



2021
Annual Report

Letter to
Stockholders

Proxy

10-K

Dear Geron Stockholder,

At Geron, we remain committed to our vision of becoming a leader in the treatment of hematologic malignancies. We aim to change the course of these diseases and improve as well as extend the lives of patients. As our development efforts mature, we expect imetelstat to provide significant benefit for patients and maximize value for our stockholders by addressing the critical unmet medical needs in lower risk myelodysplastic syndromes (MDS) and refractory myelofibrosis (MF).

2021 was a significant year in the journey of Geron. We advanced both Phase 3 clinical trials toward important readouts, which if positive, could change the treatment landscapes in both lower risk MDS and refractory MF due to the disease modification potential offered by imetelstat.

In October 2021, we completed patient enrollment in IMerge Phase 3, the clinical trial of imetelstat in lower risk MDS. Since then, our clinical teams have been working diligently to ensure top-line results from this registration trial will read out in early January 2023. If the differentiated clinical profile of imetelstat seen in our IMerge Phase 2 trial is confirmed in the IMerge Phase 3 trial, we expect imetelstat to play a very meaningful role in the treatment of lower risk MDS patients because of its ability to treat broadly across both ring sideroblast positive and ring sideroblast negative subtypes, as well as provide durable transfusion independence, which current treatments available today do not offer. In our Phase 2 trial, we reported a median duration of transfusion independence of approximately 20 months, with some patients being transfusion-free for over a year. In addition, transfusion independence and hematologic improvement-erythroid responses were reported across different patient subtypes.

With imetelstat having Fast Track designation granted by the U.S. Food and Drug Administration for this indication, and assuming positive top-line results, we expect to submit a U.S. regulatory application for approval of imetelstat in lower risk MDS in the first half of 2023. If approval is obtained, we expect our commercial launch of imetelstat in the U.S. for lower risk MDS to occur in the first half of 2024.

We also made progress in our second Phase 3 trial, IMpactMF, with 50% of the sites being opened for enrollment. In 2022, we plan to open the remaining selected sites. IMpactMF is the first and only Phase 3 trial in refractory MF using overall survival as a primary endpoint. We believe positive results from this trial will deliver a much needed treatment option for these patients by providing improved overall survival for the large population of Intermediate-2/High-Risk MF patients who otherwise would have a dismal prognosis after failing JAK inhibitor therapy. Based on our current assumptions, we expect the first data analysis from

IMpactMF, called an interim analysis, may occur in 2024. At the interim analysis, if the pre-specified statistical overall survival criterion is met, then we expect such data may support the U.S. registration of imetelstat in refractory MF.

Beyond the Phase 3 trials, in 2021 we started several new programs that are designed to broaden imetelstat's potential in additional indications and combination regimens with modest initial costs. These include a study of imetelstat in combination with the leading JAK inhibitor, ruxolitinib, in frontline MF patients. The goal of this study, called IMproveMF, is to bring imetelstat's disease modification potential to MF patients earlier in their disease. Our planned investigator-led studies, named IMpress and TELOMERE, will evaluate imetelstat as a single agent and in combination with certain current standard of care therapies in acute myeloid leukemia (AML) and higher risk MDS. These studies seek to harness imetelstat's mechanism of action to inhibit the proliferation of the malignant stem and progenitor cells driving those diseases. In addition, we also have preclinical experiments ongoing at MD Anderson Cancer Center to evaluate imetelstat's potential to treat lymphoid hematologic malignancies. Last but not least, our discovery research program to identify compounds for next generation telomerase inhibitors provides an opportunity to develop a broader franchise around telomerase inhibition.

Finally, in parallel with our continuing efforts to prepare for potential launch and commercialization of imetelstat in the U.S., we are actively engaging in discussions with potential partners and exploring avenues of mutual interest. These efforts are led and supported by the newest member of our management team, Ed Koval, who joined in December as Geron's Executive Vice President and Chief Business Officer.

In summary, we look forward to 2022 being a pivotal year for the future of both imetelstat and Geron. We believe we are firmly on a path to create value for patients and stockholders alike. Thank you for your continued support.

Sincerely,



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

March 14, 2022

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 Geron Stockholder Letter 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 forward-looking statements include, without limitation, those regarding: (i) that imetelstat has potential disease-modifying activity; (ii) that for IMerge Phase 3, Geron expects top-line results for IMerge Phase 3 will be available in early January 2023, and with positive results, Geron expects to submit a U.S. application for approval in the first half of 2023 and if approval is obtained, to have a U.S. commercial launch in lower risk MDS in the first half of 2024; (iii) that for IMPactMF, Geron expects: (xx) to open the remaining selected sites in 2022 and (yy) an interim analysis to occur in 2024 that may support the U.S. registration of imetelstat in refractory MF; (iv) that Geron has started several new programs designed to broaden imetelstat’s potential in additional indications and combination regimens; and (v) 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 as well as the Russia/Ukraine conflict 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 the Russia/Ukraine conflict, as well as 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) and (iv) 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 in (ii), (iii) and (iv) above; (h) whether regulatory authorities require an additional clinical trial for approval even if IMerge Phase 3 or IMPactMF meet their respective primary endpoints; (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, the Russia/Ukraine conflict 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 IMPactMF, whether due to the current or evolving effects of the COVID-19 pandemic, the Russia/Ukraine conflict or otherwise; and (l) whether Geron is able to enroll IMPactMF at a pace that would enable an interim analysis in 2024. 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, 2021 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

EXECUTIVE MANAGEMENT

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, Business
Operations and Chief Alliance Officer

Andrew J. Grethlein, Ph.D.
Executive Vice President,
Chief Operating Officer

Anil Kapur
Executive Vice President,
Corporate Strategy and Chief
Commercial Officer

Edward E. Koval
Executive Vice President,
Chief Business 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

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

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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

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**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, 2021

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____ .
Commission File Number: 000-20859

GERON CORPORATION
(Exact name of registrant as specified in its charter)

Delaware
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 \$376,700,000 based upon the closing price of the registrant's common stock on June 30, 2021 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, 2022, there were 323,731,591 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Document	Form 10-K Parts
Portions of the Registrant's definitive proxy statement for the 2022 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2021.	III

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

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 or geopolitical events, 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. The summary below is qualified in its entirety by that more complete discussion of such risks and uncertainties. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. You should consider carefully the risks and uncertainties described under “Risk Factors” in Part I, Item 1A of this annual report on Form 10-K as part of your evaluation of an investment in our common stock.

Risks Related to the Development of Imetelstat

- 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 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, including as a result of civil unrest or military conflicts around the world, specifically the conflict in Ukraine and Russia, 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.
- Imetelstat may continue to 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.

- 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 our current Phase 3 clinical trials, IMerge Phase 3 and IMPactMF, and may delay IMProveMF, our planned Phase 1 combination clinical trial in frontline Intermediate-2 or High-risk myelofibrosis, or frontline MF, and our planned investigator-led clinical trials in acute myeloid leukemia, or AML, and Intermediate-2 or High-risk myelodysplastic syndromes, or higher risk MDS. Additionally, the COVID-19 pandemic 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 our 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 seven 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 third parties 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 legal and contractual obligations related to privacy and information security. Our actual or perceived failure, or that of third parties upon which we rely, to comply with such obligations could harm our business.
- Additionally, if our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences.
- Changes in and failures to comply with privacy and data protection obligations 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, a first-in-class telomerase inhibitor. Geron's vision is to become a leader in the treatment of blood cancers, or hematologic malignancies, and is committed to improving and extending the lives of patients by changing the course of these diseases by targeting telomerase. We believe data from our prior Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells enabling recovery of bone marrow and normal blood cell production, which indicate potential disease-modifying activity. We believe this potential disease modification may differentiate imetelstat from other currently approved and investigational treatments in myeloid hematologic malignancies.

We are conducting two ongoing Phase 3 clinical trials that are designed to enable registration of imetelstat: (i) IMerge Phase 3 in lower risk MDS, and (ii) IMpactMF in refractory MF. In the first half of 2022, we plan to start IMproveMF, a Phase 1 clinical trial of imetelstat in combination with ruxolitinib in frontline MF patients. In addition, in 2022, in collaboration with key opinion leaders with expertise in AML, we plan to support one or more investigator-led clinical trials in AML and higher risk MDS to evaluate imetelstat as a single agent and in combination with venetoclax or hypomethylating agents, or HMAs.

For IMerge Phase 3, we expect top-line results to be available in early January 2023, based on current planning assumptions. Assuming the results of IMerge Phase 3 support regulatory submissions, we plan to submit a New Drug Application, or NDA, in the U.S. in the first half of 2023, and a marketing authorization application, or MAA, in Europe in the second half of 2023, for imetelstat in lower risk MDS. Under either priority or standard review for the NDA and, upon potential approval by the FDA, we expect that commercial launch of imetelstat in lower risk MDS in the U.S. could occur as early as the first half of 2024. In Europe, we anticipate review of the MAA by the European Medicines Agency, or EMA, could take approximately 12 months and, if approved, that commercial launch of imetelstat in lower risk MDS in Europe could occur as early as the second half of 2024.

For IMpactMF, under current planning assumptions, we expect the trial to be fully enrolled in 2024. In addition, we expect the interim analysis for overall survival, or OS, for IMpactMF may 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.

Imetelstat has been granted Fast Track designations by the 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 myelofibrosis, or MF, who have relapsed after or are refractory to treatment with a janus associated kinase, or JAK, inhibitor, also known as relapsed/refractory MF. In October 2021, we gained access to the Innovative Licensing and Access Pathway, or ILAP, in the United Kingdom, or U.K., through the receipt of an Innovation Passport for imetelstat to treat lower risk MDS.

Stage-Gated Milestone-Driven Commercial Plans for Imetelstat

If imetelstat is approved for marketing by regulatory authorities, we plan to commercialize imetelstat ourselves in the U.S. and may seek commercialization partners for territories outside of the U.S. Given these plans, we have developed a potential commercial launch plan that is driven by the achievement of certain clinical milestones, such as achieving top-line results in lower risk MDS in early January 2023. In 2022, we plan to conduct preliminary commercial preparations, such as enhancing and/or establishing company processes and systems to support a potential commercial launch if imetelstat is approved in lower risk MDS, refining market research in lower risk MDS and refractory MF and hiring commercial leadership in pricing, market analytics and marketing. In addition, we plan to evaluate our strategy for potential commercialization of imetelstat in Europe.

Financial Resources

As of December 31, 2021, we had approximately \$212.7 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities. Under current planning assumptions, we believe our existing capital resources will be sufficient to fund our current level of operations until the end of the first quarter of 2023. If top-line results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, we will require additional capital to reach top-line results in IMerge Phase 3. In any event, we will require substantial additional funding to further advance the imetelstat program, including through completion of IMerge Phase 3 and IMPactMF and conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in lower risk MDS and refractory MF.

Orphan Drug Designations and Market Exclusivity

Imetelstat has been granted orphan drug designations for both the treatment of myelodysplastic syndromes, or MDS, and MF in the U.S. and in Europe. In the U.S., under the Orphan Drug Act of 1983, orphan drug designation would convey market exclusivity in the designated indication for seven years after drug product approval. Thus, if we were to receive drug product approval in the U.S. for imetelstat in lower risk MDS in the first half of 2024, we anticipate that imetelstat will have orphan drug market exclusivity in the U.S. for such indication until the first half of 2031.

In Europe, under the European Union Orphan drug regulation (EC) No. 141/2000, orphan drug designation would convey 12 years of market exclusivity, assuming we maintain orphan drug designation and fulfill the agreed upon pediatric investigation plan under the European Union Orphan drug regulation (EC) No. 141/2000. Thus, if we were to receive drug product approval in Europe for imetelstat in lower risk MDS in the second half of 2024, we anticipate that imetelstat will have orphan drug market exclusivity in Europe for such indication until the second half of 2036.

Patents and Patent Term Extensions

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

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

In Europe, our composition of matter patent coverage expires in September 2024, and our method of treatment patent rights for MDS and MF expire in November 2033 in member countries of the European Patent Convention. One of our patents in each member country of the European Patent Convention may be eligible for patent term extension under a Supplementary Protection Certificate, or SPC, permitted under European Council (EC) Regulation No. 469/2009, or the European SPC Regulation, upon receipt of drug product approval, such as, for example, our method of treatment patent for MDS.

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.

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

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

Imetelstat: The First Telomerase Inhibitor to Advance to Clinical Development

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

Imetelstat is a lipid conjugated 13-mer oligonucleotide that we designed to be complementary to and bind with high affinity to the RNA template of telomerase, thereby directly inhibiting telomerase activity. Imetelstat does not act as an antisense inhibitor of protein translation. The compound has a proprietary thio-phosphoramidate backbone, which is designed to provide resistance to the effect of cellular nucleases, thus conferring improved stability in plasma and tissues, as well as improved binding affinity to its target. To improve the ability of imetelstat to penetrate cellular membranes, we conjugated the oligonucleotide to a lipid group. Imetelstat's IC50, or half maximal inhibitory concentration, is 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 μ M observed at 41 – 45 hours after a 7.5 mg/kg dose in patients. Imetelstat also has been shown in non-clinical studies to exhibit relatively preferential inhibition of the clonal proliferation of malignant progenitor cells compared to normal progenitor cells. For these reasons, imetelstat has been studied as a potential treatment for malignant diseases.

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

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 Myelodysplastic Syndromes (MDS)

Unmet Medical Need in Lower Risk MDS for Broad and Durable Transfusion Independence

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

MDS is the most common of the myeloid malignancies. There are approximately 60,000 people in the U.S. living with the disease and approximately 16,000 reported new cases of MDS in the U.S. every year. MDS is primarily a disease of the elderly, with median age at diagnosis around 70 years. The majority of patients, approximately 70%, fall into what are considered to be the lower risk groups at diagnosis, according to the International Prognostic Scoring System that assigns relative risk of progression to AML and overall survival by taking into account the presence of a number of disease factors, such as cytopenias and cytogenetics.

Chronic anemia is the predominant clinical problem in patients who have lower risk MDS. Typically, these patients are treated with ESAs, such as erythropoietin, or EPO. Although ESAs provide an improvement in anemia in approximately 50% of patients, the effect is transient with a median duration of response of approximately two years. Once ESAs fail for patients, HMAs and lenalidomide have been used to improve anemia, but with limited success, such as reported 8-week red blood cell transfusion independence, or RBC-TI, rates of 17% for azacitidine, an HMA, and 27% for lenalidomide. In April 2020, a new drug, Reblozyl (luspatercept) was approved for use in a subgroup of lower risk MDS patients – those with ringed sideroblasts. Such patients comprise approximately 15% to 30% of all lower risk MDS patients. The majority of patients who do not have ringed sideroblasts or who no longer respond to ESAs or other available drug therapies become dependent on red blood cell transfusions due to low hemoglobin. Serial red blood cell transfusions can lead to elevated levels of iron in the blood and other tissues, which the body has no normal way to eliminate. Iron overload is a potentially dangerous condition. Published studies in patients with MDS have shown that iron overload resulting from regular red blood cell transfusions is associated with a poorer overall survival and a higher risk of developing AML. We believe that, to date, no drug therapy has been shown prospectively to alter or delay the course of the disease in any human clinical trial.

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 (7.5 mg/kg dose administered as an intravenous infusion every four weeks) 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.

IMerge Phase 3 is a double-blind, 2:1 randomized, placebo-controlled clinical trial that, based on discussions with U.S. and European regulatory authorities, is designed to 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 a 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.

The primary efficacy endpoint of IMerge Phase 3 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. IMerge Phase 3 is designed with >85% power to detect a statistically significant difference in 8-week RBC-TI rate between imetelstat and placebo (one-sided alpha=0.025) such as, for exemplary purposes only, an 8-week RBC-TI rate of 30% for the imetelstat arm and 7.5% for the placebo arm. Top-line results from IMerge Phase 3 may differ from this example.

Key secondary endpoints for IMerge Phase 3 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, which is a rise in hemoglobin of at least 1.5 g/dL above the pretreatment level for at least eight weeks or a reduction of at least four units of RBC transfusions over eight weeks compared with the prior RBC transfusion burden. Other secondary 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.

Current Status of IMerge Phase 3

In October 2021, we completed patient enrollment in IMerge Phase 3. To enable an earlier clinical cut-off date for the data to be used for the primary analysis of safety and efficacy of imetelstat, including durability of transfusion independence, we shortened the protocol-specified follow-up period after the last patient was enrolled from 15 months to 12 months. Based on current planning assumptions, we project top-line results from IMerge Phase 3 will be available in early January 2023. Our ability to conduct and complete IMerge Phase 3, including reporting top-line results, 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 until after the end of the first quarter of 2023.

Broad and Durable Transfusion Independence and Potential Disease-Modifying Activity Observed in IMerge Phase 2

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.

We reported more mature data from 38 patients in IMerge Phase 2 in June 2020. As reported previously, 42% (16/38) of patients achieved the primary endpoint of 8-week RBC-TI, and 75% (12/16) of these patients showed a hemoglobin rise of at least 3 g/dL during the transfusion free interval when compared to pretreatment level. Another important observation was the 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 approximately 20 months. We believe such durability would provide significant and meaningful clinical benefit to lower risk MDS patients, given their chronic anemia and the debilitating impact of serial RBC transfusions, and suggests potential recovery of normal blood cell production. Additionally, transfusion independence and hematologic improvement-erythroid responses, or HI-E, were reported across different patient subgroups, including by ringed sideroblast, or RS, sub-type, baseline transfusion burden and serum erythropoietin levels.

Importantly, we observed depletion of cytogenetic abnormalities and reductions in mutations associated with lower risk MDS, and these data have been correlated with transfusion independence. We believe the durability of transfusion independence, molecular data and correlations from IMerge Phase 2 provide strong evidence of disease modification potential of imetelstat treatment, which we believe differentiates imetelstat from other currently approved and investigational treatments for lower risk MDS.

The safety profile in IMerge Phase 2 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. 4/38 patients (11%) 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 8/38 patients (21%); however, only one was assessed as related to imetelstat.

IMerge Phase 2 is closed to new patient enrollment, and no patients remain in the treatment phase of the trial. Remaining patients in IMerge Phase 2 are being followed in accordance with the clinical trial protocol.

Second Indication in Phase 3 Clinical Development: Myelofibrosis (MF)

Unmet Medical Need in Refractory MF for Improvement in Overall Survival

MF, a type of myeloproliferative neoplasm, is a chronic blood cancer in which abnormal or malignant precursor cells in the bone marrow proliferate rapidly, causing scar tissue, or fibrosis, to form. As a result, normal blood production in the bone marrow is impaired and may shift to other organs, such as the spleen and liver, which can cause them to enlarge substantially. People with MF may have abnormally low or high numbers of circulating RBCs, white blood cells or platelets, and abnormally high numbers of immature cells in the blood or bone marrow. MF patients can also suffer from debilitating constitutional symptoms, such as drenching night sweats, fatigue,

severe itching, or pruritus, abdominal pain, fever and bone pain. There are approximately 13,000 patients living with MF in the U.S. and approximately 3,000 reported new cases each year. 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. Drug therapies currently approved by the FDA and other regulatory authorities for treating these MF patients include JAK inhibitors, ruxolitinib and fedratinib, as well as pacritinib, a kinase inhibitor. Currently, no drug therapy is approved for those patients who fail or no longer respond to JAK inhibitor treatment, and median survival for MF patients after discontinuation from ruxolitinib is only approximately 14 – 16 months, representing a significant unmet medical need.

IMpactMF: Ongoing Phase 3 Clinical Trial in Refractory MF

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

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

IMpactMF is designed with >85% power to detect a 40% reduction in the risk of death (hazard ratio=0.60; one-sided alpha=0.025), such as, for exemplary purposes only, 23 months for the imetelstat arm and 14 months for the BAT arm. Results from interim or final analyses from IMpactMF may differ from this example. 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, in which the alpha spend is expected to be approximately 0.01, is planned to be conducted after approximately 70% of the total projected number of events 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

IMpactMF opened for patient screening and enrollment in December 2020. As of December 31, 2021, we had 96 sites open for patient enrollment. The first patient was dosed in April 2021. Given the uncertain and unpredictable impact of the COVID-19 pandemic on our clinical trial activities, including the constraints on clinical site personnel resources due to other competing trials in MF at the sites where IMpactMF is planned to be conducted, under current planning assumptions, we expect IMpactMF to be fully enrolled in 2024. In addition, we expect the interim analysis for IMpactMF may 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 or geopolitical events. In addition, our ability to enroll, conduct and complete IMpactMF depends on whether we can obtain and maintain the relevant clearances from regulatory authorities and other institutions to enroll, conduct and complete the trial, and our ability to raise additional capital in order to complete the trial.

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

The IMbark Phase 2 clinical trial was designed to evaluate two dosing regimens of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered by intravenous infusion every three weeks) in patients with 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.

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 14 – 16 months in medical literature. To evaluate this benefit, we conducted an analysis of OS for patients treated with imetelstat 9.4 mg/kg in IMbark compared to OS calculated from real world data, or RWD, collected at the Moffitt Cancer Center for patients who had discontinued treatment with ruxolitinib, a JAK inhibitor, and who were subsequently treated with BAT. To make a comparison between the IMbark data and RWD, a cohort from the real-world dataset was identified that closely matched the IMbark patients, using guidelines for inclusion and exclusion criteria as defined in the IMbark clinical protocol, such as platelet count and spleen size. Calculations from two propensity score analysis approaches resulted in a median OS of 30.7 months for the imetelstat-treated patients from IMbark, which is more than double the median OS of 12.0 months using RWD for patients treated with BAT. These analyses also indicated a 65% – 67% lower risk of death for the imetelstat-treated patients vs. BAT-treated patients. We believe these analyses suggest potentially favorable OS for imetelstat-treated relapsed/refractory MF patients in IMbark, compared to BAT in closely-matched patients from RWD.

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

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

Planned Exploratory Clinical Trials in Additional Indications

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

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

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

We plan to conduct IMproveMF at three clinical sites in the U.S. with the first clinical site expected to open for enrollment in the first half of 2022.

Investigator-Led Clinical Trials in Acute Myeloid Leukemia (AML) and Higher Risk Myelodysplastic Syndromes (Higher Risk MDS)

We are planning to explore the potential utility of imetelstat in AML and higher risk MDS. At previous medical conferences, we have reported non-clinical data in AML cell lines, mouse models and AML patient samples. Based on these non-clinical data, we believe imetelstat has the potential to be used as a single agent and in combination with other drugs commonly used to treat AML and higher risk MDS.

To enable our internal resources to remain focused on our ongoing Phase 3 clinical trials, we plan to collaborate with key opinion leaders in the fields of AML and higher risk MDS to conduct potential investigator-led clinical trials in AML and higher risk MDS, either using imetelstat as a single agent or in combination with other drugs that are the standards of care. We expect these planned investigator-led clinical trials to begin in 2022.

Research Programs

Preclinical Lymphoid Hematologic Malignancy Program

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

Based on this scientific hypothesis, we have initiated a preclinical research project with MD Anderson Cancer Center to determine the potential application of imetelstat in lymphoid hematologic malignancies. We expect preliminary results from this research in 2022.

Next Generation Telomerase Inhibitor Discovery Program

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

Impact of COVID-19 on Our Business

As of the date of this filing, uncertainty continues to exist concerning the ultimate duration and severity of the COVID-19 pandemic. At the end of 2021 and early in 2022, COVID-19 cases were increasing due to the spread of COVID-19 variants, including the Delta and Omicron variants, leading to the re-implementation of mask restrictions, social distancing and other restrictions in many regions. In addition, the variable process of vaccine distribution, including booster shots, in some countries and the concern over further waves of infections are causing continued unpredictability and uncertainty about the pace at which clinical trial operations may normalize, especially given the diversion of healthcare resources to care for COVID-19 patients.

Even though we have completed patient enrollment in IMerge Phase 3, the pace of enrollment was slower than planned. For IMPactMF, in addition to the negative impact of COVID-19, site personnel resources remain constrained in the countries where we planned to conduct the trial due to the number of competing trials in MF and other oncology indications. To address these challenges, we have expanded the number of countries and sites where we plan to conduct IMPactMF. We continue to monitor each clinical site through our contract research organizations, or CROs, as well as conduct direct outreach to investigators and study staff. In addition, we plan to implement the same enrollment-boosting activities for IMPactMF that we employed for IMerge Phase 3, including engaging clinical science liaisons. Given the challenges caused by the COVID-19 pandemic, under current planning assumptions, we expect the interim analysis for IMPactMF may occur in 2024 and the final analysis in 2025.

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 visits to clinical sites and laboratories, 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 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 IMPactMF and potentially in IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, and other disruptions that could severely impact our business and the imetelstat development program.

We have taken and intend to take those actions with regard to COVID-19 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. We have allowed limited voluntary access to our offices in California and New Jersey to employees and consultants who have been vaccinated, and almost all of our employees continue to work remotely without any significant disruption to our business. We plan to continue to evaluate our business operations based on new information as it becomes available regarding the pandemic and will make changes that we consider necessary in light of any new developments.

All plans and timing expectations will be delayed or interrupted if COVID-19 pandemic conditions worsen, creating further limitations on our clinical trial and other development activities. The information provided in this section should be reviewed in the context of the section entitled “Risks Related to COVID-19” described in “Risk Factors” in Part I, Item 1A of this annual report on Form 10-K.

Intellectual Property and Exclusivity

Intellectual property, including patent protection, is very important to our business. We file patent applications in the U.S. and other jurisdictions, and we also rely on trade secret protection and contractual arrangements to protect aspects of our business. An enforceable patent with appropriate claim coverage can provide an advantage over competitors who may seek to employ similar approaches to develop therapeutics, and so the future commercial success of imetelstat, and therefore our future success, will be in part dependent on our intellectual property strategy. 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 methods of treatment and administration. The result of this process is that products in development are often protected by several families of patent filings that are filed at different times during the development process and cover different aspects of the product. Consequently, earlier filed, broad technology patents will usually expire ahead of patents covering later developments, such as product formulations and methods of treatment and administration, so that patent expirations on a product may span several years. Patent coverage may also vary from country to country based on the scope of available patent protection. There are also opportunities to obtain an extension of patent coverage for a product in certain countries, which adds further complexity to the determination of patent life.

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

Imetelstat

We have global rights to imetelstat. We own issued patents related to imetelstat in the U.S., Europe and other countries. Composition of matter patents generally provide the most material coverage, and therefore may convey competitive advantages. Because imetelstat is still under development, subsequent innovation and associated patent filings may provide additional patent coverage with later expiration dates. Examination of overseas patent applications typically lags behind U.S. examination, particularly where cases are filed first in the U.S. It may be possible to obtain patent term extensions of some patents in some countries for claims covering imetelstat, which could further extend the patent term.

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

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

In Europe, our composition of matter patent coverage expires in September 2024, and our method of treatment patent rights for MDS and MF expire in November 2033 in member countries of the European Patent Convention. One of our patents in each member country of the European Patent Convention may be eligible for patent term extension under the European SPC Regulation, upon receipt of drug product approval, such as, for example, our method of treatment patent for MDS. Our patent rights relating to imetelstat also include reagents useful in manufacturing processes for the drug, and method of treatment and kit claims, certain of which are co-owned with other entities.

If regulatory approval of imetelstat occurs after a patent has expired, we may be unable to obtain any patent term extension of that expired patent, and the scope of our patent rights will be limited. In addition, should we seek 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 U.S., the scope of protection for claims under such patent term extensions, if any, does not extend to the full scope of the claims but is limited to the product composition as approved. Thus, if we were to receive drug product approval in the U.S. for imetelstat in lower risk MDS in the first half of 2024, we may potentially extend the term of our product composition claims in the U.S. for a maximum of five years until December 2030, subject to U.S. Patent and Trademark Office, or USPTO, approval. If we do not receive a patent term extension for our U.S. composition of matter patent for imetelstat, our U.S. composition of matter patent will expire in December 2025. If we do not receive marketing approval and submit a request for an SPC before our composition of matter patents expire in countries of the European Economic Area, or EEA, our imetelstat composition of matter patents will expire in September 2024. If we receive drug product approval in Europe for imetelstat in lower risk MDS in the second half of 2024, we may potentially extend the term of our patents in the EEA for the method of treatment of MDS for a maximum of five years, from November 2033 until November 2038, subject to European Patent Office approval. If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

Upon the effective date of termination of the license and collaboration agreement, or the 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 of maintaining, prosecuting and litigating all imetelstat intellectual property that we own.

Market Exclusivity and Orphan Drug Designation

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

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

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

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

In Europe, orphan drug designation by the European Commission provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union, or EU, and where no satisfactory treatment is available. In the EU, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers, as well as protocol assistance from the EMA during the product development phase, and direct access to the centralized authorization procedure. In addition, ten years of market exclusivity is granted following drug product approval, meaning that another application for marketing authorization of a later similar medicinal product for the same therapeutic indication will generally not be approved in the EU. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable to not justify maintenance of market exclusivity.

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

In Europe, under the European Union Data Exclusivity Directive 2004/27/EC, upon drug product approval a new medicinal product is entitled to eight years of data exclusivity and two years of market exclusivity, conferring a total of ten years of exclusivity for the first-approved indication. Thus, if we receive drug product approval in Europe for imetelstat in lower risk MDS in the second half of 2024, we anticipate receiving a total of ten years of exclusivity for lower risk MDS, until the second half of 2034. Separately, orphan drug designation under the European Union Orphan drug regulation (EC) No. 141/2000 confers market exclusivity for ten years following drug product approval for each of the orphan disease indications. Thus, if we receive drug product approval in Europe for

imetelstat in lower risk MDS in the second half of 2024 and we maintain orphan drug designation, we anticipate that we may receive market exclusivity in Europe for imetelstat in lower risk MDS until the second half of 2034. In addition, if we fulfill the pediatric investigation plan agreed upon with the European Medicines Agency, such market exclusivity may be extended for an additional two years under the European Pediatric Regulation, which may enable us to receive market exclusivity in Europe for imetelstat in lower risk MDS for an additional two years, until the second half of 2036. Further, if we receive drug product approval in Europe for imetelstat for refractory MF, and we maintain orphan drug designation, we anticipate that we may receive ten years exclusivity in Europe for refractory MF following drug product approval, if any.

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.

Licensing

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 was effective as of April 12, 2021. Upon the effective date of termination, all patent rights originally conveyed under the license reverted 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 September 2018, we have engaged third-party contract manufacturers and have re-established our own manufacturing supply chain to manufacture and supply additional quantities of imetelstat that meet applicable regulatory standards for current and potential future clinical trials and potential commercial uses.

We do not have direct control over third-party personnel or operations. These third-party contract manufacturers, and/or any other third parties that we may rely upon for the manufacture and/or supply of imetelstat, typically complete their services on a proposal by proposal basis under master supply agreements and may need to make substantial investments to enable sufficient capacity increases and cost reductions, and to implement those regulatory and compliance standards necessary for successful Phase 3 clinical trials and commercial production. These third-party contract manufacturers, and/or any other third parties that we may rely upon for the manufacture and/or supply of imetelstat, may not be able to achieve such capacity increases, cost reductions, or regulatory and compliance standards, and even if they do, such achievements may not be at a commercially reasonable cost. We are responsible for establishing any long-term commitments or commercial supply agreements with any of the third-party contract manufacturers for imetelstat. The information provided in this section should be reviewed in the context of the section entitled “Risks Related to Manufacturing Imetelstat” under Part I, Item 1A, “Risk Factors” of this annual report on Form 10-K.

Competition

The pharmaceutical and biotechnology industries are characterized by intense and dynamic competition with rapidly advancing technologies and a strong emphasis on proprietary products. While we believe our proprietary oligonucleotide chemistry; experience with the biological mechanisms related to imetelstat, telomeres and telomerase; clinical data to date indicating potential disease-modifying activity with imetelstat treatment; and knowledge and expertise around the development of potential treatments for myeloid hematologic malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions 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 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., or Astex; and Reblozyl (luspatercept), a TGF-beta inhibitor, by Acceleron Pharma, Inc., or Acceleron (acquired by Merck & Co., Inc., or Merck, in November 2021), in collaboration with Celgene.

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.

In addition, there are multiple Phase 1 and Phase 2 clinical trials of other agents being developed for lower risk MDS, including but not limited to: LB-100, a PP2A inhibitor, by Lixte Biotechnology Holdings, Inc.; bemcentinib, an AXL inhibitor, by BerGenBio ASA; H3B-8800, a spliceosome inhibitor, by H3 Biomedicine, Inc.; KER-050, a TGF-beta inhibitor, by Keros Therapeutics, Inc., or Keros Therapeutics; TP-0184, an inhibitor of ALK2 or ACVR1 kinase, by Sumitomo Dainippon Pharma Oncology, Inc; ilginatinib (NS-018), a JAK2 inhibitor, by NS Pharma, Inc., a U.S. subsidiary of Nippon Shinyaku Co., Ltd., or NS Pharma; RVT-2001, a SF3B1 modulator, by Roivant Sciences Ltd.; sabatolimab (MBG453), a TIM-3 inhibitor, by Novartis AG; a lower dose of ASTX727, an oral formulation of decitabine and cedazuridine, referred to as ASTX727 LD, by Astex; ASTX030, an oral formulation of azacitidine and cedazuridine, by Astex; and a combination treatment regimen of luspatercept and lenalidomide by Bristol Myers Squibb Corporation.

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, as well as a kinase inhibitor, Vonjo (pacritinib), by CTI Biopharma, which was recently approved for the treatment of adults with intermediate or high-risk primary or secondary myelofibrosis with a platelet count below $50 \times 10^9/L$. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include ESAs, androgens, danazol, corticosteroids, thalidomide and lenalidomide.

Other therapies currently in Phase 3 development in MF, some of which may obtain regulatory approval earlier than imetelstat include momelotinib, a JAK inhibitor, by Sierra Oncology, Inc., or Sierra Oncology; or momelotinib plus AZD5153, a BET inhibitor in-licensed by Sierra Oncology from AstraZeneca in August 2021; pelabresib (CPI-0610), a BET inhibitor, by Constellation Pharmaceuticals, Inc. (acquired by MorphoSys AG in June 2021); 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 (acquired by Merck in November 2021), in collaboration with Celgene; PRM-151, an anti-fibrosis antibody, by Promedior, Inc. (acquired by Roche in February 2020); LCL-161, an inhibitor of apoptosis protein (IAP), by Novartis; KRT-232, an inhibitor of MDM2, by Kartos Therapeutics, Inc.; GB2064, a LOXL2 inhibitor, by Galecto Biotech; elraglusib (9-ING-41), a glycogen synthase kinase-3 beta inhibitor, by Actuate Therapeutics, Inc.; XPOVIO (selinexor), a nuclear export inhibitor, by Karyopharm Therapeutics, Inc.; TL-895, a tyrosine kinase inhibitor, by Telios Pharma, Inc.; IMG-7289, a LSD1 inhibitor, by Imago Biosciences, Inc.; APG-1252, a dual BCL-2/BCL-XL inhibitor, by Ascentage Pharma;

ilginatnib (NS-018), a JAK2 inhibitor by NS Pharma; and KER-050, an engineered ligand trap comprised of a modified ligand-binding domain of the TGF-beta receptor in combination with ruxolitinib, by Keros Therapeutics.

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

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

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

Government Regulation

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the development, manufacture and potential future marketing of imetelstat. Imetelstat will require regulatory approval by 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. The FDA can place an IND on clinical hold at any time, which prevents the conduct of clinical trials under the IND until safety concerns or questions are addressed by the IND sponsor to the FDA’s satisfaction.

Typically, clinical evaluation involves a time consuming and costly three phase trial process. In Phase 1, clinical trials are conducted with a small number of healthy volunteers or patients afflicted with a specific disease to assess safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. The Phase 2 trials can be conducted comparing the investigational treatment to a comparator arm, or not. If used, a comparator usually includes standard of care therapy. Safety and efficacy data from Phase 2 clinical trials, even if favorable, may not provide sufficient rationale for proceeding to a Phase 3 clinical trial. In Phase 3, large scale, multi-center, comparative trials are conducted with patients afflicted with a target disease to provide sufficient data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend, or terminate the trials. Human clinical trials must be conducted in compliance with Good Clinical Practice, or GCP, regulations and applicable laws, with the oversight of Institutional Review Boards for the protection of human subjects. The manufacture of drug product candidates is subject to requirements that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Practices, or cGMP, and applicable laws.

The results of the preclinical and clinical testing of drugs and complete manufacturing information are submitted to the FDA in the form of an NDA for review and approval prior to commencement of commercial sales. Submission of an NDA requires the payment of a substantial user fee to the FDA, which may be waived in certain cases. In responding to an NDA submission, the FDA may approve the drug for commercialization, impose limitations on its indications for use and labeling, including in the form of Risk Evaluation and Mitigation Strategies or may issue a complete response letter. Even if an NDA is approved, its sponsor is subject to ongoing and pervasive regulatory compliance requirements.

European and Other Regulatory Approval Process

Prior to initiating clinical trials in a region outside of the U.S., a clinical trial application must be submitted and reviewed by the appropriate regulatory authority 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 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.

In October 2021, we gained access to the ILAP through the receipt of an Innovation Passport for imetelstat to treat lower risk MDS. The ILAP is a new program sponsored by the Medicines and Healthcare products Regulatory Agency, or MHRA, in the U.K. post-Brexit. The objective of this new licensing and access pathway is to reduce the time to market and enable earlier patient access for innovative medicines. The Innovation Passport is the first prescribed entry point in the ILAP process. Key benefits of being within ILAP include a 150-day accelerated assessment and rolling review of an MAA, as well as opportunities for frequent interactions with the review staff at the MHRA and its partner agencies to discuss imetelstat's development, regulatory and reimbursement plans.

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

We may also be subject to additional regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These additional regulations could affect our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors. Such laws include, without limitation, state and federal 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), other healthcare professionals (such as physicians assistants and nurse practitioners), 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.

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 European Union’s General Data Protection Regulation, or EU GDPR, 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 privacy and data security laws and regulations will involve substantial costs. For example, foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR imposes heightened and codified standards for data subject consent, requiring the implementation and maintenance of technical and organizational safeguards for personal data, mandating data breach notifications to relevant supervisory authority(ies), and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. Foreign privacy laws, such as the EU GDPR, also impose strict rules on the transfer of personal data out of the applicable jurisdiction. Further, the EU GDPR provides for significant penalties (such as restrictions or prohibitions on personal data processing) and large fines for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, we expect that there will continue to be new proposed privacy laws, regulations and industry standards in the U.S. As one example, the California Consumer Privacy Act of 2018, or CCPA imposes numerous obligations on covered business. Although the CCPA exempts certain data 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. See the section titled *“We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations and actions; litigation; fines and penalties; disruptions to our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts,”* under “Risk Factors” in Part I, Item 1A of this annual report on Form 10 K for additional information about the laws and regulators to which we may become subject and about the risks to our business associated with such laws and regulations.

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 U.S. and markets in other countries, sales of imetelstat, if approved for commercial sale, will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for imetelstat.

In the U.S., third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, 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 and guidance in September 2020 providing pathways 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 January 1, 2023. 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform 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 U.S. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in imetelstat.

The U.S. and some foreign jurisdictions are considering or have enacted legislative and regulatory proposals to contain healthcare costs, as well as to improve quality and expand access. For example, in March 2010, the ACA was signed into law, which included a number of provisions of importance to the biopharmaceutical industry. There 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 June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President

Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges 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 2031 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation suspended these reductions from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. More recently, there has been heightened governmental scrutiny in the U.S. to control the rising cost of healthcare.

Information About Our Officers

The following table sets forth certain information with respect to our executive officers and other members of management as of January 31, 2022:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<u>Executive Officers</u>		
John A. Scarlett, M.D.....	70	President, Chief Executive Officer and Chairman of the Board
Olivia K. Bloom.....	53	Executive Vice President, Finance, Chief Financial Officer and Treasurer
Anil Kapur.....	52	Executive Vice President, Corporate Strategy and Chief Commercial Officer
Andrew J. Grethlein, Ph.D.	57	Executive Vice President, Chief Operating Officer
Aleksandra Rizo, M.D., Ph.D.	47	Executive Vice President, Chief Medical Officer
Stephen N. Rosenfield, J.D.	72	Executive Vice President, Chief Legal Officer and Corporate Secretary
<u>Other Members of Management</u>		
Melissa A. Kelly Behrs	58	Executive Vice President, Business Operations and Chief Alliance Officer
Edward E. Koval	59	Executive Vice President, Chief Business Officer

John A. Scarlett, M.D., has served as our Chief Executive Officer and a director since September 2011 and President since January 2012 and was appointed to Chairman of the Board in December 2018. Dr. Scarlett has served as a member of the board of directors for CytomX Therapeutics, Inc., a biopharmaceutical company focused on developing antibody therapeutics for the treatment of cancer, since June 2016. He also served as a member of the board of directors for Chiasma, Inc., a biopharmaceutical company focused on transforming injectable drugs into oral medications, since February 2015 until its acquisition by Amyrt Pharma plc, a biopharmaceutical company, in August 2021. Prior to joining Geron, Dr. Scarlett served as President, Chief Executive Officer and a member of the board of directors of Proteolix, Inc., a privately held, oncology-oriented biopharmaceutical company, from February 2009 until its acquisition by Onyx Pharmaceuticals, Inc., an oncology-oriented biopharmaceutical company, in November 2009. From February 2002 until its acquisition by Ipsen, S.A. in October 2008, Dr. Scarlett served as the Chief Executive Officer and a member of the board of directors of Tercica, Inc., an endocrinology-oriented biopharmaceutical company, and also as its President from February 2002 through February 2007. From March 1993 to May 2001, Dr. Scarlett served as President and Chief Executive Officer of Sensus Drug Development

Corporation. In 1995, he co-founded Covance Biotechnology Services, Inc., a contract biopharmaceutical manufacturing operation, and served as a member of its board of directors from inception to 2000. From 1991 to 1993, Dr. Scarlett headed the North American Clinical Development Center and served as Senior Vice President of Medical and Scientific Affairs at Novo Nordisk Pharmaceuticals, Inc., a wholly owned subsidiary of Novo Nordisk A/S. Dr. Scarlett received his B.A. degree in chemistry from Earlham College and his M.D. from the University of Chicago, Pritzker School of Medicine.

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.

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.

Melissa A. Kelly Behrs has served our Executive Vice President, Business Operations and Chief Alliance Officer since December 2021. Previously, she was our Executive Vice President, Chief Business Officer from January 2019 to December 2021, Executive Vice President, Business Development and Portfolio & Alliance Management, from February 2014 to January 2019, and our Senior Vice President, Portfolio and Alliance Management from September 2012 to February 2014. Ms. Behrs joined Geron in November 1998 as Director of Corporate Development. Since then, she has also served in various managerial positions, including General Manager, R&D Technologies; Vice President, Corporate Development; Senior Vice President, Therapeutic Development, Oncology; and Senior Vice President, Strategic Portfolio Management. From 1990 to 1998, Ms. Behrs worked at Genetics Institute, Inc., a biotechnology research and development company, serving initially as Assistant Treasurer and then as Associate Director of Preclinical Operations where she was responsible for all business development, regulatory, and project management activities for the Preclinical Development function. Ms. Behrs received a B.S. from Boston College and an M.B.A. from Babson College.

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

Employees

As of December 31, 2021, we had 69 full-time employees and three part-time employees. Ten of our employees hold Ph.D. degrees and 28 hold other advanced degrees. Of this current total workforce, 40 employees were engaged in, or directly supported, our research and development activities, and 32 employees were engaged in commercial, medical affairs, business development, legal, finance, human resources, information technology 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.

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 currently have approximately 80 active consulting agreements.

Corporate Information

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

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 completion of IMerge Phase 3 and IMPactMF and to complete the clinical, regulatory and potential commercialization activities necessary to potentially 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, such as IMproveMF, and one or more investigator-led clinical trials that we plan to support in AML and higher risk MDS;
- 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;
- report top-line results from IMerge Phase 3 in early January 2023;
- achieve adequate efficacy in IMerge Phase 3 to obtain regulatory approval, (i) in light of our decision to shorten the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable an earlier clinical cut-off date for the primary analysis, which may result in the exclusion of

clinical responses that could occur after the earlier clinical cut-off date for the primary analysis, (ii) inability to conduct the primary analysis for IMerge Phase 3, including due to further difficulties in retaining patients in the treatment or follow-up phases of the trial or (iii) for any other reasons;

- 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 agreements 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 U.S. and globally; and
- recruit and retain sufficient qualified and experienced personnel 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, civil unrest or military conflicts around the world, 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. Potential future clinical trials of imetelstat include IMproveMF, the exploratory Phase 1 trial of imetelstat in frontline MF that we plan to conduct, and one or more potential investigator-led clinical trials in AML and higher risk MDS that we plan to support. 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 current and potential future clinical trials, our operations and our business all of which depend on the continued worldwide progress toward managing this health crisis. Although vaccine distribution, including booster shots, is progressing in many countries, the emergence of COVID-19 variants, including the Delta and Omicron variants, and the resurgence of COVID-19 cases in certain regions of the world 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. Even though we have completed patient enrollment in IMerge Phase 3, the pace of enrollment was slower than planned due to the COVID-19 pandemic. For IMpactMF, site personnel resources remain constrained in the countries where we plan to conduct the trial, due to the negative impact of COVID-19 and number of competing trials in MF and other oncology indications. Under current planning assumptions for IMpactMF, we expect that the interim analysis may occur in 2024 and the final analysis in 2025. However, because the analyses for IMpactMF are event-driven, the results may be available at different times than currently expected. In addition, the conduct and completion of IMerge Phase 3 and IMpactMF, and commencement and conduct of any potential future clinical trials of imetelstat, including IMproveMF, and the investigator-led clinical trials in AML and higher risk MDS that we plan to support, could be interrupted, delayed or abandoned for a variety of reasons, including as a result of failures or delays related to:

- successfully retaining patients in, and conducting and completing, IMerge Phase 3, including completing the primary analysis for 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;
- patient recruitment, enrollment, or retention, clinical site initiation, or retention problems associated with civil unrest or military conflicts around the world, specifically the conflict in Ukraine and Russia, which could affect clinical sites participating in IMerge Phase 3 and IMPactMF, or other sites if the conflict spreads or has effects on countries outside of Ukraine and Russia;
- obtaining and/or maintaining regulatory clearances in the U.S. 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, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS;
- 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, and ensuring that such contracts contain all necessary terms and conditions required by applicable laws, including providing for valid mechanisms to engage in cross-border data transfers, as well as identifying, recruiting and training suitable clinical investigators, especially given the constraints caused by the COVID-19 pandemic and other competing clinical trials in MF and other oncology indications;
- obtaining or accessing necessary clinical data in accordance with appropriate clinical or quality practices and regulatory requirements, in a timely and accurate manner to ensure complete data sets;
- responding to safety findings, recommendations or conclusions by the internal data safety review committees, independent data monitoring committees and/or hepatic expert committees of current and 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, or reduced platelet count, 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 practices, 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 BAT, 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 U.S. 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, 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 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:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- 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;
- safety issues or adverse side effects;
- failure to demonstrate a benefit from using a drug; or
- 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, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 retaining patients in IMerge Phase 3 and enrolling or retaining patients in 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

retaining patients in IMerge Phase 3 and screening, enrolling and retaining patients in IMPactMF, whether as a result of the effects of the COVID-19 pandemic, geopolitical events, or for any other reasons, may further delay our conduct of such trials, or cause them to be discontinued. For example, we have clinical trial sites in the Ukraine and Russia, and nearby European countries, and if political or civil conditions require it, our clinical trial sites may need to delay or suspend clinical trial activities. In addition, enrollment and retention of patients in IMerge Phase 3 or IMPactMF could be disrupted by geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia).

If we experience further difficulties in retaining patients in the treatment or follow-up phase of IMerge Phase 2 and IMerge Phase 3, whether as a result of the effects of the COVID-19 pandemic, geopolitical events, or for any other reasons, our ability to continue to assess longer-term durability of RBC-TI responses would be adversely affected. The retention of patients in IMerge Phase 3 and the enrollment and retention of patients in 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;
- 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 new drugs that have been approved 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;
- 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, IMPactMF has competed and will continue to compete with, and potential future clinical trials of imetelstat such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS 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 IMPactMF or IMproveMF and planned ISTs in AML and higher risk MDS, 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 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 continue to 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 continue to 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, IMpactMF or IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS. In this regard, adverse events and dose-limiting toxicities observed in previous and ongoing clinical trials of imetelstat include:

- hematologic toxicities, such as profound and/or prolonged thrombocytopenia or neutropenia, 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 and liver function test abnormalities, as well as 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 3, IMpactMF or any potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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. In any event, 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.

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 3 and IMpactMF continue to receive imetelstat treatment, additional or more severe toxicities or safety issues, including additional non-serious or 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.

The occurrence of any of the aforementioned events could interrupt, further delay, or halt, any development and potential commercialization of imetelstat by us, as well as increase costs to develop imetelstat, 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.

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 of clinical trials with smaller sample sizes less reliable than trials with a larger number of patients. As a result, there may be less certainty that imetelstat will achieve a statistically significant effect in any future clinical trials.

For example, we shortened the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable an earlier clinical cut-off date for the primary analysis in IMerge Phase 3. Although we expect the data from the primary analysis as of the earlier clinical cut-off date to be sufficiently mature to assess the safety and efficacy of imetelstat, including durability of transfusion independence, our decision to shorten the follow-up period after the last patient has been enrolled may result in clinical responses that could occur after the 12-month clinical cut-off date being excluded from the primary analysis. The exclusion of this data from the primary analysis could reduce the overall top-line efficacy results, including durability of transfusion independence, which could result in the trial's failure, or could limit or prevent marketing approval of imetelstat in lower risk MDS by the FDA or regulatory authorities in other countries.

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.

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.

In IMerge Phase 2, the initial data review for the 25-patient expansion cohort that was conducted by our former collaboration partner in the second quarter of 2018, referred to as 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 of 42% 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 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.

Furthermore, non-clinical and clinical data are often susceptible to varying interpretations and analyses. In some instances, there can be significant variability between different clinical trials of imetelstat due to numerous factors, including changes in trial procedures set forth in trial protocols, differences in the size and type of patient populations, and changes in and adherence to the dosing regimens. For example, complete and partial remissions were observed in an investigator-sponsored pilot study of imetelstat conducted at Mayo Clinic in MF patients, 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 patients with Intermediate-2 or High-risk MF who have relapsed after or are refractory to prior treatment with a JAKi, or relapsed/refractory MF, 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 results supporting a positive benefit-risk profile 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 former collaboration partner. For example, preliminary data from IMerge Phase 2 were reported at the ASH Annual Meetings in December 2017, December 2018, December 2020 and December 2021, and at the EHA Annual Congress meetings in June 2018, June 2019, June 2020 and June 2021. 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. 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, reported data should be considered carefully and with caution, and not relied upon as indicative of future clinical results. Such additional data could result in a lower benefit-risk profile than initially expected, which could hinder the potential success of 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 myeloid hematologic malignancies, including MDS and MF, 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, our former collaboration partner’s decision to terminate its imetelstat collaboration agreement with us.

Further delay, suspension or abandonment of the development of imetelstat in myeloid hematologic malignancies, including in IMerge Phase 3 and IMpactMF, and to plan for, commence, conduct and complete potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, could have a material adverse effect on the future of imetelstat and our business prospects, and we might 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 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 imetelstat produced under applicable current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would further delay the process for any regulatory approval. Our ability to comply with these regulations and standards may be contingent upon activities conducted by third parties, and if they fail to perform in accordance with contractual obligations and legal requirements, our development of imetelstat may be interrupted, further delayed or halted. Any failures by us or third parties noted above would have a severe adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which might cause us to cease operations.

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.

Furthermore, the execution of clinical trials and the subsequent compilation and analysis of the data produced, including top-line results from IMerge Phase 3, 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 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 for 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 and other third parties. Although we carefully manage our relationships with our CROs, investigators and other third parties, we and any of these third parties may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, business prospects and the future of imetelstat.

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

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

- impede 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 to the FDA or similar regulatory authorities in other countries for regulatory approval of imetelstat, including confirming compliance with EMA and FDA regulatory commitments.

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.

Furthermore, we shortened the follow-up period after the last patient has been enrolled from 15 months to 12 months to enable an earlier clinical cut-off date for the primary analysis in IMerge Phase 3. Although we expect the data from the primary analysis as of the earlier clinical cut-off date to be sufficiently mature to assess the safety and efficacy of imetelstat, including durability of transfusion independence, our decision to shorten the follow-up period after the last patient has been enrolled may result in clinical responses that could occur after the 12-month clinical cut-off date being excluded from the primary analysis. The exclusion of this data from the primary analysis could reduce the overall top-line efficacy results, including durability of transfusion independence, which could result in the trial's failure, or could otherwise delay, limit or prevent marketing approval of imetelstat in lower risk MDS 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 the FDA or similar regulatory authorities in other countries 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 U.S. 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 U.S. 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 U.S. and an MAA in the EU. As a company, we have not previously submitted an NDA to the FDA 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 U.S. or other countries. Regulatory authorities have substantial discretion in the approval process and can delay, limit or deny approval of imetelstat or require us to conduct additional non-clinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- 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 for the U.S. and a risk management plan for the EU, including post-marketing studies, as a potential condition to approval;
- disagreement regarding the formulation, labeling and/or the specifications for imetelstat;
- 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 U.K. left the EU on January 31, 2020, commonly referred to as Brexit, and its withdrawal from the EU was completed on December 31, 2020. Although the impact of the withdrawal of the United Kingdom from the EU will not be known for some time, it has resulted in uncertainty in relation to the regulatory process in the United Kingdom, and for Europe could potentially result in a delay in the review of regulatory submissions which 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 EU 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 U.S. 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.

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.

We do not have experience as a company with activities that would be required for the commercialization of imetelstat, should we receive regulatory approval to do so. 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.

Our inability to successfully establish commercialization capabilities for imetelstat if we receive 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.

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

The FDA granted orphan drug designation to imetelstat in June 2015 for the treatment of MF and for the treatment of MDS in December 2015, and the 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 for certain reasons, including 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, or failure to complete the agreed pediatric plan, 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 low red blood cell counts, or anemia, due to lower 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.

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.

The Innovation Passport designation from the United Kingdom regulatory authorities does not guarantee marketing approval and may not lead to a faster development, regulatory review or approval process.

In October 2021, we gained access to the ILAP through the receipt of an Innovation Passport for imetelstat to treat lower risk MDS. The ILAP is a new program sponsored by the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, post-Brexit. The objective of this new licensing and access pathway is to reduce the time to market and enable earlier patient access for innovative medicines. The Innovation Passport is the first prescribed entry point in the ILAP process. Key benefits of being within ILAP include a potential 150-day accelerated assessment and rolling review of an MAA, as well as opportunities for frequent interactions with the review staff at the MHRA and its partner agencies to discuss imetelstat's development, regulatory and reimbursement plans.

Although the goal of ILAP and the Innovation Passport is to reduce the time to market and enable earlier patient access, it does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that any imetelstat MAA will be approved or that any approval will be granted within any particular timeframe. Despite receiving Innovation Passport designation, we may decide to delay or forego the commercialization of imetelstat in the U.K.

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 our ability to obtain regulatory approvals of imetelstat, and our business and business prospects could be severely harmed, and we could cease operations.

Imetelstat must 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, and to establish commercial supply agreements;
- reliance on third-party 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 potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, and potential future commercial uses, which would delay or result in a cessation of IMerge Phase 3, IMPactMF, or 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 manufacturers to perform certain process development or other technical and scientific work with respect to imetelstat, as well as to supply starting materials and manufacture drug substance and drug product. While we have established arrangements with third parties for the manufacture of imetelstat, our manufacturing supply chain is highly specialized, and as such we are reliant upon a small group of third-party manufacturers to supply starting materials, drug substance and drug product. Failure by such third-party manufacturers to perform in a timely manner, 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 manufacturers on acceptable terms, or at all. We expect to rely on third-party manufacturers 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, including for potential commercial supply of imetelstat, 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;
- capacity limitations and scheduling constraints experienced by third-party manufacturers due to scheduling and other commitments, and queued manufacturing activities in contracted facilities;
- potential shortages of available manufacturing capacity or consumable manufacturing supplies at third-party manufacturers, 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 that other delays, or potential shortages of consumable manufacturing supplies, may continue throughout 2022;
- 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 or ship 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 imetelstat to meet commercial needs;
- 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; and
- natural disasters that affect contracted facilities.

Each of these risks could lead to delays or shortages in drug supply, or the inability to manufacture or ship drug supply necessary for non-clinical and clinical activities, and commercialization. For example, manufacturing delays could adversely impact the conduct or completion of imetelstat clinical trials, such as IMerge Phase 3, IMpactMF or commencement of potential future clinical trials, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 manufacturers and/or any other manufacturers may need to make substantial investments to enable sufficient capacity increases and cost reductions, and to implement those regulatory and compliance standards necessary for successful Phase 3 clinical trials and commercial production of imetelstat. These third-party manufacturers may not be willing or able to achieve such capacity increases, cost reductions, or regulatory and compliance standards, and even if they do, such achievements may not be at commercially reasonable costs. Changing manufacturers may be prolonged and difficult due to inherent technical complexities and because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms, or at all.

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 enter into suitable commercial supply agreements, or 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 COVID-19

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

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. We have allowed limited voluntary access to our offices in California and New Jersey to employees who have been vaccinated, but almost all of our employees continue to work remotely. While almost all of our employees continue to work remotely without any significant disruption to our business, the effects of our policies regarding remote working 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 our clinical trials;
- ensure patient visits to clinical sites and laboratories;
- conduct monitoring visits;
- manufacture and/or supply study drug or other supplies;
- report trial results; or
- 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 opening, initiating and monitoring clinical trial sites. Although vaccine distribution, including booster shots, is progressing in many countries, the emergence of COVID-19 variants, including the Delta and Omicron variants, and the resurgence of COVID-19 cases in certain regions of the world causes further uncertainty and unpredictability on clinical trial activities, including clinical site initiations, patient screening and enrollment. 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, which have impacted our trial operations. Even though we have completed patient enrollment in IMerge Phase 3, the pace of enrollment was slower than planned.

For IMPactMF, in addition to the negative impact of COVID-19, site personnel resources remain constrained in the countries where we planned to conduct the trial due to the number of competing trials in MF and other oncology indications. 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 these analyses are event-driven, 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 IMPactMF and potential delays in IMProveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 visits to clinical sites and laboratories, and uncertainty how the FDA will view deviations from clinical protocols 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 healthcare 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, or delays in receiving, supplies of imetelstat from our CMOs due to among other things, staffing shortages, production slowdowns or stoppages, shipping delays, 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;
- 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;
- 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 conduct and complete IMerge Phase 3, and to enroll, conduct and complete IMPactMF and any potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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, shipping delays, 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 other delays, or potential shortages of consumable manufacturing supplies, may continue throughout 2022.

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 and our ability to further advance the imetelstat program, including through completion of IMerge Phase 3 and IMPactMF, and conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in lower risk MDS and refractory MF. If top-line results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, 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 developments include continued spread of the Delta and Omicron variants in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants that may prove especially contagious or virulent, the ultimate duration and severity of the pandemic, travel restrictions, quarantines, social distancing, shipping delays and business closure requirements in the U.S. and in other countries, and the effectiveness of vaccination programs and other actions taken globally to treat and manage this health crisis. 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 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 in current 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. Under current planning assumptions, we believe that our existing capital resources, together with future interest income, will be sufficient to fund our current level of operations until the end of the first quarter of 2023. Based on current planning assumptions, we project top-line results from IMerge Phase 3 to be available in early January 2023. If top-line results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, we will require additional capital to reach top-line results in IMerge Phase 3. In any event, we will require substantial additional funding to further advance the imetelstat program, including through completion of IMerge Phase 3 and IMPactMF and conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in lower risk MDS and refractory MF. In addition, our ability to commercialize imetelstat in the U.S., 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 clinical trials, including IMerge Phase 3 and IMPactMF, and potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 IMPactMF or any potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 IMerge Phase 3 and IMPactMF in the U.S. 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 U.S. and other countries, and the associated costs;
- the costs and timing necessary to build a sales force in the U.S. to market and sell imetelstat, should it receive regulatory approval;
- the sales price for imetelstat, if any;
- 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;
- our level of indebtedness and associated debt service obligations;
- the costs of maintaining and operating facilities in California and New Jersey, telecommunications and administrative oversight, as well as higher expenses for travel, if travel becomes possible in light of the COVID-19 pandemic; and
- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

Until we can generate a sufficient amount of revenue from imetelstat to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, which may not be possible. Availability of such financing sources may be negatively impacted with any further delays in reporting results from IMerge Phase 3 or IMPactMF. For example, if top-line

results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, we will require additional capital to reach top-line results in IMerge Phase 3, which may not be possible for us to obtain on acceptable terms, or at all.

Additional financing through public or private debt or equity financings, including pursuant to the 2020 Sales Agreement with B. Riley Securities, the remaining \$25.0 million Tranche C drawdown under the Loan Agreement 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. Similarly, the current conflict between Ukraine and Russia has created extreme volatility in the capital markets and is expected to have further global economic consequences. If the equity and credit markets deteriorate, including as a result of a resurgence of COVID-19, political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Political unrest, such as the current situation with Ukraine and Russia, may also cause volatility and disruption in the global economy. 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, including pursuant to the 2020 Sales Agreement, 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 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 drawdown, if available, of the remaining \$25.0 million of Tranche C under our Loan Agreement, will be sufficient to fund our operating plans. In this regard, under the Loan Agreement, our ability to draw down any funds under Tranche C is subject to certain conditions, including approval by an investment committee comprised of Hercules and SVB. Without investment committee approval, we will not be eligible to draw down any funds under Tranche C of the Loan Agreement, and we will need to obtain additional or alternative financing to advance our development of imetelstat.

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 completion of 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 potential future clinical trials of imetelstat, such as IMProveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 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, 2021, our accumulated deficit was approximately \$1.3 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 will not generate any significant revenues. We have no ongoing collaborations related to imetelstat and have no current plans to enter into any corporate collaboration, partnership or license agreements that result in revenues.

We also expect to experience increased negative cash flow for the foreseeable future as we fund our operations and imetelstat clinical development activities advance and research programs continue. 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 Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or 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 Internal Revenue Code of 1986, as amended, or 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, drawdowns are available in three tranches, or Tranches A, B and C, subject to certain terms and conditions, including, with respect to Tranche C, approval by an investment committee comprised of Hercules and SVB. Concurrently with the closing of the Loan Agreement, we borrowed \$25.0 million of Tranche A. In June 2021, we drew down the remaining \$10.0 million available under Tranche A and in December 2021, we drew down \$15.0 million available under Tranche B. Without investment committee approval, we will not be eligible to draw funds under Tranche C of the Loan Agreement, and we will 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 Tranche 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 and other research and development programs 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 are able to draw down Tranche C, 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, as amended in August 2021, also contains financial covenants requiring us to maintain a cash balance in an amount greater than or equal to \$30.0 million, commencing June 1, 2022, which balance minimum could be reduced to \$20.0 million upon achievement of certain regulatory milestones. Under the amended Loan Agreement, if we enter into certain licensing transactions, this cash covenant requirement would increase to \$35.0 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 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 on our business, operations, properties, assets or financial condition;
- material misrepresentations;
- occurrence of any default under any other agreement involving indebtedness in excess of specified amounts, or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect on us; and
- certain money judgments being entered against us or any portion of our assets are attached or seized.

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

RISKS RELATED TO 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 due to shortages in qualified applicants, or to maintain our current management and personnel due to the increased number of opportunities in the biotechnology sector. If we are unable to successfully retain, motivate and incentivize our existing personnel, or to attract, assimilate and retain other highly qualified management and senior personnel in the future on acceptable terms, our ability to further develop and potentially commercialize imetelstat will be impaired, and our business and the price of our common stock would be adversely impacted.

In addition, our personnel are currently performing their duties in multiple jurisdictions, and if we are unable or fail to comply with employment, tax, benefits and other laws in such jurisdictions, we may face penalties, fines or litigation. 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. In September 2021, we established a subsidiary in the U.K., and our business needs and the expansion of our workforce may require us to establish additional business offices or entities in additional jurisdictions outside of the U.S., or to retain third parties to manage employment-related matters in new countries, jurisdictions and locations. Because the legal and regulatory requirements related to the operation and maintenance of such entities, and the employment of personnel in such countries, jurisdictions and regions is multi-national and complex, we may be unable to effectively operate and maintain such entities, or be unable to attract and retain ex-U.S. personnel, which could lead to significant costs and could delay the execution of our business plans or disrupt our current and future operations. 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.

Notwithstanding our research and discovery efforts, 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 product candidates. While we recently initiated a discovery program to identify a lead compound as a potential next generation oral telomerase inhibitor, our discovery efforts are at an early stage and may not be successful. In this regard, internal discovery efforts to identify new product candidates require substantial technical, financial and human resources, and the outcome of those efforts are uncertain and unpredictable. In addition, these internal discovery efforts may initially show promise in identifying a potential product candidate, yet fail to yield a product candidate for clinical development for a number of reasons, including where the research methodology used may not be successful in identifying a potential product candidate, or where a potential product candidate may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profile or other characteristics suggesting that it is unlikely to be an effective product. Furthermore, in addition to research and development risks, any potential lead compounds identified during discovery may not be patentable, and therefore unsuitable for further development. Likewise, our research efforts to evaluate imetelstat in lymphoid hematologic malignancies may not be successful. In any event, notwithstanding our research and discovery efforts, we remain and expect to continue remain 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. Similarly, if we are unable to develop new product candidates or to develop imetelstat in lymphoid hematologic malignancies through our internal research and discovery efforts, our business and business prospects would be harmed.

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

We intend to develop imetelstat broadly for hematologic malignancies, and to potentially commercialize, market and sell imetelstat in the U.S. 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 U.S., and to provide funding for such activities. We face significant competition in seeking appropriate collaborative partners, and these potential collaborative arrangements are complex and time consuming to negotiate, document and implement. Our ability to seek and establish potential collaborative arrangements may be impacted by 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 establish collaborative arrangements on acceptable terms, or at all. In this regard, collaborative arrangements with third parties may require us to relinquish material rights, including revenue from potential commercialization, or assume material ongoing development obligations that we would have to fund or otherwise support.

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

In order to advance the imetelstat program, including through completion of IMerge Phase 3 and IMpactMF, or to commence, conduct and complete potential future clinical trials of imetelstat, such as IMproveMF and planned

investigator-led clinical trials in AML and higher risk MDS, as well as undertaking potential commercialization activities for imetelstat in the U.S., 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 U.S., 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 completion of IMerge Phase 3 and IMpactMF or 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 U.S.

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 or potential future clinical trials of imetelstat. In addition, this type of insurance may become too expensive for us to afford because of the highly risky and uncertain nature of clinical trials generally and the high cost of insurance for our business activities. We may be unable to obtain or maintain clinical trial insurance in all of the jurisdictions where we conduct current or potential future clinical trials. In addition, business liability, product liability and cybersecurity insurance are becoming increasingly expensive, particularly for biotechnology and pharmaceutical companies, and the pool of insurers offering insurance coverage to biotechnology and pharmaceutical companies generally is becoming smaller, making it more difficult to obtain insurance for our business activities at a reasonable price, or at all. Being unable to obtain or maintain product liability, clinical trial liability, cybersecurity or other insurance for our business activities in the future on acceptable terms or with adequate coverage against potential liabilities would have a material adverse effect on our business, and could cause us to cease our development of imetelstat.

We and certain of our officers have been named as defendants in two pending putative securities class action lawsuits and seven 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, 2020 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, or the 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 class action 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. On April 12, 2021, the Court granted in part and denied in part our motion to dismiss. Our answer to the amended and consolidated class action complaint was filed on May 13, 2021. On September 30, 2021, lead plaintiffs filed their motion for class certification, and on October 21, 2021, we filed our opposition to lead plaintiffs' motion for class certification. The Court heard oral argument on lead plaintiffs' motion for class certification on February 24, 2022, but has not yet issued an order deciding the motion. Discovery has commenced. Trial is scheduled to begin on October 31, 2022.

Between April 23, 2020 and June 8, 2021, seven shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former members of our board. Of these actions, or the Derivative Lawsuits, two were filed in the Northern District, two were filed in the Court of Chancery of the State of Delaware, two were filed in the U.S. District Court for the District of Delaware, and one was filed in the Superior Court of California for the County of San Mateo, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and/or 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. The status of the seven Derivative Lawsuits is currently as follows:

- On July 2, 2021, we filed a motion to dismiss the consolidated shareholder derivative actions filed in the Court of Chancery of the State of Delaware, or the Chancery Court Derivative Lawsuits. On September 1, 2021, the plaintiffs filed a consolidated amended complaint in the Chancery Court Derivative Lawsuits. On October 12, 2021, we filed our motion to dismiss the consolidated amended complaint. The Court of Chancery of the State of Delaware heard oral argument on the motion on February 15, 2022, but has not yet issued an order deciding the motion;
- The consolidated shareholder derivative actions filed in the U.S. District Court for the District of Delaware have been stayed pending the ruling on our motion to dismiss the Chancery Court Derivative Lawsuits;
- The consolidated shareholder derivative actions filed in the Northern District have been stayed pending the Northern District's ruling on lead plaintiffs' motion for class certification in the consolidated class action lawsuit described above; and
- Our motion to dismiss the shareholder derivative action pursuant to the forum selection clause in our amended and restated bylaws was filed in the Superior Court of California for the County of San Mateo on August 5, 2021. At the hearing on the motion to dismiss on November 2, 2021, the court granted our motion to dismiss and stayed the case until April 19, 2022, when the court will hold a case management conference.

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 U.S. and in other countries.

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

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

Loss or impairment of our intellectual property rights related to imetelstat might further delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval, and 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 governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The U.S. Patent and Trademark Office, or the Patent Office, and various governmental patent agencies in other countries require compliance with a number of procedural, documentary, fee payment 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 governmental 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 U.S., the natural expiration of a patent is generally 20 years after its first effective nonprovisional filing date. Given the amount of time required for the development, testing and regulatory review of imetelstat, patents protecting imetelstat (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.

In the U.S., the Hatch-Waxman Act permits one patent term extension of up to five years beyond the normal expiration of one patent per product. The length of the patent term extension is typically calculated as one half of the clinical trial period plus the entire period of time during the review of the NDA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. One 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 U.S., such as in Japan and in Europe as SPCs. If we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the United States Patent and Trademark Office, or USPTO, in the U.S., and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. Should we seek a patent term extension, we may not be granted any such patent term extension and/or the applicable time period of such patent term extension could be less than five years. Moreover, in some countries, including the U.S., the scope of protection for claims under such patent term extensions, if any, does not extend to the full scope of the claims but is limited to the product composition as approved and, for a method of treatment patent, is limited to the approved indication. Thus, for example, if we do not receive a patent term extension for our U.S. composition of matter patent for imetelstat, as approved by the regulatory authorities, our U.S. composition of matter patent will expire in December 2025. If we do not have sufficient patent life to protect imetelstat, our financial results, business and business prospects, and the future of imetelstat would be materially and adversely affected, which might cause us to cease operations.

If regulatory approval of imetelstat occurs after a patent has expired in a country that does not allow interim patent term extensions, as is the case in many countries and territories including Europe, we will be unable to obtain any patent term extension of that expired patent, and the duration of our patent rights may be limited. If we do not receive marketing approval and submit a request for an SPC before our patents expire in the EEA where we have imetelstat composition of matter patents, our imetelstat composition of matter patents will expire in September 2024. In all other countries outside the U.S. and the EEA where we have imetelstat composition of matter patents, except Japan which provides for interim extensions, either: (a) extension of patent term is not available, and the patents will expire in September 2024, or (b) we may not have market authorization in those countries in sufficient time to file an extension of patent term before our composition of matter patents expire in September 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 NDA filed with the FDA to obtain permission to sell a generic version of imetelstat. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

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

The U.S. has enacted and implemented wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act, or the AIA, signed into law on September 16, 2011. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on actions by Congress, the federal courts, and the Patent Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our existing patents or patents that we may obtain in the future. Occurrence of these events and/or significant impairment of our imetelstat patent rights would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, which might cause us to cease operations.

As a result of the AIA, in March 2013, the U.S. transitioned to a first-inventor-to-file system under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, since the publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years, we are not able to be certain upon filing 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 our former collaboration partner and assigned to us for the future development, commercialization and manufacture of imetelstat. As a result, if we are not the first-inventor-to-file, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be significant to the future success of imetelstat. Delay in the filing of a patent application for any purpose, including further development or refinement of an invention, may result in the risk of loss of patent rights.

Following the result of a referendum in 2016, the United Kingdom left the EU on January 31, 2020, commonly referred to as Brexit. The impact of the withdrawal of the United Kingdom from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain SPCs 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 Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. It is possible that implementation of the EU Patent Package will occur in the fourth quarter of 2022 or the first half of 2023. 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 during an initial seven year period after the EU Patent Package is ratified. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could either accept a Unitary Patent or validate the patent nationally, and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

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 U.S. is important to our business. Opposition proceedings require significant time and costs, and if we are unsuccessful or are unable to commit these types of resources to protect our imetelstat patent rights, we could lose our patent rights and we could be prevented or limited in the development and commercialization of imetelstat.

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 for imetelstat and our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. are less extensive than those in the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover imetelstat and our technologies. There can be no assurance that we will obtain or maintain patent rights inside or outside the U.S. under any future license agreements. In addition, the laws of some countries outside the U.S. do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 U.S. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, many countries outside the U.S. have compulsory licensing laws under which a patent owner must grant licenses to third parties. Proceedings to enforce our patent rights, even if obtained, in jurisdictions outside the U.S. 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 own and potentially develop in the future.

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

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

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

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

We may become aware of discoveries and technologies controlled by third parties that are advantageous or necessary to further develop or manufacture imetelstat. Under such circumstances, we may initiate negotiations for licenses to other technologies as the need or opportunity arises. We may not be able to obtain a license to a technology required to pursue the research, development, 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 are seeking registered trademarks for a commercial trade name for imetelstat in the U.S. and jurisdictions outside of the U.S. and failure to secure such registrations could adversely affect our business.

We are seeking registration of trademarks for a potential commercial trade name for imetelstat in the U.S. and other jurisdictions outside of the U.S. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many jurisdictions outside of the U.S., third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use for imetelstat in the U.S. and Europe must be approved by the FDA and the EMA respectively, regardless of whether we have registered it, or applied to register it, as a trademark. Both the FDA and the EMA typically conduct a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or the EMA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA and the EMA.

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

Inventions discovered under research, material transfer or other collaboration agreements may become jointly owned by us and the other party to such agreements in some cases, and may be the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who invents and owns a particular invention, or whether it is jointly owned, and disputes can arise regarding inventorship, ownership and use of those inventions. These disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business if we are not able to protect or license rights to these inventions. In addition, clinical trial investigators, scientific consultants and research collaborators generally have contractual rights to publish data and other proprietary information, subject to review by the trial sponsor. Publications by us, or by investigators, scientific consultants, previous employees, research collaborators or others, either with permission or in contravention of the terms of their agreements with us or with our past or future collaborators, may impair our ability to obtain patent protection or protect proprietary information which would have a material adverse effect on our business, and might cause us to cease operations.

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

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

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

RISKS RELATED TO 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 myeloid hematologic malignancies provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Imetelstat will compete, if approved, with other products and therapies that currently exist, are being developed or will in the future be developed, some of which we may not currently be aware of.

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., or Astex; and Reblozyl (luspatercept), a TGF-beta inhibitor, by Acceleron Pharma, Inc., or Acceleron (acquired by Merck & Co., Inc., or Merck, in November 2021), in collaboration with Celgene.

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.

In addition, there are multiple Phase 1 and Phase 2 clinical trials of other agents being developed for lower risk MDS, including but not limited to: LB-100, a PP2A inhibitor, by Lixte Biotechnology Holdings, Inc.; bemcentinib, an AXL inhibitor, by BerGenBio ASA; H3B-8800, a spliceosome inhibitor, by H3 Biomedicine, Inc.; KER-050, a TGF-beta inhibitor, by Keros Therapeutics, Inc., or Keros Therapeutics; TP-0184, an inhibitor of ALK2 or ACVR1 kinase, by Sumitomo Dainippon Pharma Oncology, Inc; ilginatinib (NS-018), a JAK2 inhibitor, by NS Pharma, Inc., a U.S. subsidiary of Nippon Shinyaku Co., Ltd., or NS Pharma; RVT-2001, a SF3B1 modulator, by Roivant Sciences, Ltd.; sabatolimab (MBG453), a TIM-3 inhibitor, by Novartis AG; a lower dose of ASTX727, an oral formulation of decitabine and cedazuridine, referred to as ASTX727 LD, by Astex; ATX030, an oral formulation of azacitidine and cedazuridine, by Astex; and a combination treatment regimen of luspatercept and lenalidomide by Bristol Myers Squibb Corporation.

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, as well as a kinase inhibitor, Vonjo (pacritinib), by CTI Biopharma, which was recently approved for the treatment of adults with intermediate or high-risk primary or secondary myelofibrosis with a platelet count below $50 \times 10^9/L$. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of

splenomegaly and co-existing cytopenias; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include ESAs, androgens, danazol, corticosteroids, thalidomide and lenalidomide.

Other therapies currently in Phase 3 development in MF, some of which may obtain regulatory approval earlier than imetelstat include momelotinib, a JAK inhibitor, by Sierra Oncology, Inc., or Sierra Oncology; or momelotinib plus AZD5153, a BET inhibitor in-licensed by Sierra Oncology from AstraZeneca in August 2021; pelabresib (CPI-0610), a BET inhibitor, by Constellation Pharmaceuticals, Inc. (acquired by MorphoSys AG in June 2021); navitoclax, a BCLXL, BCL-2 and BCLW inhibitor, by AbbVie, Inc.; and pascalisib, 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 (acquired by Merck in November 2021), in collaboration with Celgene; PRM-151, an anti-fibrosis antibody, by Promedior, Inc. (acquired by Roche in February 2020); LCL-161, an inhibitor of apoptosis protein (IAP), by Novartis; KRT-232, an inhibitor of MDM2, by Kartos Therapeutics, Inc.; GB2064, a LOXL2 inhibitor, by Galecto Biotech; elraglusib (9-ING-41), a glycogen synthase kinase-3 beta inhibitor, by Actuate Therapeutics, Inc.; XPOVIO (selinexor), a nuclear export inhibitor, by Karyopharm Therapeutics, Inc.; TL-895, a tyrosine kinase inhibitor, by Telios Pharma, Inc.; IMG-7289, a LSD1 inhibitor, by Imago Biosciences, Inc.; APG-1252, a dual BCL-2/BCL-XL inhibitor, by Ascentage Pharma; ilginatinib (NS-018), a JAK2 inhibitor by NS Pharma; and KER-050, an engineered ligand trap comprised of a modified ligand-binding domain of the TGF-beta receptor in combination with ruxolitinib, by Keros Therapeutics.

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

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 healthcare 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 therapeutic or economic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for myeloid hematologic malignancies. Third-party payors may decide that any potential improvement that imetelstat may provide to clinical outcomes in myeloid hematologic malignancies is not adequate to justify the costs of treatment with imetelstat. If the healthcare community does not accept imetelstat for any of the foregoing reasons, or for any other reasons, our ability to further develop or potentially commercialize imetelstat may be negatively impacted or precluded altogether, which would seriously and adversely affect our business and business prospects, 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 U.S. 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 imetelstat, if marketing approval is obtained. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize imetelstat, even if marketing approval is obtained, which would negatively impact our business and business prospects.

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

In the U.S. and some jurisdictions outside the U.S., there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could impact our business. 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 healthcare 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 U.S. with respect to drug pricing, including specialty drug pricing practices, in light of the rising cost of prescription drugs and biologics. Specifically, there have been U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, and reform government program reimbursement methodologies for drugs and biologics. While a number of reform measures may require additional authorization to become effective, Congress and the Biden Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. 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.

The U.S. and some jurisdictions in other countries are considering or have enacted legislative and regulatory proposals to contain healthcare costs, as well as to improve quality and expand access. For example, in March 2010, the ACA was signed into law, which included a number of provisions of importance to the biopharmaceutical industry. There have been judicial and Congressional challenges to certain aspects of the ACA, and it is possible that the ACA will be subject to judicial or Congressional challenges in the future. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. 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.

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 additional 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, including HIPAA, as amended by HITECH; and transparency laws related to payments and/or other transfers of value made to physicians, other healthcare professionals and teaching hospitals. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute imetelstat, if marketing approval is obtained. For details regarding the restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate see Item 1 “Business—Government Regulation— Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations” in this annual report on Form 10-K.

Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. If our operations are found to be in violation of any of these or any other healthcare and privacy-related regulatory laws that may apply to us, 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, CROs, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the FDA's or 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, 2012 and December 31, 2021, our stock has traded as high as \$7.79 per share and as low as \$0.75 per share. Between January 1, 2021 and December 31, 2021, the price has ranged between a high of \$2.36 per share and a low of \$1.19 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 completion of IMerge Phase 3 and IMpactMF and conducting the clinical, regulatory and potential commercialization activities necessary to potentially 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 U.S., including, if we do not obtain regulatory clearance to commence, modify, conduct or continue clinical trials of imetelstat in MF, MDS or any additional myeloid hematologic 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 or geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), 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 seven 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 one of our officers have been named as defendants in two putative securities 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, the District Court for the District of Delaware and the California Superior Court for the County of San Mateo, 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, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 February 3, 2022, the closing price of our common stock was \$0.99 per share, and while the closing price of our common stock rose to \$1.01 per share on February 4, 2022, and has subsequently remained at or above the minimum closing bid price of \$1.00 per share from February 4, 2022 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, 2021, we had 675,000,000 shares of common stock authorized for issuance and 323,731,591 shares of common stock outstanding. In addition, we had reserved 133,292,810 shares of our common stock for future issuance pursuant to our stock option and equity incentive plans and outstanding warrants as of December 31, 2021.

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 stock options and shares of common stock reserved for issuance under our stock 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 stockholders' 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

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

In the ordinary course of our business, we (and third parties upon which we rely) may collect, receive, store, process, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose, or otherwise process (commonly known as processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data and participant study related data), intellectual property, and trade secrets (collectively, sensitive information). In addition, we rely on third party service providers to establish and maintain appropriate information technology and data security protections over the information technology systems they provide us to operate our critical business systems, including cloud-based infrastructure and systems, employee email, and data storage and management systems. However, except for contractual duties and obligations, we have limited ability to control their safeguards and actions related to such matters, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties. In particular, the COVID-19 pandemic has caused us to modify our business and information technology practices, including that most of our employees continue to work remotely. Additionally, the prevalent use of mobile devices that access our sensitive information increases the risk of breaches.

Our information technology systems, including in our remote work environment as a result of the COVID-19 pandemic, and those of the third parties upon which we rely, are potentially vulnerable to evolving threats. These threats are prevalent, continue to increase, and come from a variety of sources such as “hackers,” threat or internal bad actors, personnel (such as through theft, error or misuse), sophisticated nation states and nation-state-supported actors. These threats include, but are not limited to, social-engineering attacks, malicious code or intrusions, malware, denial-of-service attacks, personnel misconduct or errors, ransomware attacks, supply-chain attacks, software bugs, computer viruses, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, natural disasters, terrorism, war, and telecommunication and electrical failures. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in operations, loss of data and income, reputational harm, and diversion of funds. If we were to experience such an attack, extortion payments might alleviate the negative impact of a ransomware attack, but we might be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products/services) or the third-party information technology systems that support us and our services. These threats may result in unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive information, such as clinical trial data or information, intellectual property, proprietary business data and personal data. The costs to us to attempt to protect against such breaches could be significant, including potentially requiring us to modify our business (including non-clinical and clinical trial activities), and while we have implemented security measures designed to protect our information technology systems and to identify and remediate vulnerabilities, such measures may not be successful. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are sophisticated in nature, and may not be detected until after a security incident has occurred.

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

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

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations and actions; litigation; fines and penalties; disruptions to our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts.

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

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (GDPR) (EU) 2016/679, or the EU GDPR, imposes strict requirements on the processing of personal data. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Certain jurisdictions, including the EU and the UK, have enacted data localization laws and cross-border personal data transfer laws, which would make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. The processing of sensitive personal data, such as physical health conditions, is a topic of active interest among foreign regulators. As we expand into countries and jurisdictions outside the U.S., we may be subject to additional laws and regulations that may affect how we conduct business. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the U.S. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal data outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. In addition, the UK similarly restricts personal data transfers outside of those jurisdictions to countries such as the U.S. that do not provide an adequate level of personal data protection. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. 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, which could divert management's attention and increase our cost of doing business; limit our ability to collaborate with parties that are subject to European and other data privacy and security laws; or require us to increase our personal data processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U.S. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health data. Additionally, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to \$7,500 per violation). While the CCPA contains limited exceptions for clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. It is anticipated that the California Privacy Rights Act of 2020, or CPRA, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of an enforcement action. Other states have also enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors).

Although we endeavor to comply with all applicable data privacy and security obligations, 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 personnel or third parties upon whom we rely fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar activities); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, our clinical trials if any); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. Moreover, trial participants or research subjects about whom we or our vendors obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

GENERAL RISK FACTORS

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), geopolitical events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), terrorism, insurrection or war, and other natural or man-made disasters or business interruptions. Furthermore, other events, such as the armed conflict between Russia and Ukraine, could lead to sanctions, embargoes, supply shortages, regional instability, geopolitical shifts, cyberattacks, other retaliatory actions, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, which could adversely impact our operations and financial results, as well as those of third parties with whom we conduct business. There is a risk that one or more of our CROs, suppliers, and other contractors and consultants might not survive an economic downturn. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to develop and potentially commercialize imetelstat could be disrupted if our operations or those of our CROs and other contractors or consultants are affected by geopolitical events, man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our CROs, contractors and consultants, and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

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 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 the past, our independent registered public accounting firm provided an opinion annually on the effectiveness of our internal control over financial reporting. As a smaller reporting company, we are no longer subject to this requirement.

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 103rd month anniversary of the commencement date of the lease. The New Jersey Lease commenced on October 1, 2019, upon our control of the office space on that date.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is quoted on the Nasdaq Global Select Market under the symbol GERN. As of March 1, 2022, there were approximately 493 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, 2021, there were no unregistered sales of equity securities by us.

ITEM 6. [RESERVED]

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

The following discussion should be read in conjunction with the section entitled “Business” in Part I, Item 1 and the audited financial statements and notes thereto included in Part II, Item 8 of this annual report on Form 10-K. The information provided should be reviewed in the context of the sections entitled “Risks Related to the Development of Imetelstat”, “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, a first-in-class telomerase inhibitor. Geron's vision is to become a leader in the treatment of blood cancers, or hematologic malignancies, and is committed to improving and extending the lives of patients by changing the course of these diseases by targeting telomerase. We believe data from our prior Phase 2 clinical trials provide strong evidence that imetelstat targets telomerase to inhibit the uncontrolled proliferation of malignant stem and progenitor cells enabling recovery of bone marrow and normal blood cell production, which indicate potential disease-modifying activity. We believe this potential disease modification may differentiate imetelstat from other currently approved and investigational treatments in myeloid hematologic malignancies.

We are conducting two ongoing Phase 3 clinical trials that are designed to enable registration of imetelstat: (i) IMerge Phase 3 in lower risk MDS, and (ii) IMpactMF in refractory MF. In the first half of 2022, we plan to start IMproveMF, a Phase 1 clinical trial of imetelstat in combination with ruxolitinib in frontline MF patients. In addition, in 2022, in collaboration with key opinion leaders with expertise in AML, we plan to support one or more investigator-led clinical trials in AML and higher risk MDS to evaluate imetelstat as a single agent and in combination with venetoclax or hypomethylating agents, or HMAs.

For IMerge Phase 3, we expect top-line results to be available in early January 2023, based on current planning assumptions. Assuming the results of IMerge Phase 3 support regulatory submissions, we plan to submit a New Drug Application, or NDA, in the U.S. in the first half of 2023, and a marketing authorization application, or MAA, in Europe in the second half of 2023, for imetelstat in lower risk MDS. Under either priority or standard review for the NDA and, upon potential approval by the FDA, we expect that commercial launch of imetelstat in lower risk MDS in the U.S. could occur as early as the first half of 2024. In Europe, we anticipate review of the MAA by the European Medicines Agency, or EMA, could take approximately 12 months and, if approved, that commercial launch of imetelstat in lower risk MDS in Europe could occur as early as the second half of 2024.

For IMpactMF, under current planning assumptions, we expect the trial to be fully enrolled in 2024. In addition, we expect the interim analysis for overall survival, or OS, for IMpactMF may 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.

Imetelstat has been granted Fast Track designations by the 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 myelofibrosis, or MF, who have relapsed after or are refractory to treatment with a janus associated kinase, or JAK, inhibitor, also known as relapsed/refractory MF. Imetelstat has also been granted orphan drug designations by the FDA in the U.S. and by the European Commission for the EMA in the EU for the treatment of myelodysplastic syndromes, or MDS, and also for the treatment of MF. In October 2021, we gained access to the Innovative Licensing and Access Pathway, or ILAP, in the U.K. through the receipt of an Innovation Passport for imetelstat to treat lower risk MDS.

Stage-Gated Milestone-Driven Commercial Plans for Imetelstat

If imetelstat is approved for marketing by regulatory authorities, we plan to commercialize imetelstat ourselves in the U.S. and may seek commercialization partners for territories outside of the U.S. Given these plans, we have developed a potential commercial launch plan that is driven by the achievement of certain clinical milestones, such as achieving top-line results in lower risk MDS in early January 2023. In 2022, we plan to conduct preliminary commercial preparations, such as enhancing and/or establishing company processes and systems to support a potential commercial launch if imetelstat is approved in lower risk MDS, refining market research in lower risk MDS and refractory MF and hiring commercial leadership in pricing, market analytics and marketing. In addition, we plan to evaluate our strategy for potential commercialization of imetelstat in Europe.

Financial Resources

As of December 31, 2021, we had approximately \$212.7 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities. Under current planning assumptions, we believe our existing capital resources will be sufficient to fund our current level of operations until the end of the first quarter of 2023. If top-line results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, we will require additional capital to reach top-line results in IMerge Phase 3. In any event, we will require substantial additional funding to further advance the imetelstat program, including through completion of IMerge Phase 3 and IMpactMF and conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in lower risk MDS and refractory MF.

Note on the COVID-19 Pandemic

The ongoing COVID-19 pandemic is having widespread, rapidly-evolving, and unpredictable impacts on global societies, economies, financial markets, and business practices. We are closely monitoring the impact of the pandemic, the identification of new variants of the COVID-19 virus and related developments, and our focus remains on promoting employee health and safety while continuing to advance the development of imetelstat. For discussion regarding the impact of the COVID-19 pandemic on our business and financial results, see the subsection entitled “Risks Related to COVID-19” under “Risk Factors” in Part I, Item 1A and Note 6 on Commitments and Contingencies – Risks Related to COVID-19 in Notes to Financial Statements of this annual report on Form 10-K.

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, 2021, we had approximately \$212.7 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities, and a long-term debt principal balance of \$50.0 million.

In June 2021, we drew down the remaining \$10.0 million available under Tranche A of the Loan Agreement with Hercules and SVB. This loan amount bears the same interest rate of 9.0% as the initial drawdown under Tranche A. In August 2021, we amended the Loan Agreement to adjust the timing threshold for certain clinical milestones associated with Tranche B under the Loan Agreement. In addition, under the amended Loan Agreement, the minimum cash covenant requirement beginning as of June 1, 2022, was increased from \$25.0 million to \$30.0 million, and the minimum cash covenant required upon the execution of certain licensing transactions being executed was increased from \$30.0 million to \$35.0 million. All other terms of the Loan Agreement were unchanged, including the maturity date, interest rate, payment terms, events of default and other covenants.

In December 2021, we drew down \$15.0 million available under Tranche B of the Loan Agreement with Hercules and SVB. This loan amount bears the same interest rate of 9.0% as the drawdowns under Tranche A. See Note 8 on Debt in Notes to Financial Statements of this annual report on Form 10-K for additional information on the Loan Agreement.

Substantially all of our revenues to date have been payments under collaboration agreements, and milestones, royalties and other revenues from our licensing arrangements. We currently have no source of product revenue. 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 under a former imetelstat 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, 2021, we had an accumulated deficit of approximately \$1.3 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 U.S. and other countries. We expect research and development expenses, general and administrative expenses, and losses to substantially increase in future periods as we continue to support the imetelstat development program 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 U.S. on our own, if regulatory approval is granted, substantial additional capital will be required. If approved for marketing by regulatory authorities outside of the U.S., 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 of this annual report on Form 10-K describes the significant accounting policies used in the preparation of our financial statements. Certain of these significant accounting estimates are considered to be critical, as defined below.

A critical accounting estimate 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 U.S., and meaningfully present our financial condition and results of operations.

We believe the following accounting estimates reflect our critical 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 12% of our total financial instruments classified as assets measured at fair value as of December 31, 2021. Financial instruments classified as Level 2 include commercial paper, government-sponsored enterprise securities, U.S. Treasury securities, municipal securities, and corporate notes, representing approximately 88% of our total financial instruments classified as assets measured at fair value as of December 31, 2021. 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 of this annual report on Form 10-K for further discussion of our operating lease obligations.

Clinical Trial Accruals

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

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. 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.

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 stock options represents the period of time that stock 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 stock 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 evaluate whether an adjustment to the assumptions of fair value of our common stock and historical volatility are required if observed prices of our common stock materially differ from historical information. We 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.

We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in research and development efforts, including the development, manufacture, regulatory approval for and commercialization of, imetelstat; uncertainty of non-clinical and clinical trial results or regulatory approvals or clearances; the future development of imetelstat by us, including any future efficacy or safety results that may cause the benefit-risk profile of imetelstat to become unacceptable; the uncertain and unpredictable drug research and discovery process; overcoming disruptions and/or delays due to the COVID-19 pandemic or geopolitical events; our need for substantial additional capital; enforcement of our patent and proprietary rights; reliance upon our CROs, contract manufacturing organizations, or CMOs, consultants, licensees, investigators and other third parties; and potential competition. In order for imetelstat to be commercialized, we must conduct non-clinical tests and clinical trials to demonstrate the safety and efficacy of imetelstat, obtain regulatory approvals or clearances and enter into manufacturing, distribution and marketing arrangements, as well as obtain market acceptance. 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 was terminated effective April 2021. In connection with these agreements, we were eligible to receive license fees, option fees, milestone payments and royalties on future sales of products, or any combination thereof. 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 divested intellectual property.

We recognized license fee revenues of \$28,000, \$55,000 and \$96,000 in 2021, 2020 and 2019, respectively, related to our various agreements. The decrease in license fee revenues in 2021 and 2020 primarily reflects a reduction in the number of active license agreements in 2020 for research licenses related to our hTERT technology, due to the patent expirations on such technology.

We recognized royalty revenues of \$1.4 million, \$198,000 and \$364,000 in 2021, 2020 and 2019, respectively. Royalty revenues in 2021, 2020 and 2019 primarily reflect estimated royalties from sales of cell-based research products from our divested stem cell assets. The increase in royalty revenues in 2021 primarily reflects retroactive royalties of approximately \$911,000 on product sales of cell-based research products. The decrease in royalty revenues in 2020 primarily reflects expiration of licenses which eliminated the obligation to pay royalties on product sales.

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. Absent the one-time payment of retroactive royalties, we expect revenues in 2022 to be lower than 2021 as a result of reduced royalties from sales of cell-based research products from our divested stem cell assets.

Research and Development Expenses

During the years ended December 31, 2021, 2020 and 2019, imetelstat was the sole development program we supported. In 2021, we also supported a research discovery program related to potential next generation telomerase inhibitors. For the imetelstat program, we incur direct external, personnel related and other research and development costs. For the years ended December 31, 2021, 2020 and 2019, direct external expenses included costs for our CROs, consultants and other clinical-related vendors, as well as expenses for contract manufacturing and quality activities. For the year ended December 31, 2019, direct external expenses also included 100% of the clinical development costs incurred by Janssen for operational support of the imetelstat program during the transition period. Personnel-related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for our employees involved with ongoing research and development efforts. Other research and development expenses primarily consist of research-related overhead associated with allocated expenses for rent and maintenance of facilities and other supplies.

Research and development expenses for the years ended December 31, 2021, 2020 and 2019 were as follows:

(In thousands)	Year Ended December 31,		
	2021	2020	2019
Direct external research and development expenses:			
Clinical program: Imetelstat.....	\$ 61,516	\$ 33,838	\$ 39,263
Personnel related expenses	19,716	14,566	10,126
All other research and development expenses.....	4,495	3,084	2,683
Total.....	<u>\$ 85,727</u>	<u>\$ 51,488</u>	<u>\$ 52,072</u>

The increase in research and development expenses in 2021 primarily reflects higher direct external costs to support the conduct of the ongoing Phase 3 clinical trials, IMerge and IMPactMF, as well as increased costs for producing validation batches at contract manufacturers to enable future production of imetelstat for clinical and potential commercial purposes. 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 to us from Janssen, 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. In addition, personnel-related expenses have increased in 2021 and 2020 as a result of additional development and manufacturing headcount being hired.

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, the planned IMproveMF trial and planned investigator-led trials in AML and higher risk MDS. 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 \$29.7 million, \$25.7 million and \$20.9 million for the years ended December 31, 2021, 2020 and 2019, respectively. The increase in general and administrative expenses in 2021 primarily reflects new costs in connection with pre-commercial activities, including costs of \$2.8 million for modernizing our internal infrastructure to support a potential commercial launch, and higher legal costs of \$1.3 million. The increase in 2020 primarily reflects higher personnel-related costs of \$2.6 million for additional headcount to support growing operational activities associated with international clinical trial activities and higher overall company headcount and increased legal costs of \$1.6 million. We expect general and administrative expenses to increase in the future as the imetelstat program matures and potential commercialization preparatory activities continue.

Interest Income

Interest income was \$527,000, \$1.8 million and \$4.2 million for the years ended December 31, 2021, 2020 and 2019, respectively. The decrease in interest income in 2021 and 2020 reflects lower yields on our marketable securities portfolio due to declining interest rates. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Interest Expense

Interest expense was \$3.7 million and \$760,000 for the years ended December 31, 2021 and 2020, respectively. Interest expense reflects interest owed under the Loan Agreement, as well as amortization of associated debt issuance costs and debt discounts using the effective interest method and accrual for an end of term charge. The Loan Agreement was effective September 30, 2020. As such, no comparable interest expense amounts were recognized for the year ended December 31, 2019.

Change in Fair Value of Equity Investment

We remeasured the fair value of our equity investment at each reporting date and any resulting change in fair value based on observable price changes was included on our statements of operations. In the first quarter of 2021, we sold our entire equity investment, resulting in a net realized gain which has been recognized in other income and expense (see below). For the years ended December 31, 2020 and 2019, there was an increase in the fair value of our equity investment of \$60,000 and a decrease in fair value of our equity investment of \$195,000, respectively, resulting from observable price changes in the equity investment. As a result of the sale of our equity investment in the first quarter of 2021, no comparable change in fair value was included on our statements of operations for the year ended December 31, 2021.

Other Income and (Expense), Net

Net other income was \$1.1 million and \$168,000 for the years ended December 31, 2021 and 2020, respectively. Net other expense was \$69,000 for the year ended December 31, 2019. During the first quarter of 2021, we sold our entire equity investment resulting in a net realized gain of \$1.2 million, including foreign currency translation adjustments. During the third quarter of 2020, we recognized other income of \$182,000 for the share exchange of our equity investment upon its acquisition. Also included in other income were realized losses of \$34,000 for the sales of our equity investment during the third quarter of 2020. See Note 2 on Fair Value Measurements – Equity Investment in Notes to Financial Statements of this annual report on Form 10-K for additional information about the sales of our equity investment. Other income and (expense) also includes bank charges related to our cash operating accounts and marketable securities portfolio.

Liquidity and Capital Resources

As of December 31, 2021, we had cash, restricted cash, cash equivalents and marketable securities of \$212.7 million, compared to \$260.0 million at December 31, 2020. The decrease in cash, restricted cash, cash equivalents, and current and noncurrent marketable securities from December 31, 2020 was the net result of cash being used for operations, partially offset by the receipt of net cash proceeds of approximately \$20.4 million from sales of our common stock under the 2020 Sales Agreement, as described below, and proceeds from an additional drawdowns of debt. In June 2021, we drew down the remaining \$10.0 million available under Tranche A of the Loan Agreement. In December 2021, we drew down \$15.0 million available under Tranche B of the Loan Agreement. As of December 31, 2021, we have an outstanding principal balance of \$50.0 million in long-term debt. See Note 8 on Debt in Notes to Financial Statements of this annual report on Form 10-K for additional information on the Loan Agreement.

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

In May 2018, we entered into the 2018 Sales Agreement with B. Riley FBR, pursuant to which we could 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 the 2020 Sales Agreement 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 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. For the year ended December 31, 2021, we sold an aggregate of 10,571,556 shares of our common stock pursuant to the 2020 Sales Agreement, resulting in net cash proceeds to us of approximately \$20.4 million, after deducting sales commissions and other offering expenses payable by us. Approximately \$79.1 million of our common stock remained available for issuance under the 2020 Sales Agreement as of December 31, 2021. The 2020 Sales Agreement will expire upon the earlier of: (a) the sale of all common stock subject to the 2020 Sales Agreement, or (b) September 4, 2023.

Financing Strategy

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

Future Funding Requirements

Under current planning assumptions, we believe that our existing capital resources, together with future interest income, will be sufficient to fund our current level of operations until the end of the first quarter of 2023. Based on current planning assumptions, we project top-line results from IMerge Phase 3 to be available in early January 2023. If top-line results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, we will require additional capital to reach top-line results in IMerge Phase 3. In any event, we will require substantial additional funding to further advance the imetelstat program, including through completion of IMerge Phase 3 and IMPactMF and conducting the clinical, regulatory and potential commercialization activities necessary to potentially bring imetelstat to market in lower risk MDS and refractory MF. In addition, our ability to commercialize imetelstat in the U.S., 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 clinical trials, including IMerge Phase 3 and IMPactMF, and potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 IMPactMF or any potential future clinical trials of imetelstat, such as IMproveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 IMerge Phase 3 and IMPactMF in the U.S. 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 U.S. and other countries, and the associated costs;
- the costs and timing necessary to build a sales force in the U.S. to market and sell imetelstat, should it receive regulatory approval;
- the sales price for imetelstat, if any;
- 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;
- our level of indebtedness and associated debt service obligations;
- the costs of maintaining and operating facilities in California and New Jersey, telecommunications and administrative oversight, as well as higher expenses for travel, if travel becomes possible in light of the COVID-19 pandemic; and
- the costs of enabling our personnel to work remotely, including providing supplies, equipment and technology necessary for them to perform their responsibilities.

Until we can generate a sufficient amount of revenue from imetelstat to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, which may not be possible. Availability of such financing sources may be negatively impacted with any further delays in reporting results from IMerge Phase 3 or IMpactMF. For example, if top-line results from IMerge Phase 3 are not available until after the end of the first quarter of 2023, we will require additional capital to reach top-line results in IMerge Phase 3, which may not be possible for us to obtain on acceptable terms, or at all.

Additional financing through public or private debt or equity financings, including pursuant to the 2020 Sales Agreement with B. Riley Securities, the remaining \$25.0 million Tranche C drawdown under the Loan Agreement 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. Similarly, the current conflict between Ukraine and Russia has created extreme volatility in the capital markets and is expected to have further global economic consequences. If the equity and credit markets deteriorate, including as a result of a resurgence of COVID-19, political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Political unrest, such as the current situation with Ukraine and Russia, may also cause volatility and disruption in the global economy. 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, including pursuant to the 2020 Sales Agreement, 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 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 drawdown, if available, of the remaining \$25.0 million of Tranche C under our Loan Agreement, will be sufficient to fund our operating plans. In this regard, under the Loan Agreement, our ability to draw down any funds under Tranche C is subject to certain conditions, including approval by an investment committee comprised of Hercules and SVB. Without investment committee approval, we will not be eligible to draw down any funds under Tranche C of the Loan Agreement, and we will need to obtain additional or alternative financing to advance our development of imetelstat.

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 completion of 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 potential future clinical trials of imetelstat, such as IMProveMF and planned investigator-led clinical trials in AML and higher risk MDS, 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 \$95.6 million, \$66.7 million and \$43.8 million in 2021, 2020 and 2019, respectively. The increase in net cash used in operating activities in 2021 and 2020 primarily reflects higher payments for research and development expenses in connection with supporting the current Phase 3 clinical trials, IMerge and IMPactMF, manufacturing validation batches of imetelstat and increases in headcount.

Cash Flows from Investing Activities

Net cash provided by investing activities in 2021 and 2019 was \$71.9 million and \$27.4 million, respectively. Net cash used in investing activities in 2020 was \$105.3 million. Net cash provided by investing activities in 2021 and 2019 primarily reflects a higher rate of maturities than purchases of marketable securities. Net cash used in investing activities in 2020 primarily reflects a higher rate of purchases than maturities of marketable securities resulting from the investment of net cash proceeds from the underwritten public offering completed in 2020.

For the three years ended December 31, 2021, we purchased approximately \$1.0 million 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 2021, 2020 and 2019 was \$48.6 million, \$168.3 million and \$19.5 million, respectively. Financing activities in 2021, 2020 and 2019 primarily reflect the receipt of net cash proceeds from the sales of our common stock under the 2020 Sales Agreement in 2021, 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 2018 Sales Agreement with B. Riley FBR in 2020 and 2019 and aggregate drawdowns of \$25.0 million in each of 2021 and 2020 under the Loan Agreement with Hercules and SVB.

Contractual Obligations

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Our contractual obligations primarily consist of our obligations under non-cancellable operating leases. The aggregate amount of future operating lease payments over the term of our leases is \$6.7 million as of December 31, 2021. For additional information on our leases and timing of future payments, see Note 7 on Operating Leases in Notes to Financial Statements of this annual report on Form 10-K.

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

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, 2021 and 2020, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 \$85.7 million for the year ended December 31, 2021. As described in Note 1, research and development expenses are expensed as incurred. Research and development expenses include fees paid to contract research organizations (“CROs”), 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, the activities conducted by each clinical site, and the duration and level of activities for each patient 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 expense estimates are based on the best information available.

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 the extensive verification to determine the costs incurred and extent of the services performed by CROs and other vendors during the reporting period and as of the balance sheet date.

How We Addressed the Matter in Our Audit

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 10, 2022

GERON CORPORATION
BALANCE SHEETS

	December 31,	December 31,
	2021	2020
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 34,871	\$ 9,925
Restricted cash	364	363
Marketable securities.....	148,851	186,350
Interest and other receivables.....	1,763	722
Prepaid and other current assets	1,357	2,497
Total current assets	187,206	199,857
Noncurrent marketable securities	28,651	63,387
Property and equipment, net.....	650	658
Operating leases, right-of-use assets.....	4,727	5,295
Deposits and other assets	4,800	1,531
	\$ 226,034	\$ 270,728
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,687	\$ 6,919
Accrued compensation and benefits.....	8,099	8,218
Operating lease liabilities	901	878
Accrued liabilities	29,834	14,925
Total current liabilities.....	45,521	30,940
Noncurrent operating lease liabilities	4,267	4,799
Noncurrent debt	49,830	24,042
Total liabilities	99,618	59,781
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 3,000,000 shares authorized; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, \$0.001 par value; 675,000,000 and 450,000,000 shares authorized at December 31, 2021 and 2020, respectively; 323,731,591 and 310,566,853 shares issued and outstanding at December 31, 2021 and 2020, respectively	324	310
Additional paid-in capital.....	1,398,006	1,366,188
Accumulated deficit	(1,271,741)	(1,155,629)
Accumulated other comprehensive (loss) gain	(173)	78
Total stockholders' equity	126,416	210,947
	\$ 226,034	\$ 270,728

See accompanying notes.

GERON CORPORATION
STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2021	2020	2019
	(In thousands, except share and per share data)		
Revenues:			
License fees and royalties	\$ 1,393	\$ 253	\$ 460
Operating expenses:			
Research and development	85,727	51,488	52,072
General and administrative	29,665	25,678	20,893
Total operating expenses	115,392	77,166	72,965
Loss from operations	(113,999)	(76,913)	(72,505)
Interest income	527	1,828	4,221
Interest expense	(3,740)	(760)	—
Change in fair value of equity investment	—	60	(195)
Other income and (expense), net	1,100	168	(69)
Net loss	\$ (116,112)	\$ (75,617)	\$ (68,548)
Basic and diluted net loss per share	\$ (0.35)	\$ (0.28)	\$ (0.36)
Shares used in computing basic and diluted net loss per share	327,631,814	271,460,265	190,160,311

See accompanying notes.

GERON CORPORATION
STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,		
	2021	2020	2019
	(In thousands)		
Net loss.....	\$ (116,112)	\$ (75,617)	\$ (68,548)
Net unrealized (loss) gain on marketable securities.....	(251)	(54)	315
Comprehensive loss	\$ (116,363)	\$ (75,671)	\$ (68,233)

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				
			(In thousands, except share data)			
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 with 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	310,566,853	310	1,366,188	(1,155,629)	78	210,947
Net loss	—	—	—	(116,112)	—	(116,112)
Other comprehensive loss	—	—	—	—	(251)	(251)
Issuance of common stock in connection with at market offering, net of issuance costs of \$470	10,571,556	11	20,374	—	—	20,385
Issuance of common stock in connection with exercise of warrants	1,906,341	2	2,477	—	—	2,479
Stock-based compensation related to issuance of common stock and options in exchange for services	20,783	—	91	—	—	91
Issuances of common stock under equity plans	666,058	1	796	—	—	797
Stock-based compensation for equity-based awards to employees and directors	—	—	8,080	—	—	8,080
Balances at December 31, 2021	<u>323,731,591</u>	<u>\$ 324</u>	<u>\$ 1,398,006</u>	<u>\$ (1,271,741)</u>	<u>\$ (173)</u>	<u>\$ 126,416</u>

See accompanying notes.

GERON CORPORATION
STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2021	2020	2019
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$ (116,112)	\$ (75,617)	\$ (68,548)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	215	158	64
Accretion and amortization on investments, net.....	1,424	818	(1,534)
Amortization of debt issuance costs/debt discount.....	893	179	—
Gain on sales of available for sale securities	—	(19)	—
Net gain on exchange and sales of equity investment	(1,233)	(148)	—
Change in fair value of equity investment, including foreign currency translation.....	—	(163)	196
Stock-based compensation for services by non-employees.....	91	85	68
Stock-based compensation for employees and directors	8,080	6,895	6,079
Amortization related to 401(k) contributions	—	—	9
Amortization of right-of-use assets	568	777	712
Changes in assets and liabilities:			
Interest and other receivables	(1,041)	80	366
Prepaid and other current assets	1,317	(1,286)	121
Deposit and other assets.....	(3,807)	(206)	(964)
Accounts payable.....	(232)	5,731	199
Accrued compensation and benefits	(119)	3,388	2,188
Amount due to Janssen Biotech, Inc.....	—	(14,269)	11,659
Accrued liabilities	14,909	7,397	6,211
Operating lease liabilities	(509)	(452)	(655)
Net cash used in operating activities	(95,556)	(66,652)	(43,829)
Cash flows from investing activities:			
Purchases of property and equipment.....	(207)	(401)	(413)
Purchases of marketable securities	(177,434)	(313,201)	(153,467)
Proceeds from sales of securities available for sale.....	—	7,681	—
Proceeds from maturities of marketable securities	247,994	200,262	181,280
Proceeds from sales of equity investment.....	1,594	339	—
Net cash provided by (used in) investing activities	71,947	(105,320)	27,400
Cash flows from financing activities:			
Proceeds from issuances of common stock from equity plans	797	208	204
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	20,385	4,075	19,295
Proceeds from exercise of warrants	2,479	16	—
Proceeds from debt financing, net of paid debt issuance costs and debt discounts.....	24,895	23,863	—
Net cash provided by financing activities.....	48,556	168,346	19,499
Net increase (decrease) in cash, cash equivalents and restricted cash.....	24,947	(3,626)	3,070
Cash, cash equivalents and restricted cash at the beginning of the period	10,288	13,914	10,844
Cash, cash equivalents and restricted cash at the end of the period.....	<u>\$ 35,235</u>	<u>\$ 10,288</u>	<u>\$ 13,914</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 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.

Net Loss Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the periods presented without consideration of potential common shares. In May 2020, we entered into an underwriting agreement in connection with a public offering of our common stock, pursuant to which we issued a pre-funded warrant to purchase 8,335,239 shares of our common stock, or the pre-funded warrant, together with accompanying warrants to purchase shares of our common stock. 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 applicable, since the exercise price is negligible, and the pre-funded warrant may be exercised at any time.

Diluted net income per share would be calculated by adjusting the weighted-average number of shares of common stock outstanding for the dilutive effect of additional shares of common stock that would have been outstanding if potentially dilutive securities had been issued, as determined using the treasury-stock method. Potential dilutive securities consist of outstanding stock options and warrants to purchase our common stock. Diluted net loss per share excludes potential dilutive securities for all periods presented as their effect would be anti-dilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented in the accompanying statements of operations. Since we incurred a net loss for 2021, 2020, and 2019, the diluted net loss per share calculation excludes potential dilutive securities of 105,725,875, 101,881,391 and 38,151,906 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. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper and corporate notes.

We classify our marketable debt securities as available for sale. We record available for sale debt securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in interest income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest income on our 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, 2021, 2020 and 2019. See Note 2 on Fair Value Measurements.

Equity Investments

We measure our investment in equity securities at fair value at each reporting date. Changes in fair value resulting from observable price changes are included in change in fair value of equity investment and changes in fair value resulting from foreign currency translation are included in other expense on our 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 estimated rate to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment as of the lease commencement date. We may adjust the right-of-use assets for certain adjustments, such as initial direct costs paid or incentives received. In addition, we include any options to extend or terminate the lease in the expected lease term when it is reasonably certain that we will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term.

For lease agreements entered into after January 1, 2019 that include lease and non-lease components, such components are generally accounted for separately. We have also elected not to recognize on our 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. In 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. Under these agreements, non-refundable upfront fees and annual license maintenance fees were considered fixed consideration, while milestone payments and royalties were identified as variable consideration.

As of June 30, 2021, no active license agreements remain. The license related to our specialized oligonucleotide backbone chemistry, as well as patent rights covering the synthesis of monomers, the building blocks of oligonucleotides, terminated effective April 2021.

In connection with the divestiture of 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 divested intellectual property.

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

Milestone Payments. At the inception of each agreement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. For milestones that we do not deem to be probable of being achieved, the associated milestone payments are fully constrained and the value of the milestone is excluded from the transaction price with no revenue being recognized. For example, milestone payments that are not within our control, such as regulatory-related accomplishments, are not considered probable of

being achieved until those accomplishments have been communicated by the relevant regulatory authority. Once the assessment of probability of achievement becomes probable, we recognize revenue for the milestone payment. At each reporting date, we assess the probability of achievement of each milestone under 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-led clinical trials, raw materials to manufacture clinical trial drugs, manufacturing costs for research and clinical trial materials, sponsored research at other labs, consulting, costs to maintain technology licenses, 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 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.

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

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

Accumulated Other Comprehensive Gain (Loss)

Accumulated other comprehensive gain (loss) includes certain changes in stockholders' equity which are excluded from net income (loss). Accumulated other comprehensive (loss) gain on our balance sheets as of December 31, 2021 and 2020, respectively, 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 Pronouncement – Recently Adopted

In October 2020, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2020-08, *Codification Improvements to Subtopic 310-20, Receivables — Nonrefundable Fees and Other Costs*, or ASU 2020-08, which clarifies that “an entity should reevaluate whether a callable debt security is within the scope of paragraph 310-20-35-33 for each reporting period.” We adopted ASU 2020-08 as of January 1, 2021. The adoption of this new guidance did not have a material impact on our financial statements.

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 fiscal years beginning after December 15, 2022, using a modified retrospective approach, for smaller reporting companies. 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.

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, or ASU 2020-06. The key elements of ASU 2020-06 aim to reduce unnecessary complexity in GAAP for certain financial instruments with characteristics of liabilities and equity. In addressing the complexity, the FASB focused on amending the guidance on convertible instruments and the guidance on the derivatives scope exception for contracts in an entity's own equity. For convertible instruments, the FASB decided to reduce the number of accounting models for convertible debt instruments and convertible preferred stock. For contracts in an entity's own equity, the FASB observed that the application of the derivatives scope exception guidance results in accounting for some contracts as derivatives while accounting for economically similar contracts as equity. The FASB also decided to improve and amend the related earnings per share guidance. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years for public business entities that are not smaller reporting companies. For all other entities, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. We plan to adopt ASU 2020-06 as of January 1, 2024. 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, 2021 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds.....	\$ 24,207	\$ —	\$ —	\$ 24,207
Commercial paper	7,499	—	—	7,499
	<u>\$ 31,706</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 31,706</u>
Restricted cash:				
Money market fund	\$ 93	\$ —	\$ —	\$ 93
Certificate of deposit	271	—	—	271
	<u>\$ 364</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 364</u>
Marketable securities:				
U.S. Treasury securities (due in less than one year)	\$ 15,585	\$ —	\$ (18)	\$ 15,567
U.S. Treasury securities (due in one to two years)	1,524	—	(3)	1,521
Municipal securities (due in one to two years)	3,000	—	(15)	2,985
Government-sponsored enterprise securities (due in less than one year)	12,500	—	(7)	12,493
Commercial paper (due in less than one year)	84,398	2	(38)	84,362
Corporate notes (due in less than one year)	36,444	2	(17)	36,429
Corporate notes (due in one to two years)	24,224	—	(79)	24,145
	<u>\$ 177,675</u>	<u>\$ 4</u>	<u>\$ (177)</u>	<u>\$ 177,502</u>

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 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, 2021 and 2020 were as follows:

<u>(In thousands)</u>	<u>Less Than 12 Months</u>		<u>12 Months or Greater</u>		<u>Total</u>	
	<u>Estimated Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>	<u>Gross Unrealized Losses</u>
As of December 31, 2021:						
U.S. Treasury securities (due in less than one year)....	\$ 15,567	\$ (18)	\$ —	\$ —	\$ 15,567	\$ (18)
U.S. Treasury securities (due in one to two years)	1,521	(3)	—	—	1,521	(3)
Municipal securities (due in one to two years).....	2,985	(15)	—	—	2,985	(15)
Government-sponsored enterprise securities (due in less than one year).....	1,500	—	4,993	(7)	6,493	(7)
Commercial paper (due in less than one year).....	66,872	(38)	—	—	66,872	(38)
Corporate notes (due in less than one year)....	16,001	(17)	—	—	16,001	(17)
Corporate notes (due in one to two years)	24,145	(79)	—	—	24,145	(79)
	<u>\$ 128,591</u>	<u>\$ (170)</u>	<u>\$ 4,993</u>	<u>\$ (7)</u>	<u>\$ 133,584</u>	<u>\$ (177)</u>

(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
As of December 31, 2020:						
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>

The gross unrealized losses related to U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, commercial paper and corporate notes as of December 31, 2021 and 2020 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, 2021 and 2020 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 other-than-temporary impairment. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. We currently do not intend to sell these securities before recovery of their amortized cost bases.

Fair Value on a Recurring Basis

We categorize financial instruments recorded at fair value on our 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. Commercial paper, U.S. Treasury securities, municipal securities, government-sponsored enterprise securities, 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, 2021 and 2020 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		
As of December 31, 2021:					
Money market funds ⁽¹⁾	\$ 24,207	\$ —	\$ —	\$ 24,207	
U.S. Treasury securities ⁽²⁾⁽³⁾	—	17,088	—	17,088	
Municipal securities ⁽³⁾	—	2,985	—	2,985	
Government-sponsored enterprise securities ⁽²⁾	—	12,493	—	12,493	
Commercial paper ⁽¹⁾⁽²⁾	—	91,861	—	91,861	
Corporate notes ⁽²⁾⁽³⁾	—	60,574	—	60,574	
Total.....	<u>\$ 24,207</u>	<u>\$ 185,001</u>	<u>\$ —</u>	<u>\$ 209,208</u>	
As of December 31, 2020:					
Money market funds ⁽¹⁾	\$ 4,356	\$ —	\$ —	\$ 4,356	
U.S. Treasury securities ⁽²⁾⁽³⁾	—	10,705	—	10,705	
Government-sponsored enterprise securities ⁽²⁾⁽³⁾ ...	—	28,757	—	28,757	
Commercial paper ⁽²⁾	—	112,409	—	112,409	
Corporate notes ⁽²⁾⁽³⁾	—	97,866	—	97,866	
Equity investment ⁽⁴⁾	—	361	—	361	
Total.....	<u>\$ 4,356</u>	<u>\$ 250,098</u>	<u>\$ —</u>	<u>\$ 254,454</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 reassessed the fair value of our equity investment in Sienna at each reporting date and any resulting change in fair value was recognized on our 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 year ended December 31, 2019, we recognized a decrease in fair value of equity investment of \$195,000 related to observable

price changes. For the years ended December 31, 2020 and 2019 we also recognized a gain of \$103,000 and a loss of \$1,000, respectively, related to foreign currency translation from Australian dollar to U.S. dollar, which were included in other income and expense on our statements of operations.

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

Credit Risk

We currently place our cash, restricted cash, cash equivalents and marketable securities with 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, government-sponsored enterprise securities, U.S. Treasury securities, municipal securities, commercial paper and corporate notes. Our investment policy, approved by the audit committee of our board of directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations.

3. PROPERTY AND EQUIPMENT

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

(In thousands)	December 31,	
	2021	2020
Furniture and computer equipment	\$ 1,171	\$ 1,079
Leasehold improvements	129	192
	1,300	1,271
Less accumulated depreciation and amortization	(650)	(613)
	<u>\$ 650</u>	<u>\$ 658</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 myeloid hematologic malignancies. 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 remained 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. This agreement was terminated effective April 2021.

5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(In thousands)	December 31,	
	2021	2020
CRO and clinical trial costs	\$ 22,804	\$ 11,800
Manufacturing activities	4,123	1,903
Professional legal and accounting fees	2,030	640
Interest payable	336	194
Other	541	388
	<u>\$ 29,834</u>	<u>\$ 14,925</u>

6. COMMITMENTS AND CONTINGENCIES

Purported Securities Lawsuits

Between January 23, 2020 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 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 class action 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. On April 12, 2021, the Court granted in part and denied in part our motion to dismiss. Our answer to the amended consolidated class action complaint was filed on May 13, 2021. On September 30, 2021, lead plaintiffs filed their motion for class certification, and on October 21, 2021, we filed our opposition to lead plaintiffs' motion for class certification. The Court heard oral arguments on lead plaintiffs' motion for class certification on February 24, 2022, but has not yet issued an order deciding the motion. Discovery has commenced. Trial is scheduled to begin on October 31, 2022.

Between April 23, 2020 and June 8, 2021, seven shareholder derivative actions were filed, naming as defendants certain of our current officers and certain current and former members of our board. Of these actions, or the Derivative Lawsuits, two were filed in the Northern District, two were filed in the Court of Chancery of the State of Delaware, two were filed in the U.S. District Court for the District of Delaware, and one was filed in the Superior Court of California for the County of San Mateo, respectively. The plaintiffs in the Derivative Lawsuits allege breach of fiduciary duty and/or 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. The status of the seven Derivative Lawsuits is currently as follows:

- On July 2, 2021, we filed a motion to dismiss the consolidated shareholder derivative actions filed in the Court of Chancery of the State of Delaware, or the Chancery Court Derivative Lawsuits. On September 1,

2021, the plaintiffs filed a consolidated amended complaint in the Chancery Court Derivative Lawsuits. On October 12, 2021, we filed our motion to dismiss the consolidated amended complaint. The Court of Chancery of the State of Delaware heard oral argument on the motion on February 15, 2022, but has not yet issued an order deciding the motion;

- The consolidated shareholder derivative actions filed in the U.S. District Court for the District of Delaware have been stayed pending the ruling on our motion to dismiss the Chancery Court Derivative Lawsuits;
- The consolidated shareholder derivative actions filed in the Northern District have been stayed pending the Northern District's ruling on lead plaintiffs' motion for class certification in the consolidated class action lawsuit described above; and
- Our motion to dismiss the shareholder derivative action pursuant to the forum selection clause in our amended and restated bylaws was filed in the Superior Court of California for the County of San Mateo on August 5, 2021. At the hearing on the motion to dismiss on November 2, 2021, the court granted our motion to dismiss and stayed the case until April 19, 2022, when the court will hold a case management conference.

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 (i) above the Vice President level, (ii) hired by the Company before January 1, 2022, or (iii) 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 three 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, 2021, all our executive officers have employment agreements with provisions that may provide greater severance benefits than those in the Severance Plan.

Risks Related to COVID-19

As of the date of this filing, significant uncertainty exists concerning the ultimate duration and severity of the COVID-19 pandemic. Although we are seeing the number of COVID-19 cases declining in certain regions, other regions are experiencing a resurgence of COVID-19 cases. In addition, the emergence of COVID-19 variants, including the Delta and Omicron variants, the variable process of vaccine distribution, including booster shots, in some countries and the concern over further waves of infections are causing continued unpredictability and uncertainty about the pace at which clinical trial operations may normalize to allow patients and healthcare workers to return to clinical sites.

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, delays in clinical site initiation and patient enrollment in IMPactMF, IMproveMF and the planned investigator-led clinical trials in AML and higher risk MDS and other disruptions that could severely impact our business and the imetelstat development program.

We have taken and intend to take those actions with regard to COVID-19 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. In response to the COVID-19 pandemic and "shelter in place" and similar orders issued by state and local governments, we have allowed limited voluntary access to our offices in California and New Jersey to employees who have been vaccinated, and almost all of our employees continue to work remotely without any significant disruption to our business. 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 complete IMerge Phase 3 and 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 U.S. 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.

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 were 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 103rd month anniversary of the commencement date of the lease. The New Jersey Lease commenced on October 1, 2019, upon our control of the office space on that date. Based on the initial term of the New Jersey Lease of 11 years, the right-of-use asset and corresponding operating lease liability was approximately \$2,356,000, which represented the present value of lease payments over the initial lease term, net of a seven-month rent abatement period, using an incremental borrowing rate of 8% based on information available as of October 1, 2019. Under the New Jersey Lease, we are also obligated to pay certain variable expenses separately from the base rent, including electricity and common area maintenance. Such costs are being expensed in the period they are incurred. As of December 31, 2021, the remaining lease term for the New Jersey Lease is 8.8 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, 2021, the remaining lease term for the Foster City Lease is 5.5 years.

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

(In thousands)	Year Ended December 31,		
	2021	2020	2019
Operating lease costs	\$ 946	\$ 1,143	\$ 783
Variable lease costs ⁽¹⁾	252	293	17
Total lease costs	<u>\$ 1,198</u>	<u>\$ 1,436</u>	<u>\$ 800</u>

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

The undiscounted future non-cancellable lease payments under the New Jersey Lease and the Foster City Lease as of December 31, 2021 were as follows (in thousands):

2022	\$ 937
2023	962
2024	988
2025	1,014
2026	1,040
Thereafter	<u>1,767</u>
Total lease payments	6,708
Less: imputed interest	<u>(1,540)</u>
Total	<u>\$ 5,168</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 was drawn in June 2021, (ii) Tranche B loan of up to \$15,000,000 which was fully drawn in December 2021, and (iii) Tranche C loan of up to \$25,000,000 which is available to be drawn through December 31, 2022, subject to approval by an investment committee comprised of Hercules and SVB. As of December 31, 2021, a total of \$50,000,000 has been drawn under the Loan Agreement.

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, 2021) less 3.25%. The drawdowns under Tranche A and Tranche B currently bear an interest rate of 9.0%. The Term Loan provides for an initial interest-only payment period from the Closing Date until November 1, 2022. Upon the achievement of certain clinical milestones, the interest-only period was extended for an additional six months until May 1, 2023. Upon the achievement of certain regulatory and financial milestones, the interest-only period may be extended for another six months until November 1, 2023. 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. In August 2021, we amended the Loan Agreement to adjust the timing threshold for certain clinical milestones associated with Tranche B under the Loan Agreement. In addition, under the amended Loan Agreement, the minimum cash covenant requirement beginning as of June 1, 2022, was increased from \$25,000,000 to \$30,000,000. Such minimum cash covenant is permanently reduced to \$20,000,000 if certain regulatory milestones are achieved as set forth in the Term Loan. The minimum cash covenant required upon the execution of certain licensing transactions being executed was increased from \$30,000,000 to \$35,000,000. All other terms of the Loan Agreement were unchanged, including the maturity date, interest rate, payment terms, events of default and other covenants. We are in compliance with the covenants under the Term Loan as of December 31, 2021.

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, 2021, the net carrying value of loan amounts under Tranche A and B was \$49,830,000, which includes the principal amount of \$50,000,000 less the net unamortized discounts and debt issuance costs of \$863,000 plus accrued end of term charge of \$693,000. The carrying value of the debt approximates the fair value as of December 31, 2021. The debt discounts and debt issuance costs are being amortized to interest expense over the life of loan amounts under Tranche A and B 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, 2021 (in thousands):

2022	\$	4,510
2023		25,352
2024		33,140
Total		<u>63,002</u>
Less: amount representing interest		(9,727)
Less: unamortized debt discount and issuance costs.....		(863)
Less: unamortized end of term charge.....		(2,582)
Less: current portion of debt.....		—
Noncurrent portion of debt.....	\$	<u><u>49,830</u></u>

9. STOCKHOLDERS' EQUITY

Authorized Common Stock

In May 2021, our stockholders approved an amendment to our Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 450,000,000 to 675,000,000 shares.

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 2021 and 2020, stock purchase warrants for 1,906,341 and 12,500 shares of our common stock were exercised, respectively, and we received proceeds of \$2,479,000 and \$16,000, respectively. As of December 31, 2021, the pre-funded warrant to purchase 8,335,239 shares of our common stock was outstanding and stock purchase warrants to purchase 55,773,466 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 could 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. For the year ended December 31, 2021, we sold an aggregate

of 10,571,556 shares of our common stock pursuant to the 2020 Sales Agreement, resulting in net cash proceeds to us of approximately \$20,385,000, after deducting sales commissions and other offering expenses payable by us. The 2020 Sales Agreement will expire upon the earlier of: (a) the sale of all common stock subject to the 2020 Sales Agreement, or (b) September 4, 2023.

Equity Plans

2011 Incentive Award Plan

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

Service-based stock options under the 2011 Plan generally vested over a period of four years from the date of the stock 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 Equity Incentive Plan, and the 2011 Plan as such shares become available from time to time, referred to as the Prior Plans' Returning Shares. Such Prior Plans' Returning Shares become available for issuance under the 2018 Plan if outstanding stock awards granted under the 2002 Equity Incentive Plan and the 2011 Plan, after May 15, 2018, expire or terminate for any reason prior to exercise or settlement or are forfeited, cancelled or otherwise returned to us because of the failure to meet a contingency or condition required for the vesting of such shares, or, subject to certain exceptions, are reacquired or withheld (or not issued) by us to satisfy a tax withholding obligation in connection with a stock award. In May 2021 and June 2020, our stockholders approved amendments to our 2018 Equity Incentive Plan to increase the total number of shares issuable under such plan by 12,500,000 and 5,700,000 shares of our common stock, respectively.

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

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

Under certain circumstances, stock options may be exercised prior to vesting, subject to our right to repurchase the shares underlying such stock option at the exercise price paid per share. Our repurchase rights would generally terminate on a vesting schedule identical to the vesting schedule of the exercised stock option. During 2021 and 2020, we did not repurchase any shares under the 2018 Plan. As of December 31, 2021, we have no shares outstanding subject to repurchase under the 2018 Plan.

As of December 31, 2021, 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 a stock 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 stock 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.

In the first quarter of 2022, our board of directors further amended the Non-Employee Director Compensation Policy and increased the First Director Option to 200,000 shares of common stock and the Subsequent Director Option to 125,000 shares of common stock.

2006 Directors' Stock Option Plan

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

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

2018 Inducement Award Plan

In December 2018, our board of directors approved the adoption of the 2018 Inducement Award Plan, or the Inducement Plan, pursuant to which we reserved 3,000,000 shares of 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, February 2021, May 2021 and February 2022, 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, 800,000, 5,000,000 and 1,000,000 shares, respectively. As a result, an aggregate total of 16,100,000 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.

For the years ended December 31, 2021, 2020 and 2019, we issued 20,783, 17,986, and 29,150 shares of common stock, respectively, from the Directors Market Plan. The weighted average grant date fair value of stock granted during the years ended December 31, 2021, 2020 and 2019 was \$1.38, \$1.60 and \$1.50 per share, respectively. The total fair value of vested stock grants during 2021, 2020 and 2019 was \$29,000, \$29,000 and \$44,000, respectively.

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

	Shares Available For Grant	Number of Shares	Outstanding Stock Options		
			Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2020	7,257,747	43,663,691	\$ 2.12		
Additional shares authorized	18,300,000	—	\$ —		
Stock options granted	(9,562,106)	9,562,106	\$ 1.81		
Awards granted.....	(20,783)	—	\$ —		
Stock options exercised	—	(451,853)	\$ 1.23		
Stock options cancelled/forfeited/expired	2,788,535	(2,821,535)	\$ 2.31		
Balance at December 31, 2021	<u>18,763,393</u> ⁽¹⁾	<u>49,952,409</u> ⁽²⁾	\$ 2.06	6.09	\$ 890
Stock options exercisable at December 31, 2021		<u>30,459,136</u>	\$ 2.35	4.82	\$ 547
Stock options fully vested and expected to vest at December 31, 2021		<u>49,085,603</u>	\$ 2.06	6.06	\$ 878

(1) In February 2022, our Compensation Committee approved an amendment to increase the reserve for the Inducement Plan from 15,100,000 to 16,100,000 shares of common stock.

(2) Includes 6,050,000 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 \$1.22 per share as of December 31, 2021, which would have been received by the option holders had all the option holders exercised their stock options as of that date.

We have not granted any stock options with an exercise price below or greater than the fair market value of our common stock on the date of grant in 2021, 2020, and 2019. As of December 31, 2021, 2020 and 2019, there were 30,459,136, 25,721,508 and 19,915,713 exercisable stock options outstanding at weighted average exercise prices per share of \$2.35, \$2.54 and \$2.86, respectively.

The total pretax intrinsic value of stock options exercised during 2021, 2020, and 2019 was \$93,000, \$17,000 and \$80,000, respectively. Cash received from the exercise of stock options in 2021, 2020, and 2019 totaled approximately \$556,000, \$25,000 and \$163,000, 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, 2021, an aggregate of 531,697 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, 2021, 2020 and 2019 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 2021, 2019 and 2018, our board of directors awarded 550,000, 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 stock options table above. Performance-based stock options vest only upon achievement of discrete strategic milestones. Stock-based compensation expense for performance-based stock options is recognized over the period from the date the performance condition is determined to be probable of occurring through the date the applicable condition is expected to be met and is reduced for estimated forfeitures, as applicable. If the performance condition is not considered probable of being achieved, no stock-based compensation expense is recognized until such time as the performance condition is considered probable of being achieved, if ever. 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, 2021, 2020 and 2019, 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 and employee stock purchases for the years ended December 31, 2021, 2020 and 2019 which was allocated as follows:

(In thousands)	Year Ended December 31,		
	2021	2020	2019
Research and development.....	\$ 3,597	\$ 2,337	\$ 1,640
General and administrative	4,483	4,558	4,439
Stock-based compensation expense included in operating expenses	<u>\$ 8,080</u>	<u>\$ 6,895</u>	<u>\$ 6,079</u>

The fair value of stock options granted in 2021, 2020, and 2019 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Dividend yield	0%	0%	0%
Expected volatility range	0.775 to 0.783	0.781 to 0.793	0.792 to 0.980
Risk-free interest rate range.....	0.51% to 1.30%	0.31% to 1.62%	1.50% to 2.56%
Expected term range	5.5 yrs	5.25 yrs	5.25 - 6.44 yrs

The fair value of employee stock purchases in 2021, 2020, and 2019 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Dividend yield	0%	0%	0%
Expected volatility range	0.507 to 0.707	0.478 to 0.818	0.646 to 1.653
Risk-free interest rate range.....	0.09% to 0.16%	0.16% to 1.57%	1.94% to 2.63%
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 stock options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that stock options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Based on the Black Scholes option-pricing model, the weighted average estimated fair value of stock options granted during the years ended December 31, 2021, 2020 and 2019 was \$1.17, \$0.88 and \$0.94 per share, respectively. The weighted average estimated fair value of employees' purchase rights for the years ended December 31, 2021, 2020 and 2019 was \$0.56, \$0.62 and \$0.66 per share, respectively. As of December 31, 2021, 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 \$12,341,000, which is expected to be recognized over the next 28 months on a weighted-average basis.

Stock-Based Compensation to Service Providers

We grant stock options to consultants from time to time in exchange for services performed for us. In general, the stock options vest over the contractual period of the consulting arrangement. The fair value of stock options held by consultants is recorded as operating expenses over the vesting term of the respective equity awards. With the adoption of Accounting Standards Update 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, in the first quarter of 2019, the measurement date of stock options granted to consultants was fixed at the grant date. We recorded stock-based compensation expense of \$62,000, \$56,000 and \$24,000 for the vested portion of the fair value of stock options held by consultants in 2021, 2020, and 2019, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2021 is as follows:

Outstanding stock options	49,952,409
Stock options and awards available for grant.....	18,763,393
Employee stock purchase plan	468,303
Warrants outstanding.....	64,108,705
Total	<u>133,292,810</u>

10. INCOME TAXES

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

	2021	2020	2019
Tax at statutory rate	21.0%	21.0%	21.0%
State income tax, net of federal benefit	9.0	6.9	12.2
Federal and state tax credits	5.7	5.3	4.0
Stock-based compensation	(1.2)	(0.5)	(0.8)
Net operating loss not benefitted.....	(5.4)	(6.9)	(5.8)
Other	(0.2)	(0.3)	(0.2)
Change in valuation allowance.....	(28.9)	(25.5)	(30.4)
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>2021</u>	<u>2020</u>
	(In thousands)	
Net operating loss carryforwards	\$ 241,300	\$ 217,100
Federal and state tax credits	49,600	42,800
Capitalized research and development.....	6,900	6,000
Stock-based compensation	10,200	9,400
Operating lease liabilities.....	1,400	1,200
Other.....	2,600	2,100
Total deferred tax assets	<u>312,000</u>	<u>278,600</u>
Less: valuation allowance	<u>(310,700)</u>	<u>(277,200)</u>
Net deferred tax assets	1,300	1,400
Operating leases, right-of-use assets	<u>(1,300)</u>	<u>(1,400)</u>
Total deferred tax liabilities.....	<u>(1,300)</u>	<u>(1,400)</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 \$33,500,000 and \$19,300,000 for the years ended December 31, 2021 and 2020 respectively.

As of December 31, 2021, we had domestic federal net operating loss carryforwards of approximately \$973,800,000. Of this, \$714,700,000 will expire at various dates beginning in 2022 through 2037 and the remaining will carryforward indefinitely under the new tax laws, but is subject to an 80% taxable income limitation for tax years beginning after 2020. As of December 31, 2021, we had state net operating loss carryforwards of approximately \$526,300,000 expiring at various dates beginning in 2028 through 2041, if not utilized. We also had federal tax credit carryforwards of approximately \$53,500,000 expiring at various dates beginning in 2022 through 2041, if not utilized. Our state tax credit carryforwards of approximately \$20,400,000 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. In 2021, we assessed our eligibility to claim a refund of employer taxes available under the Employee Retention Credit provisions of the CARES Act. As of December 31, 2021, we calculated eligible credits of approximately \$1,152,000 provided by the CARES Act which have recognized as a receivable and offset to salaries costs in operating expenses in the fourth quarter of 2021.

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, 2021, we had approximately \$21,300,000 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, 2020	\$	19,100
Decrease related to prior year tax positions		—
Increase related to current year tax positions		2,200
Balance as of December 31, 2021	\$	<u>21,300</u>

If applicable, we would classify interest and penalties related to uncertain tax positions in income tax expense. Through December 31, 2021, 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, 2022. 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,		
	2021	2020	2019
		(In thousands)	
Supplemental operating and investing activities:			
Net unrealized (loss) gain on marketable securities	\$ (251)	\$ (54)	\$ 315
Operating lease assets obtained in exchange for operating lease liabilities.....	—	3,575	2,473
Interest paid	\$ 2,704	\$ 388	\$ —

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, 2021.

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, 2021 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, 2021.

(IV) Report of Independent Registered Public Accounting Firm

This annual report on Form 10-K does not include an attestation report of our independent registered public accounting firm. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting as long as we are a smaller reporting company pursuant to the provisions of Rule 12b-2 of the Exchange Act.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Certain information required by Part III is omitted from this annual report on Form 10-K because we will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for Geron’s Annual Meeting of Stockholders expected to be held in May 2022, 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. 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 ACCOUNTANT FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

Included in Part II, Item 8 of this Report:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm.....	93
Balance Sheets—December 31, 2021 and 2020	95
Statements of Operations—Years Ended December 31, 2021, 2020 and 2019	96
Statements of Comprehensive Loss—Years Ended December 31, 2021, 2020 and 2019	97
Statements of Stockholders’ Equity—Years Ended December 31, 2021, 2020 and 2019	98
Statements of Cash Flows—Years Ended December 31, 2021, 2020 and 2019	99
Notes to Financial Statements	100

(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 Certificate of Incorporation	3.1	8-K	May 18, 2012	000-20859
3.3	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	June 7, 2019	000-20859
3.4	Certificate of Amendment of the Restated Certificate of Incorporation	3.1	8-K	May 13, 2021	000-20859
3.5	Amended and Restated Bylaws of Registrant	3.1	8-K	March 19, 2010	000-20859
3.6	Amendment to Amended and Restated Bylaws of Registrant	3.4	8-K	November 22, 2017	000-20859
4.1	Description of Capital Stock				
4.2	Form of Common Stock Certificate	4.1	10-K	March 15, 2013	000-20859
4.3	Form of Pre-Funded Warrant to Purchase Common Stock	4.1	8-K	May 26, 2020	000-20859
4.4	Form of Warrant to Purchase Common Stock	4.2	8-K	May 26, 2020	000-20859
10.1	Form of Indemnification Agreement	10.1	10-K	March 7, 2012	000-20859
10.2	Amended and Restated 2006 Directors' Stock Option Plan*	10.5	10-Q	November 7, 2013	000-20859
10.3	2011 Incentive Award Plan*	10.1	8-K	May 16, 2011	000-20859
10.4	Form of Stock Option Agreement under 2011 Incentive Award Plan*	10.11	10-K	March 15, 2013	000-20859
10.5	Form of Restricted Stock Award Agreement under 2011 Incentive Award Plan*	10.12	10-K	March 15, 2013	000-20859
10.6	Form of Non-Employee Director Stock Option Agreement under 2011 Incentive Award Plan*	10.2	10-Q	May 7, 2015	000-20859
10.7	2018 Equity Incentive Plan, as amended*	10.1	8-K	May 13, 2021	000-20859
10.8	Form of Employee Stock Option Agreement under 2018 Equity Incentive Plan*	10.3	8-K	May 18, 2018	000-20859
10.9	Form of Employee Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.11	10-K	March 7, 2019	000-20859
10.10	Form of Non-Employee Director Stock Option Agreement under 2018 Equity Incentive Plan*	10.4	8-K	May 18, 2018	000-20859
10.11	Form of Non-Employee Director Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.13	10-K	March 7, 2019	000-20859
10.12	Form of Performance-Vesting Stock Option Agreement under 2018 Equity Incentive Plan*	10.14	10-K	March 7, 2019	000-20859
10.13	Form of Performance-Vesting Stock Option Agreement under 2018 Equity Incentive Plan, as amended*	10.15	10-K	March 7, 2019	000-20859
10.14	2018 Inducement Award Plan, as amended February 16, 2022*				
10.15	Form of Stock Option Agreement under 2018 Inducement Award Plan*	10.2	8-K	December 14, 2018	000-20859

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
10.16	Form of Stock Option Agreement under 2018 Inducement Award Plan, as amended*	10.19	10-K	March 7, 2019	000-20859
10.17	Form of Performance-Vesting Stock Option Agreement under 2018 Inducement Award Plan*	10.20	10-K	March 7, 2019	000-20859
10.18	2014 Employee Stock Purchase Plan*	10.1	8-K	May 23, 2014	000-20859
10.19	Non-Employee Director Compensation Policy, as amended February 12, 2020*	10.24	10-K	March 11, 2020	000-20859
10.20	Non-Employee Director Compensation Policy, as amended February 16, 2022 and March 7, 2022*				
10.21	Directors' Market Value Stock Purchase Plan, effective October 1, 2018*	10.1	10-Q	November 1, 2018	000-20859
10.22	Amended and Restated Severance Plan, effective as of January 1, 2022*				
10.23	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
10.24	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
10.25	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
10.26	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
10.27	Employment Agreement between the Registrant and Aleksandra K. Rizo, effective as of January 15, 2019*	10.34	10-K	March 7, 2019	000-20859
10.28	Employment Agreement between the Registrant and Anil Kapur, effective as of December 2, 2019*	10.33	10-K	March 12, 2020	000-20859
10.29	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
10.30	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
10.31	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
10.32†	Loan and Security Agreement, dated September 30, 2020, amongst Registrant, Hercules Capital, Inc., and Silicon Valley Bank	10.1	10-Q	November 5, 2020	000-20859
10.33†	Amendment to Loan and Security Agreement, dated August 12, 2021, amongst Registrant, Hercules Capital, Inc., and Silicon Valley Bank	10.1	10-Q	August 16, 2021	000-20859
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 10, 2022				

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
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 10, 2022				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 10, 2022**				
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 10, 2022**				
101	The following materials from the Registrant's annual report on Form 10-K for the year ended December 31, 2021, formatted in Inline Extensible Business Reporting Language (iXBRL) include: (i) Balance Sheets as of December 31, 2021 and 2020, (ii) Statements of Operations, Comprehensive Loss, Stockholders' Equity and Cash Flows for each of the three years in the period ended December 31, 2021, 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 Statements (Form S-8, Nos. 333-239324 and 333-258864) 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, and
- 9) Registration Statement (Form S-8, No. 333-136330) pertaining to the 2002 Equity Incentive Plan and the 2006 Directors' Stock Option Plan;

of our report dated March 10, 2022, with respect to the financial statements of Geron Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/Ernst & Young LLP

Redwood City, California
March 10, 2022

**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 10, 2022

/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 10, 2022

/s/ OLIVIA 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, 2021 (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 10, 2022

/s/ JOHN A. SCARLETT

JOHN A. SCARLETT, M.D.

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

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

**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, 2021 (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 10, 2022

/s/ OLIVIA 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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