comments by securities analysts or other third parties, including blogs, articles and other media;
- large stockholders exiting their position in our common stock or an increase in the short interest in our common stock;
- announcements of or developments concerning pending and potential future litigation;
- the issuance of common stock to partners, vendors or investors to raise additional capital; and
- the occurrence of any other risks and uncertainties discussed under the heading “Risk Factors.”

Stock prices and trading volumes for many biopharmaceutical companies fluctuate widely for a number of reasons, including factors which may be unrelated to their businesses or results of operations, such as media coverage, statements made on message boards and social media forums, legislative and regulatory measures and the activities of various interest groups or organizations. In addition to the risk factors described in this section, overall market volatility, as well as general domestic or international economic, market and political conditions, including those resulting from the effects of the COVID-19 pandemic, could materially and adversely affect the market price of our common stock and the return on our stockholders’ investment in our securities.

In addition, as further discussed in the Risk Factor above entitled “*We and certain of our officers have been named as defendants in two pending putative securities class action lawsuits and four shareholder derivative lawsuits. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management’s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in their outcome*”, we and two of our officers have been named as defendants in two putative class action lawsuits. In addition, certain of our current officers and current and former board members have been named as defendants in the Derivative Lawsuits filed in the Northern District, the Court of Chancery of the State of Delaware, and the District Court for the District of Delaware, respectively. Such lawsuits have often been instituted against companies, including us, whose securities have experienced periods of volatility in market price. The pending lawsuits and any lawsuits brought against us in the future could result in substantial costs, which would hurt our financial condition and results of operations and divert management’s attention and resources, which could result in delays of IMerge Phase 3 and IMPactMF and/or could preclude or delay potential future clinical trials, or could preclude or delay commercialization efforts.

***We may fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.***

Our common stock currently trades on The Nasdaq Global Select Market. The Nasdaq Stock Market LLC has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum closing bid price of \$1.00 per share of our common stock. On March 12, 2020, the closing price of our common stock was \$0.99 per share, and while the closing price of our common stock rose to \$1.03 per share on March 19, 2020, and has subsequently remained at or above the minimum closing bid price of \$1.00 per share from March 19, 2020 through the date of this filing, it may in the future fall below the closing minimum bid price of \$1.00 per share. If the closing bid price of our common stock were to remain below \$1.00 per share for 30 consecutive trading days, or we do not meet other listing requirements, we would fail to be in compliance with Nasdaq's listing standards. There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement once the temporary suspension is lifted, The Nasdaq Stock Market LLC may initiate the delisting process with a notification letter. If we were to receive such a notification, we would be afforded a grace period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock would need to maintain a minimum closing bid price of at least \$1.00 per share for a minimum of 10 consecutive trading days. In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

***The sale of a substantial number of shares may adversely affect the market price of our common stock.***

As of December 31, 2020, we had 450,000,000 shares of common stock authorized for issuance and 310,566,853 shares of common stock outstanding. In addition, we had reserved 118,156,885 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants as of December 31, 2020.

Future sales of our common stock or the perception that such sales could occur, or the issuance of common stock to fund our operations and imetelstat development, including pursuant to the 2020 Sales Agreement with B. Riley Securities, could cause immediate dilution and adversely affect the market price of our common stock. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding warrants, also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities, which could negatively affect the market price of our common stock and the return on your investment.

***Our undesignated preferred stock may inhibit potential acquisition bids; this may adversely affect the market price of our common stock and the voting rights of holders of our common stock.***

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.

In addition, 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 in our charter, bylaws and Delaware law may inhibit potential acquisition bids for us, which may 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.

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.

***Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.***

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 will be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders;
- any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws; or
- any action asserting a claim governed by the internal affairs doctrine.

While the exclusive forum provisions in our bylaws do not apply to lawsuits brought to enforce a duty or liability created by the Exchange Act or the Securities Act of 1933, as amended, or any claim for which the federal courts have exclusive jurisdiction, these provisions may nonetheless limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our current or former directors, officers, or other employees, which may discourage such lawsuits against us and our current or former directors, officers, and other employees. Alternatively, 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.

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

*Significant disruptions of information technology systems, including cloud-based systems, or breaches of data security could adversely affect our business.*

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including cloud-based systems, to support business processes as well as internal and external communications. In particular, the COVID-19 pandemic has caused us to modify our business and information technology practices, including the requirement that our employees work remotely and not in our offices. Our information technology systems, including in our remote work environment as a result of the COVID-19 pandemic, and those of our collaborators, service providers and contractors, are potentially vulnerable to breakdown, data corruption, malicious intrusion, malware, computer viruses, natural disasters, terrorism, war, and telecommunication and electrical failures that may result in damage to or the impairment of key business processes, or the unauthorized, unlawful or accidental loss, corruption, access, acquisition or disclosure of confidential information, such as clinical trial data or information, intellectual property, proprietary business information and personal information. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures designed to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. In addition, we rely on our collaborators, service providers, including our CROs, and contractors to establish and maintain appropriate information technology systems and data security protections. However, except for contractual duties and obligations, we have limited ability to control their safeguards and actions related to such matters. If such a breach were to occur and cause interruptions in our operations, it could result in a material disruption of our imetelstat development program. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the data.

In addition, our information technology systems, as well as those of our collaborators, service providers and contractors, are potentially vulnerable to security breaches, whether by employees, contractors, consultants, malware, phishing attacks, or other cyber-attacks, that may expose confidential information, intellectual property, proprietary business information or personal information to unauthorized persons. If a security breach affects our systems or those of third parties upon which we rely, corrupts our data or results in the unauthorized disclosure or release of personal information by our collaborators, service providers, contractors or us, our reputation could be materially damaged, and we could be subject to significant fines, increased costs or loss of revenue. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media, individuals, collaborators or other relevant stakeholders pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, as well as contracts, if applicable. These may include state data breach notification laws and the EU General Data Protection Regulation (EU) 2016/679, or GDPR. Accordingly, a data security breach or privacy violation that leads to unauthorized access to, acquisition, disclosure or modification of personal information (including health information), that prevents access to personal information or materially compromises the privacy, security, availability, integrity or confidentiality of the personal information, could result in processing penalties, fines, increased costs or loss of revenue as a result of:

- harm to our reputation;
- additional compliance obligations or enforcement measures under U.S. federal and state laws, and foreign laws;
- remediation and corrective action we undertake as required by law or as otherwise necessary;
- litigation and potential civil or criminal liability; and
- requirements to verify the accuracy of affected data.

Many of our contracts with relevant stakeholders such as collaborators include obligations to use industry-standard or reasonable measures to safeguard personal information. A security breach could lead to claims against us by relevant stakeholders. In addition, our non-compliance with our data privacy obligations in our contracts, or our

inability to ensure that our service providers also comply with such obligations to relevant stakeholders, may cause us to breach our contracts. As a result, we could be subject to legal action or the relevant stakeholders could end their relationships with us. 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 or damages.

If we are unable to prevent data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive study participant data. In addition, breaches and other compromises of our data can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access our information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures designed to protect our information technology systems, because the techniques used to compromise our systems, obtain unauthorized access, disable or degrade service, or sabotage systems, change frequently, become more sophisticated, and often are not recognized until launched against a target, we or our collaborators, service providers or contractors may be unable to anticipate these techniques or to implement adequate preventative measures. 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.

***Changes in and failures to comply with United States federal and state as well as foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.***

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidances, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about study subjects and healthcare providers in connection with clinical trials in the United States and abroad. These laws, regulations and guidances 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 our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and guidances is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing processing of personal information could result in negative publicity, diversion of management time and effort and proceedings (including investigations) against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, California enacted the California Consumer Privacy Act, or CCPA, which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA, in part, requires covered businesses to provide new disclosures to California residents and provide such residents new ways to opt-out of certain disclosures of personal information. In addition, the CCPA provides a private right action for data breaches, which is expected to increase data breach litigation. It is anticipated that the California Privacy Rights Act of 2020, or CPRA, will expand the CCPA on January 1, 2023 when the CPRA becomes operative. These laws exemplify the vulnerability of our business to the evolving regulatory environment related to personal data. As we expand our operations, these and similar laws may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Our operations abroad may also be subject to increased scrutiny or attention from foreign data protection authorities. Many foreign jurisdictions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CROs, contractors and other relevant stakeholders must comply. For example, the EU adopted the GDPR, which went into effect in May

2018 and introduces strict requirements for processing the personal information of EU residents, including clinical trial data. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health conditions, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement such as data processing penalties and monetary fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. As we expand into countries and jurisdictions outside the United States, we may be subject to additional laws and regulations that may affect how we conduct business.

European data protection laws, including the GDPR, generally restrict the transfer of personal information from Europe, including the European Economic Area (EEA), United Kingdom (U.K.) and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. For example, we became originally Privacy Shield certified by the U.S. Department of Commerce's International Trade Administration in April 2019. However, the Court of Justice of the European Union (CJEU) invalidated the EU-U.S. Privacy Shield on July 16, 2020 and similarly, on September 8, 2020, the Swiss Federal Data Protection and Information Commissioner declared the Swiss-US Privacy Shield inadequate to protect the transferred personal data. Nonetheless, the U.S. Department of Commerce continues to administer the Privacy Shield program to maintain the Privacy Shield Frameworks and we continue to be bound by the Privacy Shield obligations. The same CJEU decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Authorities in the U.K. may similarly invalidate use of the EU-U.S. Privacy Shield and raise questions on the viability of the Standard Contractual Clauses as mechanisms for lawful personal information transfers from the United Kingdom to the United States. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Although we rely primarily on clinical trial participants' explicit consent to transfer their personal information from Europe to the United States and other countries, in certain cases we have relied on the EU-U.S. Privacy Shield and the Standard Contractual Clauses. As such, if we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or implement another valid compliance mechanism, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal information from Europe. Inability to import personal information from Europe to the United States or other countries may also limit our ability to conduct clinical trial activities in Europe; collaborate with other entities subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense. In November 2020, EU regulators proposed a new set of Standard Contractual Clauses, which impose additional obligations and requirements with respect to the transfer of EU personal data to other jurisdictions, which may increase the legal risks and liabilities under the GDPR and local EU laws associated with cross-border data transfers, and result in material increased compliance and operational costs. Moreover, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

In addition, it is unclear whether the transfer of personal information from the EU to the U.K. will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the U.K. and the EU, transfers of personal information from the EEA to the U.K. are not considered restricted transfers under the GDPR for a period of up to four months from January 1, 2021 with a potential two-month extension. However, unless the EU Commission makes an adequacy finding with respect to the U.K. before the end of that period, the U.K. will be considered a "third country" under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers lawful under the GDPR. Additionally, although U.K. privacy, data protection and data security laws are designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

We publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, collaborators, contractors, service providers or vendors fail to act in accordance with our published policies and documentation. Such failures can subject us to potential foreign,

local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, trial participants or research subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Compliance with applicable privacy and data security laws and regulations as well as contractual obligations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms to ensure compliance with the such data protection obligations. If we fail to comply with any data protection obligations, we may face significant fines, penalties and litigation that could adversely affect our business, financial condition and results of operations.

## GENERAL RISK FACTORS

***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 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 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. For example, the Tax Act significantly revised the Internal Revenue Code of 1986, as amended, or the Code. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Act may adversely affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation with adverse effect on us. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation. 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 under the Tax Act 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.

***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. 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 as a result of the COVID-19 pandemic. 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.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **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 103<sup>rd</sup> 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**

Between January 23 and March 5, 2020, three putative securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed on March 19, 2020. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, or the Northern District, were consolidated by the Court on May 14, 2020, and on August 20, 2020, the lead plaintiffs filed a consolidated class action complaint. The consolidated class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to IMbark during the period from March 19, 2018 to September 26, 2018. The consolidated complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose facts related to the alleged failure of IMbark to meet the two primary endpoints of the trial, spleen response rate and Total Symptom Score, and that our stock price dropped when such information was disclosed. The plaintiffs in the consolidated class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On October 22, 2020, lead plaintiffs filed an amended consolidated class action complaint. We filed a motion to dismiss the amended consolidated class action complaint on November 23, 2020. The hearing on the motion to dismiss was held on February 8, 2021.

Between April 23, 2020 and November 12, 2020, four shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former board members. Of these actions, or the Derivative Lawsuits, one was filed in the Northern District, one was filed in the Court of Chancery of the State of Delaware, and two were filed in the U.S. District Court for the District of Delaware, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and violations of Section 14 of the Exchange Act, based on the same underlying facts as the consolidated class action lawsuit described above. The plaintiffs seek damages, corporate governance reforms, equitable relief, restitution, and an award of reasonable costs, including attorneys' fees. All four Derivative Lawsuits have been deferred until 30 days after an order on our motion to dismiss the amended class action complaint in the consolidated class action lawsuit has been made.

The pending 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 the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements if we do not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if we do prevail.

## **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 March 1, 2021, there were approximately 507 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, 2020, there were no unregistered sales of equity securities by us.

### ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

### 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", "Risks Related to COVID-19" and "Risks Related to Regulatory Compliance Matters 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*

Geron is a late-stage clinical biopharmaceutical company that is focused on the development and potential commercialization of imetelstat, an innovative therapeutic for hematologic myeloid malignancies. Geron's vision is to be recognized as a leader in the treatment of hematologic malignancies. Geron is committed to improving and extending the lives of patients by changing the course of these diseases by targeting telomerase. We are currently focused on the development and potential commercialization of imetelstat, a first in class telomerase inhibitor, and are conducting two ongoing Phase 3 clinical trials that are intended to enable registration: (i) IMerge Phase 3 in Low or Intermediate-1 risk myelodysplastic syndromes, or lower risk MDS, and (ii) IMpactMF in Intermediate-2 or High-risk myelofibrosis, or refractory MF.

Like many other biopharmaceutical companies, we have experienced and continue to experience delays in clinical site initiations, as well as patient screening and enrollment in our clinical trials due to the COVID-19 pandemic. At the beginning of 2020, the pace of site opening and patient screening and enrollment was in line with our expectations. However, in the spring of 2020, the COVID-19 pandemic began to rapidly affect clinical trial sites around the world. Many of our clinical sites established self-imposed holds on site initiations and enrollment during this period out of concern for patient exposure to COVID-19 and due to lack of available staff. As a result, we experienced significant delays in site initiations, as well as patient screening and enrollment, in IMerge Phase 3. During the summer of 2020, as the number of COVID-19 cases declined due to public health safety measures, some clinical sites removed their self-imposed holds on site initiations and enrollment, which improved the momentum of patient enrollment. However, beginning in November 2020, another steep rise in COVID-19 cases in most of the countries where IMerge Phase 3 is being conducted again negatively impacted the pace of enrollment. The emergence of COVID-19 variants also began, causing further unpredictability and uncertainty about the pace at which patients and healthcare workers would be able to return to clinical sites.

Since vaccine distribution has commenced in many countries, and we have begun to see the number of COVID-19 cases declining, we currently believe our clinical trial operations may normalize in the next several months. However, the pace at which any normalization may occur remains uncertain and unpredictable. Taking into account these dynamic and evolving circumstances, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023. If full enrollment in IMerge Phase 3 completes after the third quarter of 2021, top-line results will not be available by the end of 2022.

For IMpactMF, COVID-19 has also negatively impacted clinical trial activities. In addition, in 2020 a number of competing trials were initiated in MF and other oncology indications in the countries where we planned to conduct IMpactMF. As a result of these factors, site personnel resources are constrained at many clinical sites, causing delays in site initiation activities. Although we have expanded the number of countries and sites where we plan to conduct the trial, we now expect IMpactMF to be fully enrolled in 2024. Given these challenges, under current planning assumptions, we expect the interim analysis for IMpactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, the results may be available at different times than currently expected. All plans and timing expectations are subject to risks and uncertainties described in “Risk Factors” in Part I, Item 1A of this annual report on Form 10-K, including the effects of the COVID-19 pandemic, as described below.

We believe that data from two prior Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells in hematologic myeloid malignancies, potentially resulting in meaningful clinical benefits for patients. Data reported from our Phase 2 clinical trial in lower risk MDS provide evidence that imetelstat may achieve meaningful and durable transfusion independence and increase in hemoglobin levels, suggesting potential recovery of normal blood cells. Similarly, data reported from our Phase 2 clinical trial in myelofibrosis, or MF, suggest imetelstat potentially improves overall survival, or OS, for MF patients who have relapsed after or are refractory to prior treatment with a janus kinase, or JAK, inhibitor, or relapsed/refractory MF. Additionally, from these Phase 2 clinical trials, we have observed depletion of cytogenetic abnormalities and reductions in key driver mutations of the underlying diseases in both lower risk MDS and MF patients, as well as improvement in bone marrow fibrosis in MF patients, all of which we believe provides evidence of disease-modifying activity. Furthermore, these molecular and histology data have been correlated with the clinical benefits of transfusion independence in lower risk MDS and improved OS in relapsed/refractory MF. We believe the clinical benefits, molecular observations and correlations from these two Phase 2 trials highlight the magnitude of imetelstat’s unique mechanism of action of telomerase inhibition, and provide strong evidence that imetelstat may alter the course of MDS and MF. We believe this disease-modifying activity has the potential to differentiate imetelstat from other currently approved and investigational treatments for MDS and MF.

Imetelstat has been granted Fast Track designations by the United States Food and Drug Administration, or FDA, for the treatment of 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, and for the treatment of patients with relapsed/refractory MF. Imetelstat has also been granted orphan drug designations by the FDA in the United States and by the European Commission for the European Medicines Agency, or EMA, in the European Union, or EU, for the treatment of MDS and also for the treatment of MF.

In 2021, we have begun preparations for the future submissions of a New Drug Application, or NDA, in the United States, and a Marketing Authorization Application, or MAA, in Europe, for imetelstat in lower risk MDS, both of which we plan to submit in 2023, assuming enrollment in IMerge Phase 3 is completed by end of 2021, and top-line results from IMerge Phase 3 are available in 2023 supporting such submissions. We intend to discuss with the FDA options for a rolling submission process, as allowed under imetelstat's Fast Track designation in lower risk MDS. Under either a six-month priority review or a standard ten-month review process, upon potential approval by the FDA, we expect that commercial launch of imetelstat in lower risk MDS in the United States could occur in 2024. In Europe, we anticipate review of the MAA by the European Medicines Agency, or EMA, could take approximately 12 months and commercial launch of imetelstat in lower risk MDS in Europe could occur in 2024.

If imetelstat is approved for marketing by regulatory authorities, we plan to commercialize imetelstat independently in the United States and may seek potential commercialization partners for territories outside of the United States. In 2021, we plan to conduct preliminary commercial preparations, such as building the internal infrastructure to support a commercial launch, conducting market research and hiring commercial leadership in medical affairs, pricing and market access and market analytics.

### ***Impact of COVID-19 on Our Business***

The COVID-19 pandemic has resulted, and is expected to continue to result, in significant economic disruption, and has adversely affected and will likely continue to adversely affect our business. As of the date of this filing, significant uncertainty exists concerning the ultimate duration and severity of the COVID-19 pandemic. We are actively monitoring the situation and have taken and intend to take those actions that may be required by federal, state or local authorities or that we determine are in the best interests of our patients, investigators, employees and stockholders. For example, we have restricted access to our offices in California and New Jersey to essential activities for the health and safety of our employees and in compliance with local "shelter-in place" orders and suspended non-essential travel worldwide. Our employees have been able to work remotely without significant disruption to our business.

As discussed above, like many other biopharmaceutical companies, we have experienced and continue to experience delays in clinical site initiations and patient screening and enrollment in our clinical trials, IMerge Phase 3 and IMpactMF, due to the COVID-19 pandemic. We continue to monitor each clinical site through our contract research organizations, or CROs, as well as to conduct direct outreach to investigators and study staff. Due to the recent decline in COVID-19 cases and the commencement of vaccine distribution, we currently believe our clinical trial operations may normalize in the next several months. However, the pace at which any normalization may occur remains uncertain and unpredictable. Taking into account these dynamic and evolving circumstances, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available during the time period from the end of 2022 to the first half of 2023.

For IMpactMF, in addition to the negative impact of COVID-19, in 2020 a number of competing trials in MF and other oncology indications were initiated in the countries where we planned to conduct IMpactMF. As a result of these factors, site personnel resources are constrained at many clinical sites, causing delays in site initiation activities. Although we have expanded the number of countries and sites where we plan to conduct the trial, we now expect IMpactMF to be fully enrolled in 2024. Given these challenges, under current planning assumptions, we expect the interim analysis for IMpactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, the results may be available at different times than currently expected.

The fluidity and dynamic nature of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect COVID-19 will have on our clinical trials, our operations and our business, all of which are highly reliant on the continued worldwide progress toward managing this health crisis. All plans and timing expectations will be delayed or interrupted if COVID-19 pandemic conditions continue unabated, or worsen, creating further limitations on our clinical trial activities.

In alignment with recent guidance from the FDA on clinical trials, “FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards,” together with other national and regional guidelines outside the United States, we have taken steps designed to address unavoidable protocol deviations caused by COVID-19 illness and/or COVID-19 control measures. In addition, we issued an Urgent Safety Measure together with a Dear Investigator Letter to all of our clinical sites involved with IMerge Phase 3 to apply certain measures to protect patient safety that include enhanced ongoing monitoring for signs and symptoms of or exposure to COVID-19 as well as guidance for withholding treatment to patients who have tested positive, who show signs and/or symptoms of COVID-19, or who have potential exposure to COVID-19. Similar guidance has been provided in our clinical trial protocol for IMpactMF.

### ***Imetelstat – A Unique Drug Candidate Directed at a Novel Target Designed to Result in Disease-Modifying Activity***

Telomerase is an enzyme that is upregulated in many malignant stem and progenitor cells and allows them to proliferate without limitation, thereby driving tumor growth and progression. Imetelstat, our proprietary telomerase inhibitor, was designed to directly inhibit telomerase in malignant cells with continuously upregulated telomerase. We have global rights to imetelstat, which was discovered and first developed at Geron.

Data from our Phase 2 imetelstat clinical trials in lower risk MDS and relapsed/refractory MF showed dose- and exposure-dependent reductions of previously known pharmacodynamic markers, or biomarkers, of telomerase inhibition, such as telomerase activity, telomere length and expression of human telomerase reverse transcriptase, or hTERT, thereby indicating the on-target mechanism of action of imetelstat. Furthermore, these reductions in telomerase biomarkers correlated to better clinical outcomes for patients with higher telomerase activity, higher hTERT level and shorter telomere length. These biomarker data and the evidence of reductions in key driver mutations for MDS and MF, as well as cytogenetically abnormal clones, have been correlated to the clinical benefits observed in our Phase 2 clinical trials. In addition, these molecular data indicate by targeting telomerase, imetelstat inhibits the uncontrolled proliferation of malignant stem and progenitor cells resulting in apoptosis of malignant cells. We believe that the totality of these data provide strong evidence of disease-modifying activity of imetelstat treatment, which we believe has the potential to differentiate imetelstat from other currently approved and investigational treatments for MDS and MF.

### ***Compelling and Differentiating Phase 2 Data Support Phase 3 Development***

In lower risk MDS, we reported more mature data from 38 patients in the Phase 2 portion of the IMerge clinical trial, or IMerge Phase 2, in June 2020. As reported previously, 42% (16/38) of patients achieved the primary endpoint of 8-week transfusion independence, and 75% (12/16) of these patients showed a hemoglobin rise of at least 3 grams per deciliter during the transfusion free interval when compared to pretreatment level. An important observation from the more mature data set was the longer durability of transfusion independence, including 29% (11/38) of patients being transfusion-free for more than one year, and a median duration of transfusion independence of 20 months. Such durability provides significant and meaningful clinical benefit to lower risk MDS patients, given their chronic anemia and the debilitating impact of serial blood transfusions, and further supports the disease-modifying potential of imetelstat treatment. Additional information about this more mature data is described in this annual report on Form 10-K under “Business” in Part I, Item 1, under the sub-section entitled, “More Mature Data from IMerge Phase 2 Continue to Differentiate Imetelstat in Lower Risk MDS”, including safety data, which remained consistent with safety data from prior clinical trials of imetelstat in hematologic malignancies.

In relapsed/refractory MF, we previously reported efficacy and safety data 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 13 – 16 months in medical literature. In IMbark, patients also experienced other clinical benefits, including symptom improvement, spleen reduction and bone marrow fibrosis improvement. We reported recent correlation analyses from IMbark in June 2020 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. Given the shortened survival for refractory MF patients, extended median OS would provide substantial clinical benefit. Additional information about the correlation analyses is described in this annual report on Form 10-K under “Business” in Part I, Item 1, under the sub-section entitled, “Recently Reported Analyses of IMbark Phase 2 Data Provide Evidence of Improvement in OS and Disease-Modifying Potential of Imetelstat.”

### ***Ongoing Phase 3 Development***

IMerge Phase 3 is a double-blind, randomized, placebo-controlled clinical trial that, based on discussions with U.S. and European regulatory authorities, we believe may support, if successful, the registration of imetelstat in lower risk MDS. The trial is designed to enroll approximately 170 patients with lower risk transfusion dependent MDS relapsed/refractory to ESA, who have not received prior treatment with either a hypomethylating agent, or HMA, or lenalidomide and are non-del(5q). IMerge Phase 3 is being conducted at over 100 medical centers globally, including North America, Europe, Middle East and Asia. In December 2020, we achieved 50% of the planned patient enrollment, and in March 2021, we attained 65% of the planned patient enrollment. Taking into account the dynamic and evolving circumstances of COVID-19 on our clinical trial activities, under current planning assumptions, we expect IMerge Phase 3 to be fully enrolled in the second half of 2021. Depending on the timing of full enrollment, we expect top-line results from IMerge Phase 3 to be available in the time period from the end of 2022 to the first half of 2023.

IMPactMF is designed to be an open label 2:1 randomized, Phase 3 clinical trial to evaluate imetelstat versus best available therapy, or BAT, in approximately 320 patients with Intermediate-2 or High-risk MF who are refractory to prior treatment with a JAK inhibitor, or refractory MF. Based on our discussions with the FDA, we believe the current design of IMPactMF may support, if the trial is successful, the registration of imetelstat in refractory MF. Currently, we expect to engage over 180 sites to participate in IMPactMF across North America, South America, Europe, Australia and Asia. In December 2020, we opened the first three trial sites to patient enrollment.

Given the challenges caused by COVID-19 on our clinical trial activities, under current planning assumptions, we expect the interim analysis for IMPactMF to occur in 2024 and the final analysis in 2025. Because these analyses are event-driven, the results may be available at different times than currently expected. At the interim analysis, if the pre-specified statistical OS criterion is met, we expect such data may support the registration of imetelstat in 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 after the interim analysis.

### ***Plan for Potential Commercialization of Imetelstat***

In 2021, we have begun preparations for the future submissions of an NDA for imetelstat in the United States, and an MAA in Europe, for imetelstat in lower risk MDS, both of which we plan to submit in 2023, assuming enrollment in IMerge Phase 3 is completed by end of 2021, and top-line results from IMerge Phase 3 are available in 2023 supporting such submissions. We intend to discuss with the FDA options for a rolling submission process, as allowed under imetelstat’s Fast Track designation in lower risk MDS. Under either a six-month priority review or a standard ten-month review process, upon potential approval by the FDA, we expect that commercial launch of imetelstat in lower risk MDS could occur in the United States in 2024. In Europe, we anticipate review of the MAA by the EMA could take approximately 12 months and commercial launch of imetelstat in lower risk MDS in Europe could occur in 2024.

If imetelstat is approved for marketing by regulatory authorities, we plan to commercialize imetelstat ourselves in the United States and may seek potential commercialization partners for territories outside of the United States. Given these plans, we have developed a potential commercial launch plan, which includes potential financing plans that are driven by the achievement of certain clinical milestones, such as top-line results. In 2021, we plan to conduct preliminary commercial preparations, such as building the internal infrastructure to support a commercial launch, conducting market research and hiring commercial leadership in medical affairs, pricing and market access and market analytics.

### ***Potential Patent Term Extensions and Market Exclusivity***

We have issued U.S. and European patents pertaining to treatment of MF and MDS with imetelstat that extend patent coverage into 2033.

We also hold issued patents covering imetelstat composition of matter. In the United States, our composition of matter patent coverage extends through 2025. In Europe, our composition of matter patent coverage expires in 2024, and includes patent rights in Germany, France, the United Kingdom, and other member countries of the European Patent Convention. Potential patent term extensions may be available to extend our imetelstat composition of matter patent terms in the United States up to 2030 through provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (as amended), or the Hatch-Waxman Act, and in Europe up to 2029 under a Supplementary Protection Certificate, or SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation. In the United States and in Europe, the scope of protection under such a patent term extension, if any were granted, would be defined by the description of the imetelstat product as approved for marketing. An additional six-month extension of the protection under any SPC granted may be available in Europe pursuant to European Regulation (EC) No. 1901/2006 (Pediatric Regulation), or the European Pediatric Regulation. However, such pediatric extension of SPC protection is not available if a one-year extension of marketing exclusivity has already been granted in respect of a new pediatric indication.

Upon drug product approval, there are additional extensions of regulatory exclusivity which we may receive. We have orphan drug designations for both MDS and MF in the United States and in Europe. In the United States, under the Orphan Drug Act of 1983, orphan drug designation allows for market exclusivity for seven years following drug product approval for the orphan disease indication. In Europe, under the European Union Orphan drug regulation (EC) No. 141/2000, orphan drug designation allows for market exclusivity for ten years following drug product approval for each of the orphan disease indications, with the potential for extension of market exclusivity for two years pursuant to the European Pediatric Regulation. If we are unable to maintain orphan drug designation, upon drug product approval:

- In the United States, we may have five years of new chemical entity, or NCE exclusivity, which includes data and market exclusivity, under the Hatch-Waxman Act; and
- In European countries, we may have eight years of data exclusivity plus two years of market exclusivity through provisions of the European Union Data exclusivity Directive 2004/27/EC, with the potential for extension of market exclusivity for one year for a new pediatric indication being authorized.

In addition, a six month pediatric extension may be available in the United States pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, to the longest extension or exclusivity period available under a patent term extension, the NCE exclusivity period or the orphan drug exclusivity period.

### **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, 2020, we had approximately \$260.0 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities, and long-term debt principal balance of \$25.0 million.

On September 30, 2020, or the Closing Date, we, Hercules Capital, Inc., or Hercules, and Silicon Valley Bank, or SVB, entered into a loan and security agreement, or the Loan Agreement, for an aggregate principal amount up to \$75.0 million that can be drawn in three tranches as follows: (i) Tranche A loan of up to \$35.0 million of which \$25.0 million was funded on the Closing Date and the remaining \$10.0 million is available to be drawn until June 15, 2021, (ii) Tranche B loan of up to \$15.0 million which is available to be drawn from January 1, 2021 to December 15, 2021, subject to achievement of certain clinical milestones, and (iii) Tranche C loan of up to \$25.0 million available to be drawn through December 31, 2022, subject to approval by an investment committee comprised of Hercules and SVB. As of December 31, 2020, \$25.0 million under Tranche A has been drawn, and there have been no other amounts drawn under the other Tranches.

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 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 agreed to pay B. Riley Securities 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 Securities under the 2020 Sales Agreement. In connection with the 2020 Sales Agreement, we terminated the At Market Issuance Sales Agreement that we entered on May 18, 2018, or the 2018 Sales Agreement, with B. Riley FBR, Inc., or B. Riley FBR. On September 4, 2020, we filed a registration statement on Form S-3, or the registration statement, which includes a prospectus, pursuant to which we may offer and sell, from time to time after the effectiveness of the registration statement, shares of our common stock having an aggregate offering price of up to \$100.0 million under the 2020 Sales Agreement.

On May 27, 2020, we completed an underwritten public offering of 107,049,375 shares of our common stock and a pre-funded warrant to purchase 8,335,239 shares of our common stock, together with accompanying warrants to purchase 57,692,307 shares of our common stock, or the stock purchase warrants. The combined public offering price of the common stock and accompanying stock purchase warrants was \$1.30 per share. The combined public offering price of the pre-funded warrant and accompanying stock purchase warrants was \$1.299 per share. The net cash proceeds from this offering were approximately \$140.2 million, after deducting the underwriting discount and other offering expenses paid by us, and excludes any future proceeds from the exercise of the pre-funded warrant or the stock purchase warrants.

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. While we reported a small profit for the year ended December 31, 2015 due to our recognition of revenue in connection with the upfront payment from Janssen under the Collaboration Agreement, until 2015 we had never been profitable, and have not reported any profit since. 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, 2020, we had an accumulated deficit of approximately \$1.2 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 will require significant additional clinical testing prior to possible regulatory approval in the United States 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 through late-stage development, including the conduct and completion of IMerge Phase 3 and ImpactMF. To further advance the imetelstat program, including conducting the clinical and regulatory activities necessary to obtain regulatory approval for imetelstat and establishing sales and marketing capabilities to commercialize imetelstat in the United States on our own, if regulatory approval is granted, substantial additional capital will be required. If approved for marketing by regulatory authorities outside of the United States, we may seek potential commercialization partners for such territories. We do not expect imetelstat to be commercially available for many years, if at all.

## **Critical Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Note 1 of Notes to Financial Statements describes the significant accounting policies used in the preparation of our financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (i) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (ii) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

Estimates and assumptions about future events and their effects cannot be determined with certainty. We base our estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as our operating environment changes. These changes historically have been minor and have been included in the financial statements as soon as they became known. Based on a critical assessment of our accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that our financial statements are stated fairly in accordance with accounting principles generally accepted in the United States, and meaningfully present our financial condition and results of operations.

We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements:

### ***Fair Value of Financial Instruments***

We categorize financial instruments recorded at fair value on our 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. Following is a description of the valuation methodologies used for financial instruments measured at fair value on our balance sheets, including the category for such financial instruments.

Financial instruments classified as Level 1 include money market funds and certificates of deposit, representing approximately 2% of our total financial instruments classified as assets measured at fair value as of December 31, 2020. Financial instruments classified as Level 2 include commercial paper, U.S. government-sponsored enterprise securities, U.S. Treasury securities, corporate notes and equity investments, representing approximately 98% of our total financial instruments classified as assets measured at fair value as of December 31, 2020. The price for each security at the measurement date is derived from various sources. Periodically, we assess the reasonableness of these sourced prices by comparing them to the prices provided by our portfolio managers from broker quotes as well as reviewing the pricing methodologies used by our portfolio managers. Historically, we have not experienced significant deviation between the sourced prices and our portfolio managers' prices.

For a further discussion regarding fair value measurements, see Note 2 on Fair Value Measurements in Notes to Financial Statements of this annual report on Form 10-K.

### ***Leases***

On January 1, 2019, we adopted the provisions of Accounting Standards Codification 2016-02, *Leases (Topic 842)*, or ASU 2016-02. Financial results for the reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Accounting Standards Codification Topic 840, *Leases*, or Topic 840.

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 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 to calculate the present value is typically not readily determinable. As such, significant management judgment is required to estimate the incremental borrowing rate, which is the rate incurred 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 evaluate the assumptions used in estimating the incremental borrowing rate by reviewing industry and regional data for operating leases and loans with similar terms. We have not made any revisions to borrowing rate estimates. If the basis for the incremental borrowing rate estimate were to change, then the present value of remaining lease payments could differ significantly which would affect the value recognized for the right-of-use assets and corresponding lease liabilities on our balance sheets. See Note 7 on Operating Leases in Notes to Financial Statements for further discussion of our operating lease obligations.

On March 10, 2020, a new operating lease commitment for our offices in Foster City, California commenced 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 \$3.4 million, 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.

### ***Revenue Recognition***

Beginning January 1, 2018, 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 Topic 606, 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. 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. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as noncurrent deferred revenue.

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.

Our revenues historically have consisted of collaboration revenue, license fees and royalties. Collaboration revenue primarily represented amounts earned under the Collaboration Agreement with Janssen for the imetelstat program. Effective September 28, 2018, the Collaboration Agreement with Janssen was terminated. As a result, we will not receive any milestone payments or royalties from Janssen for the development or commercialization of imetelstat. License fees and royalty revenue primarily represents amounts earned under agreements that out-license our technology to various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable upfront license payments in cash or equity securities, annual license maintenance fees, cost sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. Non-refundable upfront fees, annual license maintenance fees and funding of research and development activities are considered fixed consideration, while milestone payments and royalties are identified as variable consideration.

*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 period, 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. 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 our 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.

*Cost Sharing Arrangements.* Research and development and other expenses being shared by both parties under an agreement are recorded as earned or owed based on the performance obligations by both parties under the respective agreement. For arrangements in which we and our collaboration partner in the agreement are exposed to significant risks and rewards that depend on the commercial success of the activity, we recognize payments between the parties on a net basis and record such amounts as a reduction or addition to research and development expense. For arrangements in which we have agreed to perform certain research and development services for our collaboration partner and are not exposed to significant risks and rewards that depend on the commercial success of the activity, we recognize the respective cost reimbursements as revenue under the collaboration agreement over time in a manner proportionate to the costs we incurred to perform the services using the input method.

Revenue recognition for licenses and collaboration agreements requires significant judgment. Our assessments and estimates are based on contractual terms, historical experience and general industry practice. Revisions in these values or estimations have the effect of increasing or decreasing license fee or collaboration revenue in the period of revision. As of December 31, 2020, we have not made any revisions to revenue recognition estimates.

### ***Clinical Trial Accruals***

Our current imetelstat clinical trials are being supported by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In that event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. For the clinical development activities previously conducted by Janssen under the former Collaboration Agreement, we monitored patient enrollment levels and related activities to the extent possible through discussions with Janssen personnel and based our estimates of clinical trial costs on the best information available at the time.

### ***Valuation of Stock-Based Compensation***

We measure and recognize compensation expense for all share-based payment awards to our employees and directors, including service-based and performance-based stock options, restricted stock awards and employee stock purchases related to our Employee Stock Purchase Plan, or ESPP, based on estimated grant-date fair values for these instruments. The grant-date fair value of share-based payment awards is amortized over the vesting period of the awards using a straight-line method and reduced for estimated forfeitures. For performance-based stock options with vesting conditioned 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 that assessment of the probability of the performance condition being met changes, the impact of the change in estimate would be recognized in the period of the change. 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 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.

Option-pricing model assumptions, such as expected volatility, expected term and risk-free interest rate, impact the fair value estimate. Expected volatilities are based on historical volatilities of our stock since traded options on our common stock do not correspond to option terms and trading volume of options is limited. The expected term of options represents the period of time that options granted are expected to be outstanding. In deriving this assumption, we review actual historical exercise and post-vesting cancellation data and the remaining outstanding options not yet exercised or cancelled. For performance-based stock options, we also assess the projected timing of potential achievement of the milestones. The expected term of employees' purchase rights under our ESPP is equal to the purchase period. The risk-free interest rate is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term in effect on the date of grant. Forfeiture rates are estimated based on historical data and are adjusted, if necessary, over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from their estimate.

We evaluate the assumptions used in estimating grant-date fair values of our share-based payment awards by reviewing current trends in comparison to historical data on an annual basis. We have not revised the methods by which we derive assumptions in order to estimate grant-date fair values of our share-based payment awards. If factors change and we employ different assumptions in future periods, the stock-based compensation expense that we record for share-based payment awards to employees and directors may differ significantly from what we have recorded in the current period.

## **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. For example, in 2015 we reported net income for the first time due to recognition of revenue in connection with the upfront payment from Janssen under the Collaboration Agreement. Effective September 28, 2018, the Collaboration Agreement with Janssen was terminated. As a result, we will not receive any milestone payments or royalties from Janssen for the development or commercialization of imetelstat. In addition, we expect to incur increasing operating losses in the future as we support our current Phase 3 clinical trials of imetelstat, IMerge and IMPactMF.

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; overcoming disruptions and/or delays due to the COVID-19 pandemic; our need for future capital; enforcement of our patent and proprietary rights; reliance upon our 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. We do not expect to receive revenue based on sales of imetelstat for many years, if at all.

## **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 human telomerase reverse transcriptase, or 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 recently has been 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. Also, in connection with the divestiture of Geron's 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 from certain research or commercial products utilizing Geron's former intellectual property.

We recognized license fee revenues of \$55,000, \$96,000 and \$641,000 in 2020, 2019 and 2018, respectively, related to our various agreements. The decrease in license fee revenues in 2020 and 2019 primarily reflects a reduction in the number of active license agreements for research licenses related to our hTERT technology due to the patent expirations on such technology.

We recognized royalty revenues of \$198,000, \$364,000 and \$425,000 in 2020, 2019 and 2018, respectively, on product sales of telomerase detection and telomere measurement kits to the research-use-only market and cell-based research products from our divested stem cell programs. The decrease in royalty revenues in 2020 and 2019 primarily reflects expiration of licenses which eliminated the obligation to pay royalties on product sales. Royalty revenues in 2020 and 2019 primarily 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 being maintained and the underlying patent rights for the license remaining active. Historical revenues may not be predictive of future revenues. We expect revenues in 2021 to be lower than 2020 due to the termination and expiration of our license agreements related to our hTERT technology due to the patent expirations on such technology. In addition, due to disruptions caused by the COVID-19 pandemic, sales of cell-based research products from our divested stem cell programs are expected to be lower which reduces the royalties payable to us.

### **Research and Development Expenses**

During the years ended December 31, 2020, 2019 and 2018, imetelstat was the sole research and development program we supported. For the imetelstat research and development program, we incur direct external, personnel related and other research and development costs. For the years ended December 31, 2020 and 2019, direct external expenses included costs for our CROs, consultants and other clinical-related vendors and 100% of the clinical development costs incurred by Janssen for operational support of the imetelstat program during the transition period. For the year ended December 31, 2018, direct external expenses primarily consisted of our proportionate share of research and development costs incurred by Janssen under the Collaboration Agreement. Personnel related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for Geron 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 were \$51.5 million, \$52.1 million and \$13.4 million for the years ended December 31, 2020, 2019 and 2018, respectively. The decrease in research and development expenses in 2020 primarily reflects the net result of lower direct external expenses due to the completion of the imetelstat program transition, the closing of IMbark and reduced purchases of raw materials, drug substance and drug product, partially offset by higher expenses for IMerge Phase 3 and start-up activities for IMPactMF. The increase in research and development expenses in 2019 primarily reflects higher direct external costs for clinical development activities. Such costs included: a) fees to our CROs, consultants and other clinical-related vendors for imetelstat program transition; b) start-up expenses for IMerge Phase 3; c) 100% reimbursement to Janssen for operational support of the imetelstat program during the transition period and d) purchase of inventories of drug product, drug substance and raw materials from Janssen. In addition, personnel related expenses have increased in 2020 and 2019 as a result of additional development headcount being hired.

Research and development expenses for the years ended December 31, 2020, 2019 and 2018 were as follows:

<b>(In thousands)</b>	<b>Year Ended December 31,</b>		
	<b>2020</b>	<b>2019</b>	<b>2018</b>
Direct external research and development expenses:			
Clinical program: Imetelstat.....	\$ 33,838	\$ 39,263	\$ 10,353
Personnel related expenses .....	14,566	10,126	2,429
All other research and development expenses.....	3,084	2,683	650
Total.....	<u>\$ 51,488</u>	<u>\$ 52,072</u>	<u>\$ 13,432</u>

Under the terms of the Collaboration Agreement, Janssen was required to provide operational support for the imetelstat program through September 2019 during transition of the program to us, including continuing to support ongoing imetelstat clinical trials. We reimbursed Janssen for 100% of the costs for such operational support. However, costs associated with transition activities, such as transfer of the sponsorship of ongoing imetelstat clinical trials, moving databases and related systems and transmitting regulatory files, were incurred separately by each company, unless otherwise specified in the Collaboration Agreement. As of the end of September 2019, the transition of the imetelstat program to us from Janssen was completed according to the terms of the Collaboration Agreement.

We expect research and development expenses to increase in the future as we support the current two Phase 3 clinical trials of imetelstat, IMerge and IMPactMF. At this time, we cannot provide reliable estimates of how much time or investment will be necessary to advance imetelstat toward commercialization. For a more complete discussion of the risks and uncertainties associated with the development of imetelstat, see the sub-sections entitled “Risks Related to the Development of Imetelstat” and “Risks Related to Regulatory Compliance Matters and Commercialization of Imetelstat” under “Risk Factors” in Part I, Item 1A and elsewhere in this annual report on Form 10-K.

### ***General and Administrative Expenses***

General and administrative expenses were \$25.7 million, \$20.9 million and \$18.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. The increase in general and administrative expenses in 2020 and 2019 primarily reflects higher personnel-related costs for additional headcount to support growing operational activities associated with bi-coastal offices, increased company headcount and international clinical trial activities, as well as increased legal costs. We expect general and administrative expenses to increase in the future as the imetelstat program matures and potential pre-commercialization preparatory activities begin.

### ***Interest Income***

Interest income was \$1.8 million, \$4.2 million and \$3.3 million for the years ended December 31, 2020, 2019 and 2018, respectively. The decrease in interest income for the year ended December 31, 2020 primarily reflects lower yields on our marketable securities portfolio due to declining interest rates despite an increase in the size of our marketable securities portfolio. The increase in interest income for the year ended December 31, 2019 primarily reflects higher yields on a larger marketable securities portfolio. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

### ***Interest Expense***

Interest expense was \$760,000 for the year ended December 31, 2020 and reflects interest payments under our Loan Agreement with Hercules and SVB. The Loan Agreement was effective September 30, 2020. As such, no comparable interest expense amounts were recognized for the years ended December 31, 2019 or 2018.

### ***Change in Fair Value of Equity Investment***

We remeasure the fair value of our equity investment at each reporting date and any resulting change in fair value based on observable price changes is included on our statements of operations. For the years ended December 31, 2020, 2019 and 2018, there was an increase in fair value of our equity investment of \$60,000 and a decrease in fair value of our equity investment of \$195,000 and \$541,000, respectively, resulting from observable price changes in the equity investment. The fair value of our equity investment fluctuates based on changes in the stock price of the underlying equity investment and is therefore subject to volatility that could adversely affect our operating results.

### ***Gain on Settlement***

In July 2018, we and the other former shareholders of ViaGen, Inc., or ViaGen, filed an arbitration claim against Trans Ova Genetics, L.C., or Trans Ova, for alleged violations under a Share Purchase Agreement, or SPA, including failure to make payments under certain conditions. In December 2018, we and the other former shareholders of ViaGen agreed to settle the dispute for a one-time payment of \$3.7 million, of which we received \$1.5 million, which represents our 40% share of the settlement amount. With this settlement, Trans Ova has been released from any further obligations under the SPA, including any future payments. No comparable amounts were recognized in 2020 or 2019.

### ***Other Income and Expense***

Other income and expense was \$168,000, \$69,000 and \$114,000 for the years ended December 31, 2020, 2019 and 2018, respectively. During the third quarter of 2020, we recognized other income of \$182,000 for the share exchange of our equity investment in Sienna Cancer Diagnostics, Limited upon its acquisition by BARD1 Life Sciences Limited, or BARD1. Also included in other income were realized losses of \$34,000 for the sales of BARD1 shares during the third quarter of 2020. See Note 2 on Fair Value Measurement – Equity Investment in Notes to Financial Statements for further information.

Other expense primarily reflects changes in the fair value of our equity investment resulting from foreign currency translation and bank charges related to our cash operating accounts and marketable securities portfolio. The fair value of our equity investment fluctuates based on changes in the exchange rate between the U.S. dollar and Australian dollar and is therefore subject to volatility, especially in light of the unpredictable market conditions due to the COVID-19 pandemic, that could adversely affect our future operating results.

### **Liquidity and Capital Resources**

As of December 31, 2020, we had cash, restricted cash, cash equivalents and marketable securities of \$260.0 million, compared to \$159.2 million at December 31, 2019. The increase in cash, restricted cash, cash equivalents, and current and noncurrent marketable securities from December 31, 2019 was primarily the result of the receipt of net cash proceeds of approximately \$140.2 million, after deducting the underwriting discount and other offering expenses payable by us, from an underwritten public offering of 107,049,375 shares of our common stock and a pre-funded warrant to purchase 8,335,239 shares of our common stock, together with accompanying stock purchase warrants to purchase 57,692,307 shares of our common stock, that we completed on May 27, 2020. In September 2020, we drew down \$25.0 million under the Loan Agreement with Hercules and SVB resulting in net proceeds of approximately \$23.9 million, after deducting debt discounts and other debt issuance costs payable 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, municipal securities, U.S. government and agency securities, U.S. Treasury 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.

In May 2018, we entered into the 2018 Sales Agreement with B. Riley FBR, pursuant to which we may 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 FBR as our sales agent. Pursuant to the 2018 Sales Agreement, B. Riley FBR sold our common stock at market prices prevailing at the time of sale for which B. Riley FBR received an aggregate commission rate equal to up to 3.0% of the gross proceeds. From January 2020 through April 2020, we sold an aggregate of 3,496,616 shares of our common stock under the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately \$4.1 million after deducting sales commissions and other offering expenses payable by us. The 2018 Sales Agreement has been superseded by the 2020 Sales Agreement (see below).

On September 4, 2020, we entered into an At Market Issuance Sales Agreement, or the 2020 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 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 agreed to pay B. Riley Securities 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 Securities under the 2020 Sales Agreement. In connection with the 2020 Sales Agreement, we terminated the 2018 Sales Agreement. On September 4, 2020, we filed a registration statement on Form S-3, or the registration statement, which includes a prospectus, pursuant to which we may offer and sell, from time to time after the effectiveness of the registration statement, shares of our common stock having an aggregate offering price of up to \$100 million under the 2020 Sales Agreement. No shares were sold in 2020 under the 2020 Sales Agreement. See Note 9 on Stockholders' Equity in Notes to Financial Statements for further discussion of the 2020 Sales Agreement. In the first quarter of 2021, we sold an aggregate of 7,948,505 shares of our common stock pursuant to the 2020 Sales Agreement, resulting in net cash proceeds to us of approximately \$16.2 million after deducting sales commissions and estimated offering expenses payable by us. See Note 12 on Subsequent Events in Notes to Financial Statements for sales under the 2020 Sales Agreement in 2021.

We estimate that our existing capital resources and future interest income will be sufficient to fund our current level of operations through at least the next 12 months and potentially as long as through the end of 2022. If top-line results from IMerge Phase 3 are available after the end of 2022, we will require additional capital to reach top-line results. In any event, we will require substantial additional funding to further advance the imetelstat program, including through IMerge Phase 3 and IMPactMF and conducting the clinical, regulatory and potential commercialization activities necessary to bring imetelstat to market in lower risk MDS and refractory MF. In addition, our ability to commercialize imetelstat in the United States, if regulatory approval is granted, depends on us being able to establish sales and marketing capabilities.

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, and 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 will be further delayed or interrupted if COVID-19 pandemic conditions continue unabated, or worsen, creating further limitations on our clinical trial activities. 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 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 regulatory authorities in other countries;
- the scope, progress, duration, results and costs of current and potential future clinical trials, including IMerge Phase 3, IMPactMF and other potential future clinical trials of imetelstat, as well as non-clinical studies and assessments, of imetelstat;
- delays or disruptions in opening sites, screening and enrolling patients or treating and following patients, in IMerge Phase 3 or IMPactMF or any potential future clinical trials of imetelstat, whether as a result of the effects of the COVID-19 pandemic or for any other reasons;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, such as obtaining and maintaining regulatory clearances and approvals for IMPactMF in the United States and in other countries;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing imetelstat, including our ability to achieve any meaningful reduction in manufacturing costs;
- the costs of multiple third-party vendors and service providers, including our CROs and CMOs, to pursue the development, manufacturing and potential commercialization of imetelstat;
- our ability to establish, enforce and maintain collaborative or other strategic arrangements for research, development, clinical testing and manufacturing of imetelstat and potential future commercialization and marketing;
- our efforts to enhance operational, financial and management processes and systems that will be required for future development and commercialization of imetelstat, and our ability to successfully recruit and retain additional key personnel to support the development and potential future commercialization of imetelstat;
- our ability to successfully market and sell imetelstat, if imetelstat receives future regulatory approval or clearance, in the United States and other countries, and the associated costs;
- the costs and timing necessary to build a sales force in the United States to market and sell imetelstat, should it receive regulatory approval;
- the sales price for imetelstat;

- the availability of coverage and adequate third-party reimbursement for imetelstat;
- expenses associated with the pending putative securities class action lawsuits and derivative lawsuits, as well as any other potential litigation;
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation;
- the costs of maintaining and operating facilities in California and New Jersey, telecommunications and administrative oversight, as well as higher expenses for travel when travel becomes possible in light of the COVID-19 pandemic; and
- the costs of enabling our personnel to telecommute as required by federal, state and local “shelter in place” or comparable orders, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

We do not have any committed external source of funds or other support for our development and commercialization efforts. 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 with any further delays in reporting results from IMerge Phase 3 or IMPactMF.

Additional financing through public or private debt or equity financings, including pursuant to the 2020 Sales Agreement with B. Riley Securities, the Loan Agreement with Hercules and SVB, to the extent available, 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 caused by the effects of the COVID-19 pandemic, and may in the future be affected by other factors which are unpredictable and over which we have no control. In this regard, the effects of the COVID-19 pandemic 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. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development 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, your ownership interest 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 with Hercules and SVB 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, and potential future sales of our common stock, including under the 2020 Sales Agreement with B. Riley Securities or potential future drawdowns, if available, under our Loan Agreement with Hercules and SVB, will be sufficient to fund our operating plans. In any event, we will continue to need substantial additional funds to meet operational needs and capital requirements to advance the imetelstat program in clinical development, including through IMerge Phase 3 and IMPactMF and potential commercialization of imetelstat in lower risk MDS and refractory MF, 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, including completing IMerge Phase 3 and IMPactMF, or commencing, conducting or completing other potential future clinical trials of imetelstat, or pursuing potential commercialization of imetelstat, which would severely harm our business and we might cease operations.

### ***Cash Flows from Operating Activities***

Net cash used in operating activities was \$66.7 million, \$43.8 million and \$21.0 million in 2020, 2019 and 2018, respectively. The increase in net cash used in operating activities in 2020 and 2019 primarily reflects higher payments for research and development expenses in connection with supporting the ongoing conduct of IMerge Phase 3 and start-up activities for IMPactMF, increases in development headcount, the transition of the imetelstat program from Janssen to us and purchase of inventories of drug product, drug substance and raw materials from Janssen.

### ***Cash Flows from Investing Activities***

Net cash used in investing activities in 2020 and 2018 was \$105.3 million and \$77.7 million, respectively. Net cash provided by investing activities in 2019 was \$27.4 million. Net cash used in investing activities in 2020 and 2018 primarily reflects a higher rate of purchases than maturities of marketable securities resulting from the investment of net cash proceeds from financings completed in 2020 and 2018. Net cash provided by investing activities in 2019 primarily reflects a higher rate of maturities than purchases of marketable securities.

For the three years ended December 31, 2020, we purchased approximately \$830,000 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 2020, 2019 and 2018 was \$168.3 million, \$19.5 million and \$93.0 million, respectively. Financing activities in 2020, 2019 and 2018 primarily reflect the receipt of \$140.2 million in net proceeds from the underwritten public offering of common stock, pre-funded warrant and stock purchase warrants in May 2020, receipt of net cash proceeds from the sales of our common stock under the 2015 Sales Agreement with MLV and the 2018 Sales Agreement with B. Riley FBR and cash proceeds from the issuance of common stock under our employee equity plans. In addition, in September 2020, we drew down \$25.0 million under the Loan Agreement with Hercules and SVB, resulting in net proceeds of approximately \$23.9 million after deducting the debt discounts and debt issuance costs paid by us.

### ***Off-Balance Sheet Arrangements***

We have not engaged in any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The following financial statements and the related notes thereto, of Geron Corporation 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.

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## 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 balance sheets of Geron Corporation (the Company) as of December 31, 2020 and 2019, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 March 11, 2021 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 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 clinical trial expenses*

##### *Description of the Matter*

The Company recorded research and development expenses of \$51.5 million for the year ended December 31, 2020. As described in Note 1, research and development expenses are expensed as incurred. Research and development expenses include fees paid to contract research organizations ("CRO"), and other vendors, that conduct certain research and development activities on behalf of the Company. Accrued expenses for clinical trial activities performed by CROs are based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. The Company monitors patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. The accrued expenses estimates are based on the best information available at the time.

Auditing the accounting for accrued clinical trial expenses is complex because of the high volume of data used in management's estimates, the assumptions used by management to develop their estimates and verifying the cost and extent of the services performed by CROs and other vendors during the reporting period.

*How We  
Addressed  
the Matter in  
Our Audit*

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls that address the identified risks related to the Company's process used to determine the completeness and accuracy of the accrued clinical trial expenses for CROs and other vendors, including management's controls to accurately monitor and estimate the services performed by the CROs and other vendors.

To test the Company's accounting for accrued clinical trial expenses, our audit procedures included, among others, obtaining supporting evidence from third parties of the research and development activities performed for significant clinical trials and testing the accuracy and completeness of 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.  
Redwood City, California  
March 11, 2021

**GERON CORPORATION**  
**BALANCE SHEETS**

	<b>December 31,</b>	<b>December 31,</b>
	<b>2020</b>	<b>2019</b>
	<b>(In thousands, except share and per share data)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$ 9,925	\$ 13,644
Restricted cash .....	363	270
Marketable securities.....	186,350	125,681
Interest and other receivables.....	722	802
Prepaid and other current assets .....	2,497	1,211
Total current assets .....	199,857	141,608
Noncurrent marketable securities .....	63,387	19,651
Property and equipment, net.....	658	408
Operating leases, right-of-use assets.....	5,295	2,497
Deposits and other assets .....	1,531	1,353
	\$ 270,728	\$ 165,517
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 6,919	\$ 1,181
Accrued compensation and benefits.....	8,218	4,830
Amount due to Janssen Biotech, Inc. ....	—	14,269
Operating lease liabilities .....	878	354
Accrued liabilities .....	14,925	7,528
Total current liabilities.....	30,940	28,162
Noncurrent operating lease liabilities .....	4,799	2,200
Noncurrent debt .....	24,042	—
Total liabilities .....	59,781	30,362
Commitments and contingencies .....		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 3,000,000 shares authorized; no shares issued and outstanding at December 31, 2020 and 2019 .....	—	—
Common stock, \$0.001 par value; 450,000,000 shares authorized; 310,566,853 and 199,814,581 shares issued and outstanding at December 31, 2020 and 2019, respectively .....	310	200
Additional paid-in capital.....	1,366,188	1,214,835
Accumulated deficit .....	(1,155,629)	(1,080,012)
Accumulated other comprehensive gain .....	78	132
Total stockholders' equity .....	210,947	135,155
	\$ 270,728	\$ 165,517

See accompanying notes.

**GERON CORPORATION**  
**STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2020	2019	2018
	(In thousands, except share and per share data)		
Revenues:			
License fees and royalties .....	\$ 253	\$ 460	\$ 1,066
Operating expenses:			
Research and development .....	51,488	52,072	13,432
General and administrative .....	25,678	20,893	18,707
Total operating expenses .....	77,166	72,965	32,139
Loss from operations .....	(76,913)	(72,505)	(31,073)
Interest income .....	1,828	4,221	3,251
Interest expense .....	(760)	—	—
Change in fair value of equity investment .....	60	(195)	(541)
Gain on settlement .....	—	—	1,460
Other income and (expense), net .....	168	(69)	(114)
Net loss .....	\$ (75,617)	\$ (68,548)	\$ (27,017)
Basic and diluted net loss per share .....	\$ (0.28)	\$ (0.36)	\$ (0.15)
Shares used in computing basic and diluted net loss per share .....	271,460,265	190,160,311	176,504,996

See accompanying notes.

**GERON CORPORATION**  
**STATEMENTS OF COMPREHENSIVE LOSS**

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
Net loss.....	\$ (75,617)	\$ (68,548)	\$ (27,017)
Net unrealized (loss) gain on marketable securities.....	(54)	315	24
Comprehensive loss .....	\$ (75,671)	\$ (68,233)	\$ (26,993)

See accompanying notes.

**GERON CORPORATION**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2017 .....	159,877,239	\$ 160	\$ 1,089,684	\$ (985,840)	\$ (207)	\$ 103,797
Cumulative effect of accounting principle change .....	—	—	—	1,393	—	1,393
Net loss .....	—	—	—	(27,017)	—	(27,017)
Other comprehensive income .....	—	—	—	—	24	24
Issuance of common stock in connection with at market offering, net of issuance costs of \$2,282 .....	23,278,185	23	85,994	—	—	86,017
Stock-based compensation related to issuance of common stock and options in exchange for services .....	73,980	—	191	—	—	191
Issuances of common stock under equity plans .....	3,163,278	3	6,948	—	—	6,951
Stock-based compensation for equity- based awards to employees and directors .....	—	—	6,368	—	—	6,368
401(k) contribution .....	—	—	9	—	—	9
Balances at December 31, 2018 .....	186,392,682	186	1,189,194	(1,011,464)	(183)	177,733
Net loss .....	—	—	—	(68,548)	—	(68,548)
Other comprehensive income .....	—	—	—	—	315	315
Issuance of common stock in connection with at market offering, net of issuance costs of \$481 .....	13,214,867	14	19,281	—	—	19,295
Stock-based compensation related to issuance of common stock and options in exchange for services .....	29,150	—	68	—	—	68
Issuances of common stock under equity plans .....	177,882	—	204	—	—	204
Stock-based compensation for equity- based awards to employees and directors .....	—	—	6,079	—	—	6,079
401(k) contribution .....	—	—	9	—	—	9
Balances at December 31, 2019 .....	199,814,581	200	1,214,835	(1,080,012)	132	135,155
Net loss .....	—	—	—	(75,617)	—	(75,617)
Other comprehensive loss .....	—	—	—	—	(54)	(54)
Issuance of common stock, pre-funded warrant and warrants to purchase common stock in public offering, net of issuance costs of \$9,808 .....	107,049,375	107	140,077	—	—	140,184
Issuance of common stock in connection with at market offering, net of issuance costs of \$144 .....	3,496,616	3	4,072	—	—	4,075
Issuance of common stock in connection exercise of warrants .....	12,500	—	16	—	—	16
Stock-based compensation related to issuance of common stock and options in exchange for services .....	17,986	—	85	—	—	85
Issuances of common stock under equity plans .....	175,795	—	208	—	—	208
Stock-based compensation for equity- based awards to employees and directors .....	—	—	6,895	—	—	6,895
Balances at December 31, 2020 .....	<u>310,566,853</u>	<u>\$ 310</u>	<u>\$ 1,366,188</u>	<u>\$ (1,155,629)</u>	<u>\$ 78</u>	<u>\$ 210,947</u>

See accompanying notes.

**GERON CORPORATION**  
**STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
<b>Cash flows from operating activities:</b>			
Net loss .....	\$ (75,617)	\$ (68,548)	\$ (27,017)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	158	64	59
Accretion and amortization on investments, net .....	818	(1,534)	(978)
Amortization of debt issuance costs/debt discount .....	179	—	—
Gain on sales of available for sale securities .....	(19)	—	—
Net gain on exchange and sales of equity investment.....	(148)	—	—
Change in fair value of equity investment, including foreign currency translation .....	(163)	196	604
Stock-based compensation for services by non-employees .....	85	68	191
Stock-based compensation for employees and directors .....	6,895	6,079	6,368
Amortization related to 401(k) contributions.....	—	9	9
Amortization of right-of use-assets.....	777	712	—
Changes in assets and liabilities:			
Interest and other receivables.....	80	366	(528)
Prepaid and other current assets.....	(1,286)	121	(752)
Deposit and other assets .....	(206)	(964)	—
Accounts payable .....	5,731	199	479
Accrued compensation and benefits.....	3,388	2,188	(743)
Amount due to Janssen Biotech, Inc. ....	(14,269)	11,659	908
Accrued liabilities .....	7,397	6,211	391
Operating lease liabilities.....	(452)	(655)	—
Net cash used in operating activities.....	(66,652)	(43,829)	(21,009)
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment .....	(401)	(413)	(16)
Purchases of marketable securities.....	(313,201)	(153,467)	(188,365)
Proceeds from sales of securities available for sale .....	7,681	—	—
Proceeds from maturities of marketable securities .....	200,262	181,280	110,663
Proceeds from sales of equity investment .....	339	—	—
Net cash (used in) provided by investing activities .....	(105,320)	27,400	(77,718)
<b>Cash flows from financing activities:</b>			
Proceeds from issuances of common stock from equity plans.....	208	204	6,951
Proceeds from issuance of common stock and warrants in public offering, net of paid issuance costs .....	140,184	—	—
Proceeds from issuances of common stock from at market offerings, net of paid issuance costs.....	4,075	19,295	86,017
Proceeds from exercise of warrants .....	16	—	—
Proceeds from debt financing, net of paid debt issuance costs and debt discounts .....	23,863	—	—
Net cash provided by financing activities .....	168,346	19,499	92,968
Net (decrease) increase in cash, cash equivalents and restricted cash .....	(3,626)	3,070	(5,759)
Cash, cash equivalents and restricted cash at the beginning of the period.....	13,914	10,844	16,603
Cash, cash equivalents and restricted cash at the end of the period.....	<u>\$ 10,288</u>	<u>\$ 13,914</u>	<u>\$ 10,844</u>

See accompanying notes.

**GERON CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Organization**

Geron Corporation, or we or Geron, was incorporated in the State of Delaware on November 28, 1990. We are a late-stage clinical biopharmaceutical company that is focused on the development and potential commercialization of imetelstat, an innovative therapeutic for hematologic myeloid malignancies. We have global rights to imetelstat, a 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.

**Prior Period Reclassifications**

The prior period presentation of interest and other income and other expense have been updated to conform to current period presentation.

**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 and common stock issuable pursuant to the pre-funded warrant outstanding for the year ended December 31, 2020, without consideration of potential common shares. In May 2020, we entered into an underwriting agreement in connection with our public offering, or the May 2020 public offering, pursuant to which we issued 107,049,375 shares of our common stock and a pre-funded warrant to purchase 8,335,239 shares of our common stock, or the pre-funded warrant, together with accompanying warrants to purchase 57,692,307 shares of our common stock, or the stock purchase warrants. The pre-funded warrant is exercisable immediately at an exercise price of \$0.001 per share. We included the pre-funded warrant in the computation of basic net loss per share as the exercise price is negligible and may be exercised at any time until the pre-funded warrant is exercised in full. See Note 9 on Stockholders' Equity for further discussion of the May 2020 public offering.

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 potential common shares outstanding for the periods presented, 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 outstanding 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 statements of operations. Since we incurred a net loss for 2020, 2019 and 2018, the diluted net loss per share calculation excludes potential dilutive securities of 101,881,391, 38,151,906 and 27,823,845 shares, respectively, related to outstanding stock options and warrants as their effect would have been anti-dilutive.

**Use of Estimates**

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of financial statements in conformity with 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. government-sponsored enterprise securities, United States Treasury 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 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, 2020, 2019 and 2018. See Note 2 on Fair Value Measurements.

### ***Equity Investments***

With the adoption of ASU No. 2016-01, *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, or ASU 2016-01, beginning January 1, 2018, we measure the fair value of our investment in equity securities at each reporting period. 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 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 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 rate incurred 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 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

Beginning January 1, 2018, 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 and/or Collaboration 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. As of June 30, 2020, all license agreements related to our human telomerase reverse transcriptase, or hTERT, technology have been terminated or expired due to patent expirations on such technology.

As of December, 31, 2020, the remaining active license agreement is a license related to our specialized oligonucleotide backbone chemistry, as well as patent rights covering the synthesis of monomers, the building blocks of oligonucleotides. Economic terms of this agreement include non-refundable annual license maintenance payments, milestone payments upon achievement of certain research, development and regulatory milestones, and royalties on potential future product sales. This agreement was terminated effective April 2021. In connection with the divestiture of Geron's 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 Geron's former intellectual property. Under these agreements, non-refundable upfront fees and annual license maintenance fees are considered fixed consideration, while milestone payments and royalties are identified as variable consideration.

*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 our 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.

*Cost Sharing Arrangements.* Research and development and other expenses being shared by both parties under an agreement are recorded as earned or owed based on the performance obligations by both parties under the respective agreement. For arrangements in which we and our collaboration partner in the agreement are exposed to significant risks and rewards that depend on the commercial success of the activity, we recognize payments between the parties on a net basis and record such amounts as a reduction or addition to research and development expense. For arrangements in which we have agreed to perform certain research and development services for our collaboration partner and are not exposed to significant risks and rewards that depend on the commercial success of the activity, we recognize the respective cost reimbursements as revenue under the collaboration agreement over time in a manner proportionate to the costs we incurred to perform the services using the input method.

## **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 consist of expenses incurred in identifying, developing and testing product candidates resulting from our independent efforts as well as efforts associated with prior collaboration agreements. These expenses include, but are not limited to, in-process research and development acquired in an asset acquisition and deemed to have no alternative future use, payroll and personnel expense, lab supplies, non-clinical studies, clinical trials, including support for investigator-sponsored 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, our proportionate share of research and development costs under cost sharing arrangements with collaborative partners and research-related overhead. Research and development costs are expensed as incurred, including costs incurred under our collaboration and/or license agreements, if any.

Our current imetelstat clinical trials are being supported by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In that event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. For the clinical development activities previously conducted by Janssen under the former Collaboration Agreement, we monitored patient enrollment levels and related activities to the extent possible through discussions with Janssen personnel and based our estimates of clinical trial costs on the best information available at the time.

## **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 are 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 the grant-date fair values of service-based instruments on a straight-line basis over the requisite service period, which is generally the vesting period. For performance-based stock options with vesting conditioned 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 that assessment of the probability of the performance condition being met 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.

With the adoption of ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, beginning January 1, 2019, we measure share-based payments to non-employees based on the grant-date fair value of the equity awards issued. We recognize stock-based compensation expense for the grant-date fair value of the vested portion of non-employee stock-based awards on our 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 gain on our balance sheets as of December 31, 2020 and 2019 is solely comprised of net unrealized gains and losses on marketable securities.

## **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 – Recently Adopted***

In August 2018, the Financial Accounting Standards Board, or FASB, issued ASU 2018-13, *Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13, which

modifies the disclosure requirements on fair value measurements. We adopted ASU 2018-13 as of January 1, 2020. The adoption of this new guidance did not have a material impact on our financial statements.

As of January 1, 2020, we also adopted ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, or ASU 2018-18. The amended guidance precludes presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The adoption of ASU 2018-18 did not have a material impact on our financial statements given the termination of the Collaboration and License Agreement, or the Collaboration Agreement, with Janssen Biotech, Inc., or Janssen, in September 2018.

#### ***New Accounting Pronouncements – Issued But Not Yet 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 will be effective for smaller reporting companies for fiscal years beginning after December 15, 2022, using a modified retrospective approach. Early adoption is permitted. We plan to adopt ASU 2016-13 and related updates as of January 1, 2023. We do not expect the adoption of this standard to 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, 2020 were as follows:

<u>(In thousands)</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Included in cash and cash equivalents:				
Money market funds.....	\$ 4,356	\$ —	\$ —	\$ 4,356
Restricted cash:				
Money market fund .....	\$ 92	\$ —	\$ —	\$ 92
Certificate of deposit .....	271	—	—	271
	<u>\$ 363</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 363</u>
Marketable securities:				
U.S. Treasury securities (due in less than one year) .....	\$ 5,608	\$ 2	\$ —	\$ 5,610
U.S. Treasury securities (due in one to two years) .....	5,093	2	—	5,095
Government-sponsored enterprise securities (due in less than one year) .....	5,249	3	—	5,252
Government-sponsored enterprise securities (due in one to two years) .....	23,499	7	(1)	23,505
Commercial paper (due in less than one year) .....	112,388	29	(8)	112,409
Corporate notes (due in less than one year) .....	63,051	35	(7)	63,079
Corporate notes (due in one to two years) .....	34,771	33	(17)	34,787
	<u>\$ 249,659</u>	<u>\$ 111</u>	<u>\$ (33)</u>	<u>\$ 249,737</u>

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2019 were as follows:

<u>(In thousands)</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Included in cash and cash equivalents:				
Money market funds.....	\$ 6,671	\$ —	\$ —	\$ 6,671
Commercial paper .....	3,990	—	—	3,990
	<u>\$ 10,661</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,661</u>
Restricted cash:				
Certificate of deposit .....	\$ 270	\$ —	\$ —	\$ 270
Marketable securities:				
Government-sponsored enterprise securities (due in less than one year) .....	\$ 6,506	\$ 6	\$ —	\$ 6,512
Government-sponsored enterprise securities (due in one to two years) .....	6,999	1	—	7,000
Commercial paper (due in less than one year) .....	40,110	33	(3)	40,140
Corporate notes (due in less than one year) .....	78,926	116	(13)	79,029
Corporate notes (due in one to two years) .....	12,659	1	(9)	12,651
	<u>\$ 145,200</u>	<u>\$ 157</u>	<u>\$ (25)</u>	<u>\$ 145,332</u>

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, 2020 and 2019 were as follows:

(In thousands)	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
<b>As of December 31, 2020:</b>						
Government-sponsored enterprise securities (due in one to two years).....	\$ 4,999	\$ (1)	\$ —	\$ —	\$ 4,999	\$ (1)
Commercial paper (due in less than one year).....	22,956	(8)	—	—	22,956	(8)
Corporate notes (due in less than one year) .....	12,573	(7)	—	—	12,573	(7)
Corporate notes (due in one to two years)....	16,322	(17)	—	—	16,322	(17)
	<u>\$ 56,850</u>	<u>\$ (33)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 56,850</u>	<u>\$ (33)</u>
<b>As of December 31, 2019:</b>						
Commercial paper (due in less than one year).....	\$ 8,571	\$ (3)	\$ —	\$ —	\$ 8,571	\$ (3)
Corporate notes (due in less than one year) .....	26,082	(13)	—	—	26,082	(13)
Corporate notes (due in one to two years)....	11,624	(9)	—	—	11,624	(9)
	<u>\$ 46,277</u>	<u>\$ (25)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 46,277</u>	<u>\$ (25)</u>

The gross unrealized losses related to government-sponsored enterprise securities, commercial paper and corporate notes as of December 31, 2020 and 2019 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, 2020 and 2019 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 the current COVID-19 pandemic. We review our investments quarterly to identify and evaluate whether any investments have indications of possible 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 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 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 balance sheets, including the category for such financial instruments.

Money market funds are categorized as Level 1 within the fair value hierarchy as their fair values are based on quoted prices available in active markets. U.S. government-sponsored enterprise securities, U.S. Treasury securities, commercial paper, corporate notes and equity investments 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, 2020 and 2019 and indicates the fair value category assigned.

(In thousands)	Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs		
	Level 1	Level 2	Level 3		
<b>As of December 31, 2020:</b>					
Money market funds <sup>(1)</sup> .....	\$ 4,356	\$ —	\$ —	\$ 4,356	
U.S. Treasury securities <sup>(2)(3)</sup> .....	—	10,705	—	10,705	
Government-sponsored enterprise securities <sup>(2)(3)</sup> .....	—	28,757	—	28,757	
Commercial paper <sup>(2)</sup> .....	—	112,409	—	112,409	
Corporate notes <sup>(2)(3)</sup> .....	—	97,866	—	97,866	
Equity investment <sup>(4)</sup> .....	—	361	—	361	
Total.....	<u>\$ 4,356</u>	<u>\$ 250,098</u>	<u>\$ —</u>	<u>\$ 254,454</u>	
<b>As of December 31, 2019:</b>					
Money market funds <sup>(1)</sup> .....	\$ 6,671	\$ —	\$ —	\$ 6,671	
Government-sponsored enterprise securities <sup>(2)(3)</sup> .....	—	13,512	—	13,512	
Commercial paper <sup>(1)(2)</sup> .....	—	44,130	—	44,130	
Corporate notes <sup>(2)(3)</sup> .....	—	91,680	—	91,680	
Equity investment <sup>(4)</sup> .....	—	389	—	389	
Total.....	<u>\$ 6,671</u>	<u>\$ 149,711</u>	<u>\$ —</u>	<u>\$ 156,382</u>	

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

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

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

(4) Included in deposits and other assets on our balance sheets. See "Equity Investment" in this Note 2 for further discussion of this equity investment.

### 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 reassess the fair value of our equity investment in Sienna at each reporting date and any resulting change in fair value is recognized on our 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. In connection with this exchange, we recognized a gain of \$182,000 which has been included in other income and expense on our statements of operations. In the third quarter of 2020, we sold 15,322,939 shares of BARD1 and received \$339,000 in net proceeds. In connection with the sales, we also recognized \$34,000 in realized losses, which has been included in other income and expense.

Effective December 1, 2020, BARD1 completed a 1 for 30 reverse stock split. Consequently, as of December 31, 2020, we held 688,929 shares of BARD1 and the fair value of those shares was \$361,000, as reported on the Australian stock exchange and translated into U.S. dollars. For the year ended December 31, 2020, we recognized an increase in fair value of equity investment of \$60,000 related to observable price changes. For the years ended December 31, 2019 and 2018, we recognized a decrease in fair value of equity investment of \$195,000 and \$541,000, respectively, related to observable price changes. For the years ended December 31, 2020, 2019 and 2018, we also recognized a gain of \$103,000 and losses of \$1,000 and \$63,000, respectively, related to foreign currency translation from Australian dollar to U.S. dollar, which are included in other income and expense on our statements of operations.

### Credit Risk

We currently place our cash, restricted cash, cash equivalents and marketable securities with five financial 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, U.S. government-sponsored enterprise securities, U.S. Treasury 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.

### 3. PROPERTY AND EQUIPMENT

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

(In thousands)	December 31,	
	2020	2019
Furniture and computer equipment .....	\$ 1,079	\$ 1,065
Leasehold improvements .....	192	186
	1,271	1,251
Less accumulated depreciation and amortization .....	(613)	(843)
	<u>\$ 658</u>	<u>\$ 408</u>

### 4. LICENSE AGREEMENTS

#### Former Collaboration Agreement with Janssen Biotech, Inc.

On November 13, 2014, we and Janssen entered into the Collaboration Agreement under which we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all human therapeutic uses, including hematologic myeloid malignancies. Under the Collaboration Agreement, Janssen initiated two Phase 2 clinical trials of imetelstat: IMbark and IMerge. Under the terms of the Collaboration Agreement, prior to its termination, development costs for IMbark and IMerge were shared between us and Janssen on a 50/50 basis, including costs related to patents licensed to Janssen.

Janssen terminated the Collaboration Agreement effective September 28, 2018, upon which we regained the global rights to the imetelstat program and are continuing development of imetelstat on our own. As a result of the termination of the Collaboration Agreement, we will not receive any milestone payments or royalties from Janssen for the development or commercialization of imetelstat, including any clinical development or sales milestones, and Janssen has no obligations to us or any third parties, such as clinical sites or vendors, to fund any potential future imetelstat clinical trials. Under the termination provisions of the Collaboration Agreement, during transition of the

program to us, Janssen was required to provide certain operational support for the imetelstat program through September 28, 2019. Operational support from Janssen included clinical development activities, such as continuing monitoring and treatment of patients in ongoing imetelstat clinical trials. In 2019, we reimbursed Janssen 100% for the costs of such operational support.

On June 14, 2019, we entered into a Clinical Supply Agreement, or Supply Agreement, with Janssen to purchase certain inventories of drug product, drug substance and raw materials for imetelstat manufacturing. As of December 31, 2019, activities under the Supply Agreement were fully complete, resulting in an aggregate amount due to Janssen of \$14,269,000, which we paid in full in the first quarter of 2020. No amounts remain due to Janssen under the Supply Agreement as of December 31, 2020.

### **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. In January 2021, we received notice of termination of the Exclusive and Non-Exclusive License. Effective date of the termination will be in April 2021.

We remained responsible for prosecuting the patent rights under the Exclusive License, with reasonable input provided by Janssen Pharmaceuticals, and the costs for such prosecution were shared between us and Janssen Pharmaceuticals on a 50/50 basis.

## **5. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following:

<u>(In thousands)</u>	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
CRO and clinical trial costs .....	\$ 11,800	\$ 5,263
Manufacturing activities .....	1,903	1,740
Professional legal and accounting fees .....	640	318
Interest payable .....	194	—
Other.....	388	207
	<u>\$ 14,925</u>	<u>\$ 7,528</u>

## **6. COMMITMENTS AND CONTINGENCIES**

### **Purported Securities Lawsuits**

Between January 23 and March 5, 2020, three putative securities class action lawsuits were filed against us and certain of our officers. One of the lawsuits was voluntarily dismissed on March 19, 2020. The other two lawsuits, filed in the U.S. District Court for the Northern District of California, or the Northern District, were consolidated by the Court on May 14, 2020, and on August 20, 2020, the lead plaintiffs filed a consolidated class action complaint. The consolidated class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to IMbark during the period from March 19, 2018 to September 26, 2018. The consolidated complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 by failing to disclose facts related to the alleged failure of IMbark to meet the two primary endpoints of the trial, spleen response rate and Total Symptom Score, and that our stock price dropped when such information was disclosed. The plaintiffs in the consolidated putative securities class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On October 22, 2020, lead plaintiffs filed an amended consolidated class action complaint. We filed a motion to dismiss the amended consolidated class action complaint on November 23, 2020. The hearing on the motion to dismiss was held on February 8, 2021.

Between April 23 and November 12, 2020, four shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former board members. Of these actions, or the Derivative Lawsuits, one was filed in the Northern District, one was filed in the Court of Chancery of the State of Delaware, and two were filed in the District Court for the District of Delaware, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and violations of Section 14 of the Exchange Act, based on the same underlying facts as the consolidated putative securities class action lawsuit described above. The plaintiffs seek damages, corporate governance reforms, equitable relief, restitution, and an award of reasonable costs, including attorneys' fees. All four Derivative Lawsuits have been deferred until 30 days after an order on our motion to dismiss the amended class action complaint in the consolidated putative securities class action lawsuit has been made. The pending 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 the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense against the pending lawsuits and any other related lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements if we do not prevail in the defense against the pending lawsuits and any other related lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to the pending lawsuits and any other related 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 an Amended and Restated Severance Plan, or Severance Plan, that applies to all employees that are not subject to performance improvement plans, and provides 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 Plan, 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 Severance Plan, (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 Plan, a Non-Change of Control Triggering Event and Separation from Service is defined as an event where a non-executive employee is terminated by us without cause. Severance payments range from two to 18 months of base salary, depending on the employee's position with us, payable in a lump sum payment. The Severance Plan also provides that the provisions of employment agreements entered into between us and executive or non-executive employees supersede the provisions of the Severance Plan. As of December 31, 2020, all our executive officers have employment agreements with provisions that may provide greater severance benefits than those in the Severance Plan.

## **Gain on Settlement**

From November 2010 to September 2012, we owned 40% of ViaGen, Inc., or ViaGen, a company with in-house breeding services and expertise in advanced reproductive technologies for animal cloning. In September 2012, we and the other shareholders of ViaGen executed a Share Purchase Agreement, or SPA, and sold our equity interests to Trans Ova Genetics, L.C., or Trans Ova. Under the SPA, we and the other ViaGen shareholders would receive potential payments aggregating up to \$6,000,000 upon Trans Ova reaching certain commercial milestones. We and the other ViaGen shareholders were also eligible to receive potential proceeds upon the sale by Trans Ova of a non-marketable equity investment originally held by ViaGen. Payments under the SPA would be shared amongst the ViaGen shareholders according to their original equity interests in ViaGen prior to the sale to Trans Ova.

In July 2018, we and the other former shareholders of ViaGen filed an arbitration claim against Trans Ova for alleged violations under the SPA, including failure to make payments under certain conditions. In December 2018, we and the other former shareholders of ViaGen agreed to settle the dispute for a one-time payment of \$3,650,000, of which we received \$1,460,000, which represents our 40% share of the settlement amount. We recorded our settlement amount as other income on our statements of operations in 2018. With this settlement, Trans Ova was released from any further obligations under the SPA, including any future payments.

## **Risks and Uncertainties**

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. As of the date of this filing, the extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict, as the effects of the pandemic continue to evolve. Due to the dynamic and unpredictable effects of the COVID-19 pandemic, we have had and expect to continue to have disruptions and/or delays in our imetelstat development program, including with respect to our ability to initiate trial sites, enroll and assess patients, maintain patient enrollment, ensure patient clinical and lab collection visits, conduct monitoring visits, supply study drug, report trial results, and interact with regulators or other important agencies due to limitations in employee resources or otherwise. Restrictions on travel, availability of site personnel, and diversion of hospital staff and resources to COVID-19 patients, have disrupted our trial operations, as well as patient recruitment in many areas, resulting in a slowdown in patient enrollment and/or deviations from or disruptions in key clinical trial activities, such as clinical trial site initiation and monitoring. If the effects of the COVID-19 pandemic continue and persist for an extended period of time and/or become more severe, we could experience significant disruptions to our clinical development timelines, continued delays in patient enrollment in IMerge Phase 3, delays in clinical site initiation and patient enrollment in IMPactMF and other disruptions that could severely impact our business and the imetelstat development program.

In response to the COVID-19 pandemic and “shelter in place” and similar orders issued by state and local governments, we have temporarily restricted access to our offices in California and New Jersey until at least mid-2021. Our employees are conducting their work remotely, and our employees otherwise have minimal presence in our offices for essential activities. The effects of the “shelter in place” and similar orders, as well as our own policies, may negatively impact productivity, disrupt our business and continue to delay our imetelstat development program and clinical trial timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, our increased reliance on personnel working remotely could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. These and similar, and perhaps more severe, disruptions in our operations could occur which would negatively impact our business and business prospects, our financial condition and the future of imetelstat.

The effects of the COVID-19 pandemic have increased market volatility and could result in a significant long-term disruption of global financial markets, reducing or eliminating our ability to raise additional capital, which could negatively affect our liquidity, our ability to conduct and complete IMPactMF and to commence, conduct and complete any other potential future clinical trials of imetelstat. In addition, the global economic slowdown caused by the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock. The extent to which the COVID-19 pandemic impacts our business, our regulatory and clinical development activities, clinical supply chain and other business operations, as well as the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration and severity of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken

globally to contain and treat COVID-19, including broad vaccine distribution and administration. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our regulatory and clinical development activities, clinical supply chain and other business operations or the global economy as a whole. However, these effects could materially and adversely affect our business and business prospects, our financial condition and the future of imetelstat.

## **7. OPERATING LEASES**

### **Menlo Park Office Space Lease**

We had an operating lease for our office space at 149 Commonwealth Drive, Menlo Park, California, or the Menlo Park Lease, that was due to expire in January 2020. On September 10, 2019, we amended this lease agreement to extend the lease term by two months to the end of March 2020. In March 2020, in connection with the “shelter in place” orders issued by the Health Officer of the County of San Mateo and the Governor of the State of California on March 16 and March 19, 2020, respectively, which directed non-essential businesses to cease operations until the orders are rescinded, we further amended the Menlo Park Lease to extend the lease term until the 15th day after the later of: a) April 7, 2020; b) the expiration or termination of the “shelter in place” orders; or c) the modification of the “shelter in place” orders such that non-essential business operations and non-essential travel are expressly permitted. We terminated the Menlo Park Lease on May 29, 2020. The amendments to the Menlo Park Lease were treated as modifications to the existing lease agreement, and the right-of-use asset and corresponding operating lease liability were remeasured based on the present value of remaining lease payments over the remaining extended lease term as of each amendment, using the same discount rate of 5% applied as of the adoption date. For the March 2020 extensions, the additional right-of-use asset and corresponding operating lease liability was approximately \$149,000. Under the Menlo Park Lease, we were also obligated to pay certain variable expenses separately from the base rent, including taxes and common area maintenance. Such costs were considered non-lease components and were excluded from the calculation of the right-of-use asset and corresponding operating lease liability and were expensed in the period they are incurred.

### **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 103<sup>rd</sup> 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, 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, 2020, the remaining lease term for the New Jersey Lease is 9.8 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 Foster City Lease replaced our leased premises at 149 Commonwealth Drive, Menlo Park, California (see above). 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 \$3,426,000, 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, 2020, the remaining lease term for the Foster City Lease is 6.5 years.

The components of lease costs included in operating expenses for the New Jersey Lease and the Foster City Lease on our statements of operations were as follows:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Operating lease costs .....	\$ 1,143	\$ 783	\$ 678
Variable lease costs <sup>(1)</sup> .....	293	17	31
Total lease costs .....	<u>\$ 1,436</u>	<u>\$ 800</u>	<u>\$ 709</u>

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

The undiscounted future non-cancellable lease payments under the Menlo Park Lease, the New Jersey Lease and the Foster City Lease as of December 31, 2020 were as follows (in thousands):

2021 .....	\$ 913
2022 .....	937
2023 .....	962
2024 .....	988
2025 .....	1,014
Thereafter .....	2,807
Total lease payments .....	<u>7,621</u>
Less: imputed interest .....	<u>(1,944)</u>
Total .....	<u>\$ 5,677</u>

## 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 of up to \$75,000,000, or the Term Loan. The Term Loan can be drawn in three tranches as follows: (i) Tranche A loan of up to \$35,000,000 of which \$25,000,000 was funded on the Closing Date and the remaining \$10,000,000 is available to be drawn until June 15, 2021, (ii) Tranche B loan of up to \$15,000,000 which is available to be drawn from January 1, 2021 to December 15, 2021, subject to the achievement of certain clinical milestones, and (iii) Tranche C loan of up to \$25,000,000 available to be drawn through December 31, 2022, subject to approval by an investment committee comprised of Hercules and SVB. As of December 31, 2020, \$25,000,000 under Tranche A has been drawn, and there have been no other amounts drawn under the other Tranches.

The Term Loan matures on October 1, 2024, or the Loan Maturity Date, and may be extended up to an additional 12 months upon the achievement of certain clinical, 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) 9.0% plus the prime rate as reported in The Wall Street Journal (3.25% as of December 31, 2020) less 3.25%. The Tranche A Loan bears an interest rate of 9.0%. The Term Loan provides for an interest-only payment period from the Closing Date until November 1, 2022. The interest-only period may be extended up to an additional 12 months upon the achievement of certain clinical, regulatory and financial milestones. Following the expiration of the interest-only period, we will 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 Loan 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 \$5,000,000 of the outstanding loan by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest. Such prepayment is subject to a prepayment charge of 1.5% of the prepayment amount, if the prepayment is made in any of the first 36 months following the Closing Date. Thereafter, any prepayment 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, 2020. The Term Loan also contains a minimum cash covenant that requires us to hold at least \$25,000,000 in cash beginning June 1, 2022. Such minimum cash covenant

is permanently reduced to \$20,000,000 if certain regulatory milestones are achieved as set forth in the Term Loan. However, a minimum cash covenant of \$30,000,000 is required upon certain licensing transactions being executed.

In the event of default (subject, in certain instances, to specified grace periods), the principal, interest and any other monetary obligations on all the 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, 2020, the net carrying value of the Tranche A loan was \$24,042,000, which includes the principal amount of \$25,000,000 less the net unamortized discounts and debt issuance costs of \$1,063,000 plus accrued end of term charge of \$105,000. The carrying value of the debt approximates the fair value as of December 31, 2020. The debt discounts and debt issuance costs are being amortized to interest expense over the life of the Tranche A 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, 2020 (in thousands):

2021 .....	\$	2,281
2022 .....		4,184
2023 .....		13,706
2024 .....		13,098
Total .....		<u>33,269</u>
Less: amount representing interest .....		(6,632)
Less: unamortized debt discount and issuance costs .....		(1,063)
Less: unamortized end of term charge .....		(1,532)
Less: current portion of debt .....		—
Noncurrent portion of debt .....	\$	<u>24,042</u>

## **9. STOCKHOLDERS' EQUITY**

### **Public Offering**

On May 27, 2020, we completed an underwritten public offering of 107,049,375 shares of our common stock and a pre-funded warrant to purchase 8,335,239 shares of our common stock, together with accompanying stock purchase warrants to purchase 57,692,307 shares of our common stock. The shares of common stock and the pre-funded warrant were immediately separable from the stock purchase warrants. All of the securities were issued separately. The combined public offering price of the common stock and accompanying stock purchase warrants was \$1.30 per share. The stock purchase warrants have an exercise price of \$1.30 per share and are exercisable immediately. The term of the stock purchase warrants expires on the earlier to occur of (a) the date that is 30 business days following the date on which we first issue a press release disclosing, if applicable, positive top-line safety and efficacy results from IMerge Phase 3 and (b) December 31, 2025. The combined public offering price of the pre-funded warrant and accompanying stock purchase warrants was \$1.299 per share. The pre-funded warrant has an exercise price of \$0.001 per share and may be exercised at any time until the pre-funded warrant is exercised in full. The net cash proceeds from this offering were approximately \$140,184,000, after deducting the underwriting

discount and other offering expenses paid by us, and excluding any future proceeds from the exercise of the pre-funded warrant or the stock purchase warrants.

Upon the issuance of the pre-funded warrant and 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 pre-funded warrant and the 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 pre-funded warrant and the stock purchase warrants should be classified as equity with no subsequent remeasurement as long as such warrants continue to be classified as equity. In the third quarter of 2020, stock purchase warrants for 12,500 shares of our common stock were exercised, and we received proceeds of \$16,000. As of December 31, 2020, the pre-funded warrant to purchase 8,335,239 shares of our common stock was outstanding and stock purchase warrants to purchase 57,679,807 shares of our common stock were outstanding.

## **Sales Agreements**

On May 18, 2018, we entered into an At Market Issuance Sales Agreement, or the 2018 Sales Agreement, with B. Riley FBR, Inc., or B. Riley FBR, pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to \$100,000,000 in such quantities and on such minimum price terms as we set from time to time through B. Riley FBR as our sales agent. We paid B. Riley FBR 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 FBR under the 2018 Sales Agreement. From January 2020 through April 2020, we sold an aggregate of 3,496,616 shares of our common stock pursuant to the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately \$4,075,000, after deducting sales commissions and other offering expenses paid by us. The 2018 Sales Agreement has been superseded by the 2020 Sales Agreement (see below).

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 may elect to issue and sell shares of our common stock having an aggregate offering price of up to \$100,000,000 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 agreed to pay B. Riley Securities 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 Securities under the 2020 Sales Agreement. In connection with the 2020 Sales Agreement, we terminated the 2018 Sales Agreement. On September 4, 2020, we filed a registration statement on Form S-3, or the registration statement, which includes a prospectus pursuant to which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$100,000,000 under the 2020 Sales Agreement. We have not sold any shares under the 2020 Sales Agreement in 2020. See Note 12 on Subsequent Events regarding sales in the first quarter of 2021.

## **CIRM Warrant**

In connection with each disbursement under a previous loan agreement with the California Institute for Regenerative Medicine, or CIRM, we were obligated to issue to CIRM a warrant to purchase Geron common stock. Such warrants and the underlying common stock were unregistered. We have no further obligations to issue any additional warrants to CIRM. As of December 31, 2020, a warrant to purchase 537,893 shares of our common stock remained outstanding. The warrant was issued to CIRM in August 2011 at an exercise price of \$3.98 per share and expires in August 2021.

## **Equity Plans**

### **2002 Equity Incentive Plan**

The 2002 Equity Incentive Plan, or 2002 Plan, expired in May 2012. Upon the adoption of the 2011 Incentive Award Plan in May 2011 (see below), no further grants of options or stock purchase rights were made from the 2002 Plan. Options granted under the 2002 Plan expire no later than ten years from the date of grant. Option exercise prices were equal to 100% of the fair market value of the underlying common stock on the date of grant.

Service-based stock options under the 2002 Plan generally vested over a period of four years from the date of the option 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 2002 Plan remain subject to the terms of the 2002 Plan and the individual award agreements thereunder.

### ***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 options or stock purchase rights were made from the 2011 Plan. Options granted under the 2011 Plan expire no later than ten years from the date of grant. 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 the option 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 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 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 June 2020, our stockholders approved an amendment to our 2018 Equity Incentive Plan to increase the total number of shares issuable under such plan by 5,700,000 shares of our common stock.

Options granted under the 2018 Plan expire no later than ten years from the date of grant. 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 an 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 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 options generally vest over a period of four years from the date of the option grant. Performance-based 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, options may be exercised prior to vesting, subject to our right to repurchase the shares underlying such 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 option. During 2020 and 2019, we did not repurchase any shares under the 2018 Plan. As of December 31, 2020, we have no shares outstanding subject to repurchase under the 2018 Plan.

As of December 31, 2020, our Non-Employee Director Compensation Policy adopted by our board of directors in March 2014 and amended and restated in February 2020 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 an option to purchase 120,000 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 option to purchase 83,000 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 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 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 Geron common stock (subject to customary adjustments in the event of a change in capital structure) 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 January 2019, February 2020 and February 2021, our Compensation Committee approved amendments to increase the reserve of shares of our common stock under the Inducement Plan by 5,000,000, 1,300,000 and 800,000 shares, respectively. As a result, an aggregate total of 10,100,000 shares of common stock have been reserved under the Inducement Plan.

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 Geron common stock has been reserved for the Directors Market Plan. Under the Directors Market Plan, non-employee directors may purchase shares of Geron 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.

Prior to the adoption of the Directors Market Plan, we issued fully vested restricted stock awards to those non-employee directors who elected to receive common stock in lieu of cash for their services on the board and various committees. In 2020 and 2019, we issued 17,986 and 29,150 shares of common stock, respectively from the Directors Market Plan. In 2018, we issued 73,980 shares of common stock from the 2018 Plan. The weighted average grant date fair value of stock granted during the years ended December 31, 2020, 2019 and 2018 was \$1.60, \$1.50 and \$1.91 per share, respectively. The total fair value of vested stock grants during 2020, 2019 and 2018 was \$29,000, \$44,000 and \$141,000, respectively.

Aggregate option and award activity for the 2002 Plan, 2011 Plan, 2018 Plan, 2006 Directors Plan, Inducement Plan and Directors Market Plan is as follows:

	Shares Available For Grant	Number of Shares	Outstanding Options		
			Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2019.....	6,407,355	37,614,013	\$ 2.26		
Additional shares authorized .....	7,000,000	—	\$ —		
Options granted.....	(6,531,931)	6,531,931	\$ 1.37		
Awards granted.....	(17,986)	—	\$ —		
Options exercised.....	—	(21,944)	\$ 1.16		
Options cancelled/forfeited/ expired .....	400,309	(460,309)	\$ 3.48		
Balance at December 31, 2020.....	<u>7,257,747</u>	<u>43,663,691</u>	\$ 2.12	6.32	\$ 5,624
Options exercisable at December 31, 2020 .....		<u>25,721,508</u>	\$ 2.54	4.90	\$ 2,247
Options fully vested and expected to vest at December 31, 2020 ....		<u>42,621,956</u>	\$ 2.13	6.27	\$ 5,437

- (1) In February 2021, our Compensation Committee approved an amendment to increase the reserve for the Inducement Plan from 9,300,000 to 10,100,000 shares of common stock.
- (2) Includes 5,500,000 performance-based stock options granted previously that have not achieved certain strategic milestones.

The aggregate intrinsic value in the preceding table represents the total intrinsic value, based on Geron's closing stock price of \$1.59 per share as of December 31, 2020, which would have been received by the option holders had all the option holders exercised their options as of that date.

We have not granted any options with an exercise price below or greater than the fair market value of our common stock on the date of grant in 2020, 2019 or 2018. As of December 31, 2020, 2019 and 2018, there were 25,721,508, 19,915,713 and 16,464,746 exercisable options outstanding at weighted average exercise prices per share of \$2.54, \$2.86 and \$3.13, respectively.

The total pretax intrinsic value of stock options exercised during 2020, 2019 and 2018 was \$17,000, \$80,000 and \$8,812,000, respectively. Cash received from the exercise of options in 2020, 2019 and 2018 totaled approximately \$25,000, \$163,000 and \$6,929,000, 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. Under the 2014 Purchase Plan, we are authorized to sell to eligible

employees up to an aggregate of 1,000,000 shares of Geron common stock. As of December 31, 2020, an aggregate of 317,492 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. 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 Geron common stock on the employee's entry date into that offering period or (ii) the fair market value per share of Geron common stock on the purchase date. If the fair market value per share of Geron 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 statements of operations for the years ended December 31, 2020, 2019 and 2018 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 2019 and 2018, our board of directors awarded 1,000,000 and 4,500,000 performance-based stock options, respectively, to certain employees. These performance-based stock options are included in the outstanding options table above. Performance-based options vest only upon achievement of discrete strategic milestones. Stock-based compensation expense for performance-based 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. None of the performance-based stock options have vested.

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 have not recognized any stock-based compensation expense for performance-based stock options on our statements of operations for the years ended December 31, 2020, 2019 and 2018, as the achievement of the specified strategic milestones was not considered probable during that time. The following table summarizes the stock-based compensation expense related to service-based stock options, restricted stock awards and employee stock purchases for the years ended December 31, 2020, 2019 and 2018 which was allocated as follows:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Research and development.....	\$ 2,337	\$ 1,640	\$ 949
General and administrative .....	4,558	4,439	5,419
Stock-based compensation expense included in operating expenses .....	<u>\$ 6,895</u>	<u>\$ 6,079</u>	<u>\$ 6,368</u>

The fair value of stock options granted in 2020, 2019 and 2018 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Dividend yield.....	0%	0%	0%
Expected volatility range .....	0.781 to 0.793	0.792 to 0.980	0.821 to 0.990
Risk-free interest rate range .....	0.31% to 1.62%	1.50% to 2.56%	2.55% to 3.11%
Expected term range .....	5.25 yrs	5.25 - 6.44 yrs	5.25 - 6.62 yrs

The fair value of employee stock purchases in 2020, 2019 and 2018 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Dividend yield .....	0%	0%	0%
Expected volatility range.....	0.478 to 0.818	0.646 to 1.653	0.437 to 0.475
Risk-free interest rate range .....	0.16% to 1.57%	1.94% to 2.63%	1.53% to 1.76%
Expected term range.....	6 - 12 mos	6 - 12 mos	6 - 12 mos

Dividend yield is based on historical cash dividend payments and Geron has paid no cash dividends to date. The expected volatility range is based on historical volatilities of our stock, since traded options on Geron 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 options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that 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, 2020, 2019 and 2018 was \$0.88, \$0.94 and \$1.52 per share, respectively. The weighted average estimated fair value of employees' purchase rights for the years ended December 31, 2020, 2019 and 2018 was \$0.62, \$0.66 and \$0.56 per share, respectively. As of December 31, 2020, 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 \$10,690,000, which is expected to be recognized over the next 27 months on a weighted-average basis.

#### 401(k) Plan Matching Contributions

We sponsor a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code covering all full-time U.S. employees, or the Geron 401K Plan. Participating employees may contribute up to the annual Internal Revenue Service contribution limit. The Geron 401K Plan also permits us to provide discretionary matching and profit sharing contributions.

#### 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 \$56,000, \$24,000 and \$50,000 for the vested portion of the fair value of stock options held by consultants in 2020, 2019 and 2018, respectively.

## Common Stock Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2020 is as follows:

Outstanding stock options .....	43,663,691
Options and awards available for grant.....	7,257,747
Employee stock purchase plan .....	682,508
Warrants outstanding.....	<u>66,552,939</u>
Total .....	<u><u>118,156,885</u></u>

## 10. INCOME TAXES

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

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Tax at statutory rate .....	21.0 %	21.0 %	21.0 %
State income tax, net of federal benefit .....	6.9	12.2	(1.4)
Federal and state tax credits .....	5.3	4.0	3.9
Stock-based compensation.....	(0.5)	(0.8)	2.1
Net operating loss not benefitted .....	(6.9)	(5.8)	(4.3)
Other .....	(0.3)	(0.2)	(5.5)
Change in valuation allowance .....	<u>(25.5)</u>	<u>(30.4)</u>	<u>(15.8)</u>
Effective tax rate .....	<u>0.0 %</u>	<u>0.0 %</u>	<u>0.0 %</u>

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:

	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
	(In thousands)	
Net operating loss carryforwards .....	\$ 217,100	\$ 204,600
Federal and state tax credits .....	42,800	38,400
Capitalized research and development.....	6,000	5,900
Stock-based compensation.....	9,400	7,700
Operating lease liabilities.....	1,200	700
Other .....	<u>2,100</u>	<u>1,200</u>
Total deferred tax assets .....	278,600	258,500
Less: valuation allowance .....	<u>(277,200)</u>	<u>(257,900)</u>
Net deferred tax assets .....	1,400	600
Operating leases, right-of-use assets.....	<u>(1,400)</u>	<u>(600)</u>
Total deferred tax liabilities .....	<u>(1,400)</u>	<u>(600)</u>
Total net deferred tax assets.....	<u>\$ —</u>	<u>\$ —</u>

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 \$19,300,000 and \$20,800,000 for the years ended December 31, 2020 and 2019 respectively.

As of December 31, 2020, we had domestic federal net operating loss carryforwards of approximately \$898,100,000. Of this, \$744,800,000 will expire at various dates beginning in 2021 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 2021. As of December 31, 2020, we had state net operating loss carryforwards of approximately \$408,000,000 expiring at various dates beginning in 2028 through 2040, if not utilized. We also had federal tax credit carryforwards of approximately \$44,800,000 expiring at various dates beginning in 2021 through 2040, if not utilized. Our state tax credit carryforwards of approximately \$20,100,000 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.

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. We do not expect any significant benefit to our income tax provision as a result of this legislation.

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, 2020, we had approximately \$19,100,000 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, 2019.....	\$	17,700
Decrease related to prior year tax positions.....		—
Increase related to current year tax positions .....		1,400
Balance as of December 31, 2020.....	\$	<u>19,100</u>

If applicable, we would classify interest and penalties related to uncertain tax positions in income tax expense. Through December 31, 2020, 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, 2021. 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. STATEMENTS OF CASH FLOWS DATA

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
<b>Supplemental operating and investing activities:</b>			
Net unrealized (loss) gain on marketable securities.....	\$ (54)	\$ 315	\$ 24
Operating lease assets obtained in exchange for operating lease liabilities .....	3,575	2,473	—
Interest paid.....	\$ 388	\$ —	\$ —

## **12. SUBSEQUENT EVENTS**

### **2020 Sales Agreement**

In the first quarter of 2021, we sold an aggregate of 7,948,505 shares of our common stock pursuant to the 2020 Sales Agreement, resulting in net cash proceeds to us of approximately \$16,234,000 after deducting sales commissions and estimated offering expenses payable by us. See Note 9 on Stockholders' Equity for further discussion of the 2020 Sales Agreement.

### **Equity Investment**

In the first quarter of 2021, we sold all of the shares in BARD1 held by us for net proceeds of \$1,594,000. See Note 2 on Equity Investment for further discussion of BARD1.

## **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, 2020.

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, 2020 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, 2020. The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

#### **(IV) 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, 2020, 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, 2020, 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 balance sheets of the Company as of December 31, 2020 and 2019, the related statements of operations, comprehensive loss, stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated March 11, 2021 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

Redwood City, California  
March 11, 2021

#### **ITEM 9B. OTHER INFORMATION**

None.

### **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 2021, 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.

#### **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 Investor Relations section at [www.geron.com](http://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 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 “Compensation Discussion and Analysis,” “Compensation Committee Report,” “Executive Compensation Tables and Related Narrative Disclosure,” “Compensation of Directors” and “Compensation Committee Interlocks and Insider Participation” 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 ACCOUNTING 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, FINANCIAL STATEMENT SCHEDULES

### (a) (1) Financial Statements

Included in Part II, Item 8 of this Report:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm.....	97
Balance Sheets—December 31, 2020 and 2019.....	99
Statements of Operations—Years Ended December 31, 2020, 2019 and 2018.....	100
Statements of Comprehensive Loss—Years Ended December 31, 2020, 2019 and 2018.....	101
Statements of Stockholders’ Equity—Years Ended December 31, 2020, 2019 and 2018.....	102
Statements of Cash Flows—Years Ended December 31, 2020, 2019 and 2018.....	103
Notes to Financial Statements .....	104

### (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.
2.1	Asset Contribution Agreement by and among Geron Corporation, BioTime, Inc. and Asterias Biotherapeutics, Inc. (formerly known as BioTime Acquisition Corporation)	2.1	8-K	January 8, 2013	000-20859
3.1	Restated Certificate of Incorporation	3.3	8-K	May 18, 2012	000-20859
3.2	Certificate of Amendment of the Restated	3.1	8-K	May 18, 2012	000-20859

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
	Certificate of Incorporation				
3.3	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	June 7, 2019	000-20859
3.4	Amended and Restated Bylaws of Registrant	3.1	8-K	March 19, 2010	000-20859
3.5	Amendment to Amended and Restated Bylaws of Registrant	3.4	8-K	November 22, 2017	000-20859
4.1	Description of Capital Stock	4.1	10-K	March 11, 2020	000-20859
4.2	Form of Common Stock Certificate	4.1	10-K	March 15, 2013	000-20859
4.3	Form of 2011 Warrant	Attachment to 10.1	10-Q	November 3, 2011	000-20859
4.4	Form of Pre-Funded Warrant to Purchase Common Stock	4.1	8-K	May 26, 2020	000-20859
4.5	Form of Warrant to Purchase Common Stock	4.2	8-K	May 26, 2020	000-20859
10.1	Form of Indemnification Agreement	10.1	10-K	March 7, 2012	000-20859
10.2	Amended and Restated 2002 Equity Incentive Plan*	4.1	S-8	June 4, 2010	333-167349
10.3	Form of Stock Option Agreement under 2002 Equity Incentive Plan*	10.6	10-K	March 15, 2013	000-20859
10.4	Amended and Restated 2006 Directors' Stock Option Plan*	10.5	10-Q	November 7, 2013	000-20859
10.5	2011 Incentive Award Plan*	10.1	8-K	May 16, 2011	000-20859
10.6	Form of Stock Option Agreement under 2011 Incentive Award Plan*	10.11	10-K	March 15, 2013	000-20859
10.7	Form of Restricted Stock Award Agreement under 2011 Incentive Award Plan*	10.12	10-K	March 15, 2013	000-20859
10.8	Form of Non-Employee Director Stock Option Agreement under 2011 Incentive Award Plan*	10.2	10-Q	May 7, 2015	000-20859
10.9	2018 Equity Incentive Plan*	10.2	8-K	May 18, 2018	000-20859
10.10	2018 Equity Incentive Plan, as amended*	10.1	8-K	June 9, 2020	000-20859
10.11	Form of Employee Stock Option Agreement under 2018 Equity Incentive Plan*	10.3	8-K	May 18, 2018	000-20859
10.12	Form of Employee Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.11	10-K	March 7, 2019	000-20859
10.13	Form of Non-Employee Director Stock Option Agreement under 2018 Equity Incentive Plan*	10.4	8-K	May 18, 2018	000-20859
10.14	Form of Non-Employee Director Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.13	10-K	March 7, 2019	000-20859
10.15	Form of Performance-Vesting Stock Option Agreement under 2018 Equity Incentive Plan*	10.14	10-K	March 7, 2019	000-20859
10.16	Form of Performance-Vesting Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.15	10-K	March 7, 2019	000-20859
10.17	2018 Inducement Award Plan*	10.1	8-K	December 14, 2018	000-20859
10.18	2018 Inducement Award Plan, as amended January 29, 2019*	10.17	10-K	March 7, 2019	000-20859
10.19	2018 Inducement Award Plan, as amended February 11, 2020*	10.18	10-K	March 11, 2020	000-20859
10.20	2018 Inducement Award Plan, as amended February 2, 2021*				
10.21	Form of Stock Option Agreement under 2018 Inducement Award Plan*	10.2	8-K	December 14, 2018	000-20859
10.22	Form of Stock Option Agreement under 2018 Inducement Award Plan, as amended*	10.19	10-K	March 7, 2019	000-20859

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
10.23	Form of Performance-Vesting Stock Option Agreement under 2018 Inducement Award Plan*	10.20	10-K	March 7, 2019	000-20859
10.24	2014 Employee Stock Purchase Plan*	10.1	8-K	May 23, 2014	000-20859
10.25	Non-Employee Director Compensation Policy, as amended February 12, 2020*	10.24	10-K	March 11, 2020	000-20859
10.26	Directors' Market Value Stock Purchase Plan, effective October 1, 2018*	10.1	10-Q	November 1, 2018	000-20859
10.27	Amended and Restated Severance Plan, effective as of January 30, 2019*	10.28	10-K	March 7, 2019	000-20859
10.28	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
10.29	Amended and Restated Employment agreement between the Registrant and Stephen N. Rosenfield, effective as of January 31, 2019*	10.30	10-K	March 7, 2019	000-20859
10.30	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
10.31	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
10.32	Amended and Restated Employment agreement between the Registrant and Melissa A. Kelly Behrs, effective as of January 31, 2019*	10.33	10-K	March 7, 2019	000-20859
10.33	Employment Agreement between the Registrant and Aleksandra K. Rizo, effective as of January 15, 2019*	10.34	10-K	March 7, 2019	000-20859
10.34	Employment Agreement between the Registrant and Anil Kapur, effective as of December 2, 2019*	10.33	10-K	March 12, 2020	000-20859
10.35†	California Institute for Regenerative Medicine Notice of Loan Award	10.1	10-Q	November 3, 2011	000-20859
10.36	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
10.37	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
10.38	At Market Issuance Sales Agreement, dated September 4, 2020, by and between Registrant and B. Riley Securities, Inc.	10.1	8-K	September 4, 2020	000-20859
10.39†	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
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 March 11, 2021				
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 March 11, 2021				
32.1	Certification of Chief Executive Officer pursuant to				

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
	18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 11, 2021**				
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 March 11, 2021**				
101	The following materials from the Registrant's annual report on Form 10-K for the year ended December 31, 2020, formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Balance Sheets as of December 31, 2020 and 2019, (ii) Statements of Operations, Comprehensive Loss, Stockholders' Equity and Cash Flows for each of the three years in the period ended December 31, 2020, and (iii) Notes to Financial Statements				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

† Confidential treatment has been granted for certain portions of this exhibit. Omitted information has been filed separately with the Securities and Exchange Commission.

\* 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.



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

- 1) Registration Statement (Form S-3, No. 333-248637) and in the related prospectuses and prospectus supplements,
- 2) Registration Statements (Form S-3, Nos. 333-225184 and 333-238595) and in the related prospectuses and prospectus supplements,
- 3) Registration Statement (Form S-8, No. 333-239324) pertaining to the 2018 Inducement Award Plan and the 2018 Equity Incentive Plan,
- 4) Registration Statement (Form S-8, No. 333-230171) pertaining to the 2018 Inducement Award Plan,
- 5) Registration Statement (Form S-8, No. 333-228147) pertaining to the Directors' Market Value Stock Purchase Plan,
- 6) Registration Statement (Form S-8, No. 333-225190) pertaining to the 2018 Equity Incentive Plan,
- 7) Registration Statement (Form S-8, No. 333-196677) pertaining to the 2014 Employee Stock Purchase Plan,
- 8) 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,
- 9) Registration Statements (Forms S-8, No. 333-167349, No. 333-161035, No. 333-152725 and No. 333-145042) pertaining to the 2002 Equity Incentive Plan, and
- 10) Registration Statement (Form S-8, No. 333-136330) pertaining to the 2002 Equity Incentive Plan and the 2006 Directors' Stock Option Plan;

of our reports dated March 11, 2021, with respect to the financial statements of Geron Corporation 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, 2020.

/s/ Ernst & Young LLP

Redwood City, California  
March 11, 2021

**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: March 11, 2021

/s/ JOHN A. SCARLETT

JOHN A. SCARLETT, M.D.

*President, Chief Executive Officer and Chairman of the Board*

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

I, Olivia K. Bloom, 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: March 11, 2021

/s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

*Executive Vice President, Finance,*

*Chief Financial Officer and Treasurer*

**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, 2020 (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: March 11, 2021

/s/ JOHN A. SCARLETT

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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.

**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, 2020 (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: March 11, 2021

/s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

*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.

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