UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **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 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1220 Concord Avenue, Suite 600, Concord, California	**94520**
(Address of principal executive offices)	**(Zip Code)**

(925) 288-6000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	CERS	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
Preferred Share Purchase Rights
(Title of Class)

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 an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock listed on the Nasdaq Global Market, was $862 million. (1)

As of February 8, 2022, there were 173,721,524 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement in connection with the registrant's 2022 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year ended December 31, 2021 incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of $5.91 per share on June 30, 2021. Excludes 25.6 million shares of the registrant's common stock held by executive officers, directors and stockholders that the registrant has concluded were affiliates at June 30, 2021.

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For the Fiscal Year Ended December 31, 2021

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. The forward-looking statements are contained principally in Item 1, "Business," Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in Item 1A, "Risk Factors." These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These forward-looking statements may include, but are not limited to, statements about:

- ***the impact of the COVID-19 pandemic on our business and operations as well as the business or operations of our customers, manufacturers, research partners, and other third parties with whom we conduct business;***
- ***future sales of and anticipated demand for, and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT™ Blood System, including our ability to comply with applicable United States, or U.S., and foreign laws, regulations and regulatory requirements;***
- ***our ability to successfully complete the development of, receive regulatory approvals for and commercialize the red blood cell system as well as INTERCEPT Fibrinogen Complex, or IFC, pathogen reduced cryoprecipitate-poor plasma or other plasma-derived biological products using the INTERCEPT Blood System;***
- ***our strategy and the potential therapeutic applications for the INTERCEPT Blood System, including the potential of INTERCEPT-treated coronavirus convalescent plasma as a therapeutic or prophylactic treatment option for COVID-19 patients;***
- ***our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the U.S., as well as our ability to manage the risks attendant to our international operations;***
- ***the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions, including whether existing clinical data will be sufficient in order to obtain approval of our CE Mark submission for the red blood cell system;***
- ***our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System;***
- ***our ability to obtain adequate clinical and commercial supplies of the INTERCEPT Blood System from our sole source suppliers for a particular product or component they manufacture;***
- ***the initiation, scope, rate of progress, results and timing of our ongoing and proposed preclinical and clinical trials of the INTERCEPT Blood System;***
- ***the successful completion of our research, development and clinical programs and our ability to manage cost increases associated with preclinical and clinical development of the INTERCEPT Blood System;***
- ***the amount and availability of funding we may receive under our agreement with the Biomedical Advanced Research and Development Authority, or BARDA;***
- ***our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;***
- ***the ability of our products to inactivate the emerging viruses and other pathogens that we may target in the future, including SARS-CoV-2;***
- ***our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;***
- ***our estimates regarding the sufficiency of our cash resources, our ability to continue as a going concern and our need for additional funding; and***
- ***our plans, objectives, expectations and intentions and any other statements that are not historical facts.***

In some cases, you can identify forward-looking statements by terms such as "anticipate," "will," "believe," "estimate," "expect," "plan," "may," "should," "could," "would," "project," "predict," "potential," and similar expressions intended to identify such forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. There can be no assurance that any of the events anticipated by forward-

looking statements will occur or, if any of them do occur, what impact they will have on our business, results of operations and financial condition. Certain important factors could cause actual results to differ materially from those discussed in such statements, including the rate of customer adoption in the U.S. and our ability to achieve market acceptance of our products in the U.S. and international markets, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products or for product extensions or additional claims for our products, our ability to obtain reimbursement approval for our products, changes in regulatory approval requirements for our products, our ability to complete the development and testing of additional configurations or redesigns of our products, our need for additional financing and our ability to access funding under our agreement with BARDA, the impacts of regulation of our products by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fresenius Kabi AG and other third parties to manufacture and supply certain components of the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete our red blood cell system's commercial design, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002, and other factors discussed below and under the caption "Risk Factors," in Item 1A of this Annual Report on Form 10-K. We discuss many of these risks in this Annual Report on Form 10-K in greater detail in the section titled "Risk Factors" under Part I, Item 1A below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K completely. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise any forward-looking statements to reflect new information or future events, even if new information becomes available in the future. You should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Item 1A—Risk Factors" in Part I of this Annual Report on Form 10-K.

- The evolving effects of the COVID-19 pandemic have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which these effects will impact our future results of operations and overall financial performance remains uncertain.
- We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets, plasma and cryoprecipitation in the U.S., and our inability to successfully commercialize the INTERCEPT Blood System in the U.S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- The INTERCEPT Blood System may not achieve broad market adoption.
- We are exposed to risks associated with the highly concentrated market for the INTERCEPT Blood System.
- We may be unable to develop and maintain an effective and qualified U.S. based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our products in the U.S.
- We have no prior experience selling directly to hospitals or expertise complying with regulations governing finished biologics, and our inability to successfully commercialize the INTERCEPT Blood System for cryoprecipitation in the U.S would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- If our competitors develop products superior to ours, market their products more effectively, or receive regulatory approval before our products, our commercial opportunities could be reduced or eliminated.
- Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- The red blood cell system is currently in development and may never receive any marketing approvals.
- We expect to continue to generate losses. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur.

- Our company, our products, and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic and foreign authorities.
- If we or our third-party suppliers fail to comply with the U.S. Food and Drug Administration's, or FDA's, or other regulatory authorities' good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.
- If we modify our FDA-approved products, we may need to seek additional approvals, which, if not granted, would prevent us from selling our modified products.
- We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business.
- A significant portion of the funding for the development of the red blood cell system is expected to come from our BARDA agreement, and if BARDA were to eliminate, reduce or delay funding of our agreement, it would have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate our U.S. red blood cell development program or obtain alternative sources of funding.
- We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries.
- Our manufacturing supply chain exposes us to significant risks.
- We expect to continue to generate losses and we may never achieve a profitable level of operations.
- If we fail to obtain the capital necessary to fund our future operations or if we are unable to generate positive cash flows from our operations, we will need to curtail planned development or sales and commercialization activities.
- We operate a complex global commercial organization, with limited experience in many countries. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies. We may be distracted by expansion into new geographies where we do not have experience and we may be unsuccessful in monetizing such opportunities for the benefit of our organization at large.
- Risks associated with our operations outside of the United States could adversely affect our business.
- We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.

Item 1. *Business*

Overview

We are a biomedical products company focused on developing and commercializing the INTERCEPT Blood System to enhance blood safety. The INTERCEPT Blood System, which is based on our proprietary technology for controlling biological replication, is designed to reduce blood-borne pathogens in donated blood components intended for transfusion.

Our INTERCEPT Blood System is intended for use with blood components and certain of their derivatives: platelets, plasma, red blood cells and to produce IFC and pathogen reduced plasma, cryoprecipitate reduced. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals, including but not limited to FDA approval in the U.S., and Class III CE Marks in the European Union and other jurisdictions that recognize CE Mark approval, and are being marketed and sold in a number of countries around the world, including the U.S., certain countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East, and Latin America and selected countries in other regions of the world. Additionally, we have received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. In addition, the INTERCEPT Blood System for Cryoprecipitation is used to produce pathogen reduced plasma, cryoprecipitate reduced. We currently sell the platelet and plasma systems and the INTERCEPT Blood System for Cryoprecipitation using our direct sales force and through distributors and sell IFC or disposable kits to manufacture IFC in the U.S. using our direct sales force. If we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including in the U.S., we will have difficulties achieving profitability.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development. In the U.S., we are currently conducting two Phase 3 clinical trials - the RedeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional, un-treated, red blood cells and the ReCePI study to evaluate the efficacy and safety of INTERCEPT-treated red blood cells in patients requiring transfusion for acute blood loss during surgery. In Europe, we completed the

resubmission of our CE Mark application under the new Medical Device Regulation, or MDR, in June 2021; however, we do not expect an approval decision will occur for at least another 12 months, if ever.

Contribution margins from our sales is expected to be less than the cost of our operating expenses. In order to successfully commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products and product candidates, which, together with anticipated increased selling, general and administrative expenses, are expected to result in substantial operating losses. Accordingly, we may never achieve a profitable level of operations in the future.

We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Our wholly-owned subsidiary, Cerus Europe B.V., was formed in the Netherlands in 2006. Information regarding our revenues, net losses, and total assets for the last three fiscal years can be found in the consolidated financial statements and related notes found elsewhere in this Annual Report on Form 10-K.

Product Development

Background

The INTERCEPT Blood System is designed to broadly target and inactivate blood-borne pathogens, such as viruses (for example, HIV, West Nile, SARS, hepatitis B and C), bacteria and parasites, as well as potentially harmful white blood cells, while preserving the therapeutic properties of platelet, plasma, red blood cell and IFC transfusion products. The INTERCEPT Blood System has been shown to inactivate a broad array of pathogens and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective, is not available or is not performed. We believe that the INTERCEPT Blood System also has the potential to inactivate most new pathogens before they are identified and before tests are developed and adopted commercially to detect their presence in donated blood.

Products, Product Candidates and Development Activities

The following table identifies our products, product candidates and product development activities and their current status:

Product or Product Candidate Under Development	Product or Development Status
INTERCEPT Blood System—Platelets	• Commercialized in the U.S., Canada and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world • Refiling for CE Mark under MDR commenced in 2021 • Completed of U.S. post-approval haemovigilance study in 2021
INTERCEPT Blood System—Plasma	• Commercialized in the U.S. and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world • Refiling for CE Mark under MDR commenced in 2021 • Received FDA approval of the premarket approval supplement, or PMA, to produce IFC in 2020
INTERCEPT Blood System—Red Blood Cells	• U.S. Phase 3 clinical trial, known as the RedeS study, enrolling patients • U.S. Phase 3 acute anemia clinical trial, known as the ReCePI study, enrolling patients • Additional U.S. studies also planned • European Phase 3 acute anemia clinical trial completed in 2014; European Phase 3 chronic anemia clinical trial completed in 2017 • CE Mark under MDR submitted in 2021
INTERCEPT Blood System—Cryoprecipitation	• FDA approval in November 2020 • U.S. agreement with certain blood center manufacturing partners • Limited commercialization in the U.S.

INTERCEPT Blood System for Platelets, Plasma and Cryoprecipitation

The platelet system and plasma system are designed to inactivate blood-borne pathogens in platelets and plasma donated for transfusion. Both systems received CE Mark approval in Europe and FDA approval in the U.S. and are currently marketed and sold in a number of countries around the world including the U.S., Europe, the CIS, the Middle East and selected countries in other regions of the world. Separate approvals for use of INTERCEPT-treated platelet and plasma products have been obtained in France and Switzerland. In Germany and Austria, where approvals must be obtained by individual blood centers for use of INTERCEPT-treated platelets and plasma, several centers have obtained such approvals for use of INTERCEPT-treated platelets and one center has obtained such approval for use of INTERCEPT-treated plasma. Many countries outside of Europe accept the CE Mark and have varying additional administrative or regulatory processes that must be completed before the platelet system or plasma system can be made commercially available. In general, these processes do not require additional clinical trials. Regardless, some potential customers may desire to conduct their own clinical studies before adopting the platelet system or plasma system. European Union regulators have enacted legislation that requires all medical devices to comply with new MDR. We received extensions for our platelet and plasma systems to comply with such regulations until 2024. However, our platelet and plasma systems will need to be reapproved under the MDR prior to the expiration of the Medical Device Directive, or MDD, extension. The FDA has approved the platelet system for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in 100% plasma or InterSol in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease. In 2021, we completed one of the two post-approval studies that FDA required as part of its approval of the platelet system - a haemovigilance study evaluating the incidence of acute lung injury following transfusion of INTERCEPT-treated platelets. We have submitted the final report to the FDA and are waiting for FDA to inform us if we will be required to perform additional studies. The second required post-approval study - a recovery study of platelets treated with the platelet system - is currently in progress. The FDA has also approved the plasma system for ex vivo preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

We have also received FDA approval for the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce pathogen reduced plasma, cryoprecipitate reduced.

We expect our commercial efforts in 2022 will continue to largely be focused on enabling blood centers that are using INTERCEPT to increase the number of platelet and plasma units produced and made available to patients. In addition we plan to sell the INTERCEPT Blood System for Cryoprecipitation to certain blood center customers and to sell IFC to hospital customers. In addition, we will continue to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. To enable broader patient access to IFC in the U.S., U.S.-based blood centers need to complete process validations and obtain site-specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, before IFC can be made available to hospital customers outside of the state of IFC production. We have contracted with several blood centers to produce IFC for us which we plan to sell directly to hospitals. All of the blood centers that we have contracted with to produce IFC for us have submitted for their interstate licenses, or BLAs. Until BLAs are more broadly obtained by our IFC manufacturing partners, we expect that our direct sales of IFC will be limited. Further, the hospital customers of blood centers may need to complete changes to their administrative processes of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories prior to receiving INTERCEPT-treated components. In addition, we estimate that the majority of platelets used in the U.S. are collected by apheresis, which is part of our FDA-approved label for the platelet system, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. While available in Europe and other regions around the world, in order to gain FDA approval for a pathogen reduction system compatible with triple dose collections and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials, and will need to obtain FDA approval of a PMA supplement. We do not currently have plans to pursue these configurations. In addition, we may pursue development projects for other plasma derived biological products, which may require the submission and approval of additional PMA supplements for the plasma system. These development activities will be costly and may not be successful should we choose to pursue them. Our failure to seek and obtain FDA and foreign regulatory approvals of new configurations could limit revenues from sales of our products.

INTERCEPT Blood System for Red Blood Cells

The red blood cell system is designed to inactivate blood-borne pathogens in red blood cells intended for transfusion. We completed a series of *in vitro* and *in vivo* tests with the red blood cell system, including successfully completing recovery and survival studies measuring red cell recovery twenty-four hours after transfusion. Previously, we terminated Phase 3 clinical trials for acute and chronic anemia using a prior generation of the red blood cell system due to the detection of antibody reactivity to INTERCEPT-treated red blood cells, or RBCs, in two patients in the trial for chronic anemia. The antibody eventually cleared and the subjects had no adverse health consequences. After unblinding the data from the original Phase 3 clinical trials, we found that we had met the primary endpoint in the clinical trial for acute anemia. We evaluated the antibodies detected and developed process changes to diminish the likelihood of antibody reactivity in RBCs treated with our modified process. We have since successfully completed Phase 3 clinical trials of the red

blood cell system for subjects with acute and chronic anemia patients to support a CE Mark submission. We filed our application for CE Mark approval of the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the resubmission of our CE Mark application under the new MDR. However, we do not expect an approval decision will occur for at least another 12 months, if ever. See also the risk factor entitled "*The red blood cell system is currently in development and may never receive any marketing approvals" under "Item 1A—Risk Factors*" of this Annual Report on Form 10-K for additional information with respect timing of the ultimate approval decision on our CE Mark application.

We previously completed a European Phase 3 clinical trial of RBCs treated with the INTERCEPT Blood System for acute anemia in cardiovascular surgery subjects announced that the trial met its primary endpoint, with preliminary analysis demonstrating that the mean hemoglobin content (53.1g) of INTERCEPT-treated RBCs, on day 35 of storage met the protocol-defined criteria for equivalence based on the inferiority margin of 5g compared to conventional RBCs (55.8g). The randomized, double-blind, controlled, multi-center Phase 3 clinical trial of the red blood cell system evaluated the efficacy of the red blood cell system to process RBCs with quality and mean hemoglobin content (>40 g) suitable to support transfusion according to the European Directorate for the Quality of Medicines. The blood components were transfused to 51 cardiovascular surgery subjects at two German clinical trial sites to evaluate transfusion efficacy and overall safety. There were no clinically relevant trends in severe or serious treatment related adverse events by system organ class. The observed adverse events were within the expected spectrum of co-morbidity and mortality for subjects of similar age and with advanced cardiovascular diseases undergoing cardiovascular surgery requiring red cell transfusion. No subjects exhibited an immune response to INTERCEPT-treated RBCs. Additionally, we previously announced that the European Phase 3 clinical trial of chronic anemia evaluating INTERCEPT-treated RBCs in thalassemia subjects met its primary efficacy and safety endpoints. Regardless of the potential sufficiency of clinical data required to receive CE Mark approval, we understand that we will need to generate additional safety data from commercial use in order to achieve broad market acceptance, if ever approved.

In the U.S., we successfully completed a Phase 2 recovery and lifespan study. Subsequently, we initiated a double-blind Phase 3 clinical study, known as the RedeS study, to assess the safety and efficacy of INTERCEPT-treated RBCs when compared to conventional RBCs in regions impacted by the Zika virus epidemic. The RedeS study was expanded to other areas at risk for transfusion-transmitted infections due to the Zika virus, including Texas, Virginia and Florida. The FDA has agreed to modify the criteria for a clinical pause if we see three or more treatment emergent antibodies with amustaline specificity without evidence of hemolysis in patients receiving INTERCEPT-treated RBCs in our RedeS study. We will now be allowed to continue study enrollment for the RedeS study while we investigate the clinical significance of the antibodies. If we determine that there is no clinical significance and no impact on patients, then there will be no impact on study enrollment. If treatment emergent antibody reactions associated with hemolysis are observed in any of our Phase 3 trials, the FDA will require us to place a clinical hold and we will need to investigate the underlying cause. Such investigations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product's reputation and may force us to suspend or terminate development activities related to the red blood cell system in the U.S., which would have a material adverse effect on our business and business prospects. The trial has been further expanded to include a 6-month chronic phase for subjects requiring simple repeat transfusions and also to include up to thirty patients with Sickle Cell Disease requiring red cell exchange. Subjects that would qualify for inclusion into the chronic phase would be those with conditions such as Sickle Cell Disease, Thalassemia or Myelodysplasia. This expansion of study population requires the inclusion of additional sites beyond the nine currently engaged in the trial up to fifteen. RedeS is a double-blind, controlled, parallel group study where up to 800 subjects will be randomized to receive either 28 days, or 28 days plus 6 months of transfusion support with INTERCEPT-treated RBCs or conventional RBCs, with a primary endpoint of hemoglobin increment following transfusion. These data from the expanded RedeS study will support our chronic use assessment in our submission for approval to the FDA. In a second optional stage B that will only be initiated after the completion of the current study, up to 20,000 patients would receive RBC transfusion support with up to 50,000 RBC units in an open-label, single-arm treatment use study. We also received investigational device exemption, or IDE, approval from the FDA to initiate a Phase 3 clinical trial, known as the ReCePI study, that is designed to evaluate the efficacy and safety of INTERCEPT-treated RBCs in patients requiring transfusion for acute blood loss during surgery. Up to 600 subjects are expected to be transfused in up to 19 participating sites in the U.S. Subjects will be randomized on a 1:1 basis either to the treatment arm transfused with RBCs treated with or to the control arm transfused with conventional RBCs. The primary efficacy endpoint is the proportion of subjects experiencing acute kidney injury as an assessment of RBC efficacy in providing tissue oxygenation, measured as an increase in serum creatinine compared to pre-surgery, baseline levels within 48 hours after the surgery. Enrollment in the ReCePI study is underway at several sites and is expected to expand to as many as 19 sites. Enrollment in the ReCePI study began in 2019. Both RedeS and ReCePI trials have seen significant delays in subject recruitment due to COVID-19. Several participating institutions implemented policies that limited clinical research activities and some eligible subjects have rejected participation because of the need for follow up. Furthermore, some study sites have withdrawn from study participation. Additionally, delays in progressing new site commitments to participate in the trials have been seen due to hospital clinical research staff reductions and institutional commitments to COVID-19 related activities. The RedeS and ReCePI studies are being funded as part of our agreement with BARDA. In addition to successfully conducting and completing the RedeS and ReCePI studies, we also understand that one or more additional *in vitro* studies will be required to be successfully completed and submitted to the FDA before the FDA will consider our red blood cell product for approval. Should the current COVID-19 pandemic persist or resurge in areas where we are enrolling patients, our ability to complete the clinical trials timely, or at all, may be jeopardized.

Additional information regarding our interactions with the FDA, our CE Mark approval process in Europe for the red blood cell system, and potential future clinical development of the INTERCEPT Blood System in Europe and in the U.S. can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factors titled *"Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects"* and *"The red blood cell system is currently in development and may never receive any marketing approvals," as well as generally under the heading "Risks Related to Regulatory Approval and Oversight, and Other Legal Compliance Matters."*

INTERCEPT Blood System Technology

Both our platelet system and plasma system employ the same technology. Platelet or plasma components collected from blood donors are transferred into plastic INTERCEPT disposable kits and are mixed with our proprietary compound, amotosalen, a small molecule compound that has an affinity for nucleic acid.

The disposable kits are then placed in an illumination device, or illuminator, where the mixture is exposed to ultra-violet A, or UVA, light. If pathogens such as viruses, bacteria or parasites, as well as leukocytes, or white cells, are present in the platelet or plasma components, the energy from the UVA light causes the amotosalen to bond with the nucleic acid. Since platelets and plasma do not rely on nucleic acid for therapeutic efficacy, the INTERCEPT Blood System is designed to preserve the therapeutic function of the platelet and plasma components and IFC when used in human transfusions.

The ability of amotosalen to form both cross-links between strands of nucleic acid and links to single nucleic acid strands results in a strong chemical bond between the amotosalen and the nucleic acid of the pathogens. The presence of these bonds is designed to prevent replication of the nucleic acid within pathogens, effectively inactivating the pathogens. A high level of inactivation has been demonstrated in a broad range of pathogens studied by us and others in laboratory testing. For instance, INTERCEPT has demonstrated inactivation of a number of single stranded nucleic acid-based viruses such as HIV, hepatitis B, hepatitis C (using a model virus), West Nile, chikungunya and certain influenza viruses.

Following the inactivation process, residual amotosalen and by-products are reduced by more than 99% through use of a compound adsorption device, which is an integrated component of the disposable kit. We have performed extensive toxicology testing on the residual amotosalen and its by-products and good safety margins have been demonstrated. Any remaining amotosalen which may be transfused, should any exist, is rapidly excreted by humans.

Leukocytes, also known as white blood cells, are typically present in platelet and plasma components collected for transfusion and can cause adverse transfusion reactions as well as an often fatal disease called graft-versus host disease. Leukocytes, like pathogens, rely on nucleic acid for replication and cellular function. The INTERCEPT Blood System, with its combination of the amotosalen and UVA light, is designed to inactivate leukocytes in the same manner it inactivates pathogens.

Like the platelet and plasma systems, the red blood cell system is designed to prevent pathogen replication by using a small molecule additive compound to form bonds with nucleic acid in pathogens that may be present in donated red blood cell collections. The red blood cell system is designed to preserve the therapeutic qualities of the red blood cells, which, like platelets and plasma, do not rely on nucleic acid for their therapeutic efficacy. The red blood cell system uses another of our proprietary compounds, amustaline. Unlike the platelet and plasma systems, the chemical bonds from amustaline are not triggered by UVA light, but instead, by the pH level of the red blood cell components. After mixture with the red blood cell components in plastic disposable kits and resulting nucleic-acid bonding, amustaline is designed to rapidly break down into a form that is no longer chemically reactive with nucleic acid. As with the platelet and plasma systems, a high level of inactivation in a broad range of pathogens has been demonstrated with the red blood cell system in the clinical setting. We plan on conducting additional pathogen-inactivation studies of the red blood cell system, broadening our understanding of the pathogens the system may be able to inactivate.

By treating blood components with INTERCEPT within a day of collection, the inactivation of bacteria prevents bacterial growth that could create increased risk of inflammatory response or dangerous levels of endotoxins. Extensive clinical testing has been done on platelet and plasma products treated with the INTERCEPT Blood System, as well as post-marketing haemovigilance studies of the treated blood products in routine use.

We believe that, due to their mechanisms of action, the platelet system, plasma system, and red blood cell system will potentially inactivate blood-borne pathogens that have not yet been tested with our systems, including emerging and future threats to the blood supply. We do not claim, however, that our INTERCEPT Blood System will inactivate all pathogens, including prions, and our inactivation claims are limited to those contained in our product specifications. There can also be no assurance that INTERCEPT will inactivate even those pathogens where claims exist, in every instance or under every processing condition.

Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the illuminators, disposable kits and inactivation compounds that make up the INTERCEPT Blood System for use in clinical trials and for commercialization. We rely solely on Fresenius Kabi AG, or Fresenius, for the manufacture of disposable kits for the platelet and plasma systems and rely on other contract manufacturers for the production of our reagents, inactivation compounds, compound adsorption components of the disposable kits, illuminators and other disposable kits or disposable accessories used in the INTERCEPT Blood System. We currently do not have alternate manufacturers for many of the components in our products or product candidates beyond those that we currently rely on, but we are currently in the process of identifying potential alternate manufacturers for several components, reagents and compounds. Under our amended and restated manufacturing and supply agreement we entered into with Fresenius in October 2015, together with amended pricing in December 2020, Fresenius is obligated to sell, and we are obligated to purchase, finished disposable kits for our platelet, plasma and red blood cell systems. The agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. The term of the agreement with Fresenius extends through July 1, 2025, and will automatically renew for successive two-year periods unless terminated by either party upon two years' prior written notice, in the case of the initial term, or one year prior written notice, in the case of any successive renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach. Pricing under the agreement was established through 2021, and, therefore beginning in 2022 pricing be determined upon by both parties or calibrated off of the pre-existing prices using a price index for the remainder of the initial term.

Components of the compound adsorption devices used in our platelet and plasma disposable kits are manufactured by Porex Corporation, or Porex. In April 2017, we entered into an amended and restated manufacturing and supply agreement with Porex for the continued supply of the compound adsorption devices. Porex is our sole supplier for certain components of and manufacturing of the compound adsorption devices. Under the amended and restated Porex agreement, we are no longer subject to a minimum annual purchase requirement; however, Porex has the right to terminate the agreement, upon twelve months' prior written notice, if annual production falls below a mutually agreed threshold. The amended and restated Porex agreement was renewed in December 2021 and will continue until December 31, 2024. Although we are actively seeking to develop alternative manufacturers and components, commercially viable alternatives are likely several years away.

We also have an amended and restated supply agreement with Purolite LLC, formerly Purolite Corporation, or Purolite, for the supply of raw materials used to make the compound adsorption devices. The amended supply agreement expires in April 2023, and will automatically renew for an additional year unless either party has provided notice not to renew at least two years prior to the expiration. Neither party has delivered notice of its intent to terminate the agreement. Under the terms of the amended agreement, pricing is volume based and is subject to annual, prospective adjustments based on a Producer Price Index subject to an annual cap.

Pursuant to a contract that we and Nova Biomedical Corporation, or Nova, entered into in September 2008, Nova has been manufacturing the current model of illuminators for us. In July 2021, we received notice from Nova that it does not intend to renew the agreement for an additional year and as a result, our Nova agreement will expire in September 2022. Nova is currently completing a last time build of our current model illuminator, which is being phased out of manufacture due to obsolescence of certain components. As a result, we do not intend to continue manufacturing the current model illuminator. We are currently redesigning the illuminator which is expected to take more than twelve months to complete and obtain regulatory approval. Until such time as we obtain approval for the redesigned illuminator, if ever, the demand for illuminators may be higher than the remaining number of illuminators in inventory, resulting in possible customer allocations or loss of sales.

We operate with an amended manufacturing and supply agreement with Ash Stevens, Inc., or Ash Stevens, for the synthesis of amotosalen, the inactivation compound used in our platelet and plasma systems. Under this amended agreement, we are subject to minimum annual purchase requirements. We have also incurred these maintenance fees in the past. The term of the amended manufacturing and supply agreement with Ash Stevens will expire on December 31, 2023, and will continue to automatically renew for successive two-year periods, unless terminated by either party upon providing at least one year prior written notice, in our case, or at least two years prior written notice, in the case of Ash Stevens. Neither party has delivered notice of its intent to terminate the agreement.

We and our contract manufacturers purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound adsorption devices and UVA illuminators from a limited number of suppliers. Some of those raw material suppliers require minimum annual purchase amounts. While we believe that there are alternative sources of supply for such materials, parts and devices, we have not validated or qualified any alternate manufacturers. As such, establishing additional or replacement suppliers for any of the raw materials, parts and devices, if required, will likely not be accomplished quickly and could involve significant additional costs and potential regulatory reviews that could limit our ability to supply customer demand.

Certain regions that we sell into or may sell into in the future may give priority to those products that are manufactured locally in their jurisdiction. Our failure to meet these local manufacturing conditions may prevent us from successfully commercializing our product in those geographies. In addition, should we choose to manufacture locally in those jurisdictions, we would likely incur additional costs, may be unable to meet our quality system requirements or successfully manufacture products, and such activities will be a distraction from our current focus and operations. We have limited experience managing local manufacturing or working with local manufacturers in geographies or jurisdictions outside of our existing manufacturing operations.

Marketing, Sales and Distribution

The market for the INTERCEPT Blood System, including the U.S. market, is dominated by a relatively small number of blood collection organizations. Accordingly, there may be an extended period during which some potential U.S.-based customers may first choose to validate our technology or run experience studies themselves before deciding to adopt the system for commercial use, which may never occur. On October 1, 2021, all U.S. blood centers had to be compliant with the FDA guidance document, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U.S. blood centers for compliance under the Final Guidance Document, we cannot predict if U.S. customers will continue to adopt INTERCEPT over other options or at what levels.

The American Red Cross represents the largest single portion of the blood collection market in the U.S. and is one of our key customers. While we believe adoption of the INTERCEPT Blood System will afford the American Red Cross with many benefits, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make.

Furthermore, the U.S. blood banking market is undergoing consolidation which may continue and further concentrate the potential customer base. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. The largest European markets for our products are in Germany, France, and England.

In Germany, decisions on product adoption are made on a regional or blood center-by-blood center basis. While our obtaining CE Mark approval allows us to sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute, or PEI, a German governmental regulatory body overseeing the marketing authorization of certain medical products, before being allowed to sell platelet and plasma components treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, several blood centers in Germany have received such requisite approvals and authorizations for the platelet system. Given the competitive nature of the German blood banking market, pricing for blood components is relatively low compared to other markets. INTERCEPT-treated platelets received national reimbursement in Germany in 2018 at a premium to untreated platelets. While this dynamic has the potential to generate economic value for blood centers in Germany, we cannot ensure that blood centers will understand or act on the potential economic and logistical benefits of using INTERCEPT compared to conventional blood components as well as the potential safety benefits of INTERCEPT-treated blood components. Following the inclusion of pathogen-inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using the INTERCEPT Blood System. The review period for a new MAA can be twelve months or longer following submission and we cannot predict which German customers or potential customers will obtain an MAA. Without broad approvals of MAA applications obtained by potential German customers, our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect the potential for growth in that region. In addition, the reimbursement awarded to INTERCEPT in Germany may not be considered by German blood centers as attractive enough to implement pathogen reduction or cover the entirety of their blood center platelet collections which may in turn limit the market acceptance in Germany. We do not yet know if or how German blood centers plan to market and sell to their hospital customers nor do we have the ability to influence and control implementation in hospitals in Germany to administer pathogen-reduced platelets. Should German blood centers be ineffective in marketing and selling INTERCEPT-treated platelets or if hospitals object, or are slow implementing the steps needed to procure and administer pathogen reduced platelets, our market in Germany may be limited or be slow to realize acceptance.

In France, broad product adoption is dependent on a central decision by the Établissement Français du Sang, or EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France. In October 2021, we entered into a new agreement with EFS to supply platelet disposable kits. The agreement for supply of platelet disposable kits provides for a base term of two years, with two options for EFS to extend for one year each. In January 2020, we entered into a new agreement with EFS to supply plasma disposable kits and maintenance services for illuminators for a base term of two years, with two options for EFS to extend for one year each. EFS exercised the first option in September 2021. While EFS has standardized production of its platelets using the INTERCEPT Blood System, we cannot provide any assurance that the national deployment of INTERCEPT to treat platelets in France will be sustainable, or that we will be able to secure any subsequent contracts with EFS or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contracts. If we are

unable to continue to successfully support EFS' national adoption of the INTERCEPT Blood System for platelets, EFS' use of the INTERCEPT Blood System for Plasma or the final commercial terms of any subsequent contract for platelet or plasma disposable kits are less favorable than the terms under our existing contracts, our financial results may be adversely impacted.

In England, decisions on product adoption are centralized in the National Blood Service, or NHSBT, which collects, tests, processes and supplies blood products to hospitals in England and North Wales. The National Blood Service has implemented and used bacterial detection for platelets for the past several years instead of pathogen inactivation. We do not know when, if ever, the NHBST will consider adoption of a product for pathogen reduction, including INTERCEPT.

In Japan, the Japanese Red Cross controls a significant majority of blood centers and exerts a high degree of influence on the adoption and use of blood safety measures. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. Before the Japanese Red Cross considers our products, we understand that we may need to complete certain product configuration changes, which may not be economically or technologically feasible for us to complete.

The FDA has granted Breakthrough Device Designation and has since approved the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce the derivative product, pathogen reduced plasma, cryoprecipitate reduced. We have entered into manufacturing agreements with certain blood centers to produce IFC for us. In addition, we have entered into agreements with certain blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation. In order to successfully commercialize IFC, we will need to influence the market and sell directly to hospital users and blood center producers of cryoprecipitate and have begun to add resources to our existing commercial teams to commercialize IFC. We do not know if IFC will be perceived as economically attractive to hospital customers or at what price, if any, or if the investment needed to sell IFC will be sustainable. Should our sale of kits to produce IFC alienate our contracted manufacturing partners, it may put pressure on the pricing for IFC in the marketplace or limit commercialization of IFC in the U.S.

Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of coverage and adequate reimbursement from governments, managed care payors, such as insurance companies, and/or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT-treated blood products. We understand that due to the COVID-19 pandemic, many hospitals have consolidated, laid off workers or have filed for bankruptcy protection, and other hospitals may have such significant budget shortages that they are unable to afford pathogen-reduced blood components. In addition, some hospitals are seeing such a high influx of COVID-19 cases, that, regardless of whether they have sufficient staff to handle the high case load, they may be unable or unwilling to allocate sufficient resources to implement a new technology such as INTERCEPT. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the federal and, in some cases, state levels, regulators, healthcare facilities and third-party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, commercial use of our products may not be covered by governmental or commercial third-party payors for health care services and may never be covered. Even if we received national reimbursement for our products, we may not be able to convince blood center customers to change their operating practices and produce INTERCEPT-treated platelets and plasma. In the U.S., we obtained HCPCS reimbursement codes for hospital outpatient billing and payment of INTERCEPT-treated platelets and plasma in 2015, and for IFC and the derivative, pathogen-reduced plasma, cryoprecipitate reduced in 2021. We cannot guarantee that the HCPCS codes for our products will be assigned payment rates in amounts sufficient to cover the cost of our products to hospital customers.

The costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third-party payors, the costs and expenses specific to the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. Governmental or third-party payors may change reimbursement rates, year over year, or in reaction to submitted claims for reimbursement of costs and expenses related to blood components treated with INTERCEPT. If the costs to the hospital for INTERCEPT processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, or if reimbursement rates are insufficient or decreased in any given year for blood components treated with INTERCEPT, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products.

We maintain a wholly-owned subsidiary, Cerus Europe B.V., headquartered in the Netherlands, which focuses its efforts on marketing and selling the INTERCEPT Blood System in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world. We have a small scientific affairs group in the U.S. and the Netherlands that supports our commercialization efforts as well as hospital affairs professionals, to help educate hospitals and physicians on our products, clinical trial history and publications. We have a small group of individuals to which we may add to in the future to market and sell IFC in the U.S. We have a small number of employees focused on servicing the markets in Asia-Pacific and Latin American regions and rely primarily on distributors to market and sell our products in those regions.

In February 2021, we entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd., or ZBK, to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD., which we refer to as the JV, for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood transfusion for platelets and red blood cells in the People's Republic of China. We own 51% of equity in the JV. The JV will need to obtain regulatory approval for the INTERCEPT Blood System for platelets and red blood cells before it can begin commercializing in China. In order to obtain that regulatory approval, the JV may need to run additional clinical studies in China. We cannot assure you the JV will be successful in meeting the endpoint, once defined, or that it will ever receive regulatory approval.

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our products directly. In certain of these jurisdictions, we rely on these distributors to obtain any necessary in-country regulatory approvals, in addition to marketing and selling the INTERCEPT Blood System, providing customer and technical product support, maintaining inventories, and adhering to our quality system in all material respects, among other activities. Selected areas where we have entered into geographically exclusive distribution agreements include but are not limited to certain countries in the CIS, Italy, the Middle East, Latin America, South Africa and Southeast Asia. Our success in these regions is dependent on our ability to support our distributors and our distributors' ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements contribute a significant amount of our revenues. As such, declining performance or the outright termination or loss of certain distributor relationships could harm our existing business, may impact our growth potential, and could result in higher operating costs for us. As our distributors play a critical role in our commercialization efforts, we evaluate their performance on an ongoing basis. As we continue to evaluate our distributors, we may take further actions in the future which may have an impact on our operating results. In the past, we have transitioned certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors as well as transitioned some of these territories to a Cerus direct option for EFS to extend for one year each sales effort, which we believed would provide us with better visibility into and control of sales execution. We may undertake similar changes in the future. As a result, we may experience a decrease in the volume of INTERCEPT disposable kit sales for the impacted territories as outgoing distribution partners sell through their disposable kit inventory. In addition, any new distributors or our own direct sales force may require some time to develop the market with the same proficiency as previous distributors. We cannot provide assurance that any such changes will achieve the same level of operations or proficiency as previous distributors.

Government Contracts

We operate directly under two contracts with U.S. Federal Agencies, one with BARDA and another with the FDA. Revenue from the cost reimbursement provisions under our government contracts varies by year. A portion of our government contract revenue is subject to renegotiation of reimbursement rates or termination of the contract at the election of the U.S. government. In addition, U.S. government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion. Generally, government contracts, including our agreements with BARDA and the FDA, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. See Note 2 in the Notes to Consolidated Financial Statements under "Item 15—Financial Statement Schedules—Financial Statements" of this Annual Report on Form 10-K for information on significant accounting policies related to our government contract revenue and other financial information for the years ended December 31, 2021, 2020 and 2019. Further discussion of the factors impacting our government contracts revenue and the related impact on our ability to operate our business can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factors titled "*A significant portion of the funding for the development of the red blood cell system is expected to come from our BARDA agreement, and if BARDA were to eliminate, reduce, delay, or object to extension for funding of our agreement, it would have a significant, negative impact on our government contract revenues and cash flows, and we may be forced to suspend or terminate our U.S. red blood cell development program or obtain alternative sources of funding*" and *"Unfavorable provisions in government contracts, including in our contract with BARDA, may harm our business, financial condition and operating results."*

Competition

Our products face a wide variety of competition from entities competing directly with alternative pathogen reducing technologies for platelets and/or plasma, as well as from entities developing and selling diagnostic screening products to detect and prevent contaminated products from being transfused, and from process and procedural decisions involving blood banking operations including but not limited

to shortened shelf-life of blood components. Many of our competitors have mature, well-established products or have other products which are sold to U.S. based blood centers and many have more commercial resources than we do. In addition, competitors may choose to seek a lower class of approval than our products, which may be easier and less costly for them to maintain and may be perceived as sufficient by the marketplace. We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen reduction methods that are either on the market or known to us to be in development. The INTERCEPT Blood System is designed for use in blood centers, which allows for integration with current blood collection, processing and storage procedures. Certain competing products currently on the market, such as solvent detergent-treated plasma, use centralized processing that takes blood products away from the blood center in order to be treated at a central facility before being shipped back out to the blood centers or hospitals for ultimate transfusion, which may result in higher costs.

Our INTERCEPT Blood System for cryoprecipitation competes with traditional cryoprecipitate, a by-product of thawing frozen plasma and with human derived fibrinogen concentrates. While we believe that IFC has many advantages over competitors, traditional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Hospitals may not perceive the advantage of IFC over the competing products, we may be ineffective in selling biological agents directly to hospitals or be unable to convince hospitals of the economic or patient advantages relative to the competitors.

In Europe, several companies, including Grifols, Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has been issued Class II CE Marks for such system for both platelets and plasma and received Swissmedic approval for platelets. MacoPharma has received a CE Mark for a UVC-based pathogen reduction product for platelets. MacoPharma completed a Phase 3 clinical trial in Germany to generate additional data for expanded approvals. We understand that Terumo BCT also developed a pathogen reduction system for whole blood receiving a Class II CE Mark. Each of these companies' products may offer competitive advantages over our INTERCEPT Blood System.

In the U.S., INTERCEPT-treated plasma faces competition from Octapharma AG, which is currently commercializing treated fresh frozen plasma for certain indications in the U.S., as well as from diagnostic and testing companies currently approved for the detection of pathogens in donated blood products, including bacterial and viral pathogens. Our platelet product faces competition from a number of diagnostic and testing companies currently approved for the detection of pathogens including bacterial and viral pathogens in donated blood products and may face competition from other technologies if approved.

Terumo BCT's platelet, plasma or whole blood pathogen reduction product may be viewed as favorable by the Japanese Red Cross. Terumo Corporation is a large Japan-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo's resources and their pre-existing relationships with regulators and customers. Should Terumo BCT's product be approved for use and commercialized in Japan, we would likely directly compete with them and we believe we would likely need to either establish operations in Japan or partner with a local Japanese company.

We believe that the primary competitive factors in the market for pathogen reduction of blood products include the breadth and effectiveness of pathogen reduction processes, the amount of demonstrated reduction in transfusion related adverse events subsequent to adopting pathogen reduction technology, robustness of treated blood components upon transfusion, the scope and enforceability of patent or other proprietary rights, perceived product value relative to perceived risk, product supply, perceived ease of use, perception of safety, efficacy and economics of pathogen reduction systems, and marketing and sales capability. In addition, we believe the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval are also important competitive factors. We believe that the INTERCEPT Blood System will compete favorably with respect to these factors, although there can be no assurance that it will be able to do so. Our success will depend in part on our ability to convince prospective customers of the benefits of and need to adopt pathogen reduction technology and specifically our system relative to other technologies, our ability to obtain and retain regulatory approvals for our products, and our ability to continue supplying quality and effective products to our customers and prospective customers.

Patents, Licenses and Proprietary Rights

Our commercial success will depend in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2021, we owned 10 issued or allowed U.S. patents and approximately 80 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2022 and 2038. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2022 and 2024. Due to the complexity of our products, we believe it is the protection afforded to our products by the portfolio of intellectual property rights that best protect our proprietary system rather than any one particular patent or trade secret.

Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S.

We are aware of an expired U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages. Further discussion of the factors impacting our intellectual property and the related impact on our ability to operate our business can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled "*We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.*"

Seasonality

Our business is dependent on the marketing and commercialization of the INTERCEPT Blood System to customers such as blood banks, hospitals, distributors and other health care providers that have a need for a pathogen reduction system to treat blood products for transfusion. Since we have not experienced purchasing patterns from our customers based on seasonal trends, we do not expect seasonality to have a material effect on our business, although purchasing patterns and inventory levels can fluctuate.

Inventory Requirements and Product Return Rights

Our platelet and plasma disposable kits have received regulatory approval for shelf lives ranging from 18 to 24 months. Our INTERCEPT Blood System for Cryoprecipitation has received regulatory approval for a shelf life of 12 months. Illuminators and replacement parts do not have regulated expiration dates. We own raw materials, work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these finished goods and separately, components, held as work-in-process on our consolidated balance sheets, may potentially take over one year to sell or complete production before being utilized in finished disposable kits or illuminators. We maintain inventory based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory would be used for production within the next 12-month period and evaluate our finished units in order to sell to existing and prospective customers within the next 12-month period. Except for illuminators and obsolete raw materials and components, it is not customary for our production cycle for inventory to exceed twelve months. Instead, we use our best judgment to factor in lead times for the production of our finished units to meet our current demands. Occasionally, we make last-time-buys of certain components or raw materials when such components or raw materials are considered at risk of becoming obsolete which allows us to ensure continuity of production and sufficient time to develop or identify, qualify and secure alternate raw materials or components. Inventory is recorded at the lower of cost, determined on a first in, first out basis, or market value. We use judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. We rely on our direct sales team and distributors to provide accurate forecasts of sales in their territory. If our forecasts or those of our distributors are inaccurate, we could face backlog situations or conversely, may produce and carry an abundance of inventory that would consume cash faster than we have currently planned. Generally, we write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use to net realizable value in the period that it is first recognized, by using a number of factors, including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods.

We sell the INTERCEPT Blood System directly to blood banks, hospitals, universities, and government agencies, as well as to distributors in certain regions. Generally, our contracts with our customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. We plan to sell IFC directly to hospitals and may use a consigned inventory model whereby unused product at the hospital at expiration is replaced with fresh product at reduced to no cost to the hospital. We have also entered into agreements with certain blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation for their production of IFC and sale to their hospital customers. We may encounter pricing challenges and competition between the direct to hospital sales model and kit sale to blood center model.

Research and Development Expenses

A significant portion of our operating expenses is related to research and development and we intend to maintain a balanced yet strong commitment to our research and development efforts. As we look ahead, we anticipate that the regulatory submission processes related to potential PMA supplements for the platelet and plasma systems or post market approval requirements in the U.S. will require continued investment in research and development activities, as will our ongoing clinical, development and chemistry manufacturing and control, or CMC, work for our red blood cell system in Europe as well as our whole-blood initiative in collaboration with the FDA. In the U.S., we expect to incur increasing research and development expenses associated with pursuing licensure of the red blood system including the RedeS study, the ReCePI study and an additional Phase 3 clinical trial for chronic anemia in the U.S., *in vitro* studies, and

other activities to pursue FDA approval of our red blood cell system. To the extent available, many of the U.S. red blood cell activities may be reimbursed by BARDA, though no guarantee can be made that our progress will be satisfactory to BARDA or that funds will be available to either BARDA or us. Similarly, most of our whole blood program is expected to be reimbursed by the FDA, though no guarantee can be made that our progress will be satisfactory to the FDA or that funds will be available to the FDA or us. In addition, we plan to continue spending on new product development and enhancements to our illumination device and next generation of our INTERCEPT Blood System kits, which may increase research and development expenses. See Note 2 in the Notes to Consolidated Financial Statements under "*Financial Statement Schedules—Financial Statements*" of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for the years ended December 31, 2021, 2020 and 2019.

Government Regulation

We and our products are comprehensively regulated in the U.S. by the FDA and by comparable governmental authorities in other jurisdictions.

Our European investigational plan has been based on the INTERCEPT Blood System being categorized as Class III drug/device combination under the MDD. Medical devices, including INTERCEPT will need to be re-registered and approved under the new MDR which entered into application on May 26, 2021.

The European Union requires that the CE Mark be affixed to medical devices. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with the MDD, and in the future, the MDR. We initially received a CE Mark for our platelet system and separately for our plasma system in 2002 and 2006, respectively. In March 2020, we received an extension of the CE Mark approval to 2024, under the MDD. While our current extension of registration is based on the MDD for the platelet and plasma systems, we cannot assure you that these products will timely meet the requirements of the MDR prior to the expiration of the MDD. A separate CE Mark certification must be received for the red blood cell system to be sold in the European Union and in other countries recognizing the CE Mark. We filed our application for CE Mark approval of the red blood cell system in December 2018 under the MDD, and in June 2021, we completed the process to resubmit our application under the new MDR. However, we do not expect that an approval decision under the MDR will occur for at least another 12 months, if ever. In addition, France, Switzerland, Germany, and Austria require separate approvals for INTERCEPT-treated blood products.

The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern, among other things, the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and pre-market clearance or approval of products subject to regulation. The steps required before a medical device may be approved for marketing in the U.S. pursuant to a PMA include:

- preclinical laboratory and animal tests;
- submission to the FDA of an investigational device exemption for human clinical testing, which must become effective before human clinical trials may begin;
- appropriate tests to show the product's safety;
- adequate and well-controlled human clinical trials to establish the product's safety and efficacy for its intended indications;
- submission to the FDA of a PMA; and
- FDA review of the PMA in order to determine, among other things, whether the product is safe and effective for its intended uses.

The FDA has approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease, or TA-GVHD. The FDA has also approved the plasma system for *ex vivo* preparation of pathogen-reduced, whole blood derived or apheresis plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion and as an alternative to gamma irradiation for prevention of TA-GVHD. We have also recently received FDA approval for the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce pathogen reduced plasma, cryoprecipitate reduced. We plan to conduct development activities, clinical studies and *in vitro* studies for our platelet system to expand our label claims in the U.S.

As a condition to the FDA approval of the platelet system, we were required to conduct two post-approval studies of the platelet system studies - a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT-treated platelets; and a recovery study of platelets treated with the platelet system. The haemovigilance study has completed and has met its end point.

We are currently in the process of publishing those results to a peer-reviewed journal. However, we will need to successfully complete the recovery and survival study of the platelet system. Should we be unsuccessful in meeting the criteria for the recovery and survival study, use of the platelet system may be limited, require label and use restrictions or have a revocation or suspension of approval. In addition to these studies, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources. In addition, there is a risk that post-approval studies will show results inconsistent with our previous studies.

Any modifications to the platelet and plasma systems that could significantly affect their safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in their intended use, manufacture, design, components, or technology requires FDA approval of a new PMA or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier's decision. The FDA may not agree with our decisions regarding whether new submissions or approvals are necessary. Our products could be subject to recall if the FDA or other regulators determine, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. We will need to obtain regulatory approval of any future redesign of the illuminator before it can be commercialized. In addition, certain solvents we used to make the plastic beads in the plasma kit compound adsorption devices are no longer available. Although we have contracted with the manufacturer to produce a significant quantity of the existing material, we will need to qualify plastic beads produced with a new solvent prior to consuming available inventory levels. Furthermore, in order to address the entire market in the U.S., we will need to develop and test additional configurations of the platelet system, including making the platelet system compatible with random donor platelets. Our failure to obtain FDA or foreign regulatory approvals of new platelet and plasma product configurations could significantly limit product revenues from sales of the platelet and plasma systems.

With FDA approval of our platelet and plasma systems and the INTERCEPT Blood System for Cryoprecipitation, we are required to continue to comply with applicable FDA and other regulatory requirements related to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory agency requirements, including, in the U.S., ensuring that quality control and manufacturing procedures conform to FDA-mandated current Good Manufacturing Practice, or cGMP, and Quality System Regulation, or QSR, requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections. The manufacturing facility which produces our platelet and plasma systems was recently audited by the FDA. While there were not objectionable conditions observed during the audit, the FDA or other regulatory agencies may inspect and audit facilities manufacturing or products or components at any time. Complying with and resolving any audit findings may result in additional costs, changes to our manufacturers quality management systems or both. Failure to timely resolve and comply to audit findings, if any, may result in enforcement actions and may result in a disruption to the supply of our products. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Mark approval under the MDR.

We are also required to report certain adverse events and production problems, if any, to the FDA, competent authorities of the EU Member States and Notified Bodies, and foreign regulatory authorities, when applicable, and FDA, competent authorities of the EU Member States, or other foreign regulatory authorities may require us to recall products as a result of adverse events or production problems. Additionally, we are required to comply with requirements concerning advertising and promotion for our products. For example, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, uses. If the FDA, competent authorities of the EU Member States, or other foreign regulatory authorities determine that our promotional materials or training constitute promotion of an off-label use, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state, competent authorities of the EU Member States, or foreign authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, or a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA, competent authorities of the EU Member States, or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product

liability claims. We are also subject to other broadly applicable fraud and abuse and other healthcare laws and regulations, including anti-kickback, health care professional payment transparency, and health information privacy and security laws, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute our products. Any enforcement action brought by a federal, state or foreign authority could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement. In addition, our reputation could be damaged and adoption of the products could be impaired. Further discussion of the health care laws and regulations that may affect our can be found in "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled: "*We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business.*"

CBER is the center within the FDA principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our blood safety products, CBER also regulates the blood collection centers and would regulate any blood products that they prepare using the INTERCEPT Blood System. Many U.S.-based blood centers have completed and obtained site-specific licenses from CBER that allows them to make INTERCEPT-treated blood products available to their interstate hospital customers. Any significant product change that we make may require amendments or supplements to those site-specific licenses that could limit availability of INTERCEPT-treated blood products until the amendment or supplement is approved. Additionally, hospital customers of ours or of any of our blood center customers may need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories or may need to amend or adjust those codes in connection with a significant product change that we make, which may adversely impact our ability to sell products in the U.S. Increasingly, the competent authorities of other countries are also developing equivalent rules and obligations.

We supply the INTERCEPT Blood System for Cryoprecipitation to select blood centers that manufacture IFC for us. We plan to sell the finished IFC made by our manufacturing blood center partners directly to hospitals. Similar to our platelet and plasma products, any blood center manufacturing IFC will need to complete their process validations and obtain site-specific licenses from CBER before we or they can sell finished IFC to hospital customers outside of the states producing IFC. While one of our manufacturing partners received its BLA from CBER in 2021, we plan to continue working with our other U.S.-based blood centers manufacturing partners to support these activities and any delay in obtaining these licenses would adversely impact the nationwide availability of our finished IFC in the U.S. In addition, we have entered into certain agreements with blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation kits which will allow those blood centers and blood center affiliate organizations to produce finished IFC for their own sales efforts to hospitals.

The preclinical and clinical studies of the INTERCEPT Blood System for red blood cells have been conducted using prototype system disposables and devices. In addition to the clinical trials, a number of manufacturing and validation activities must be completed before we could sell the red blood cell product.

We believe that in deciding whether the INTERCEPT Blood System is safe and effective regulatory authorities have taken, and are expected to take, into account whether it adversely affects the therapeutic efficacy of blood components as compared to the therapeutic efficacy of blood components not treated with INTERCEPT. Data from human clinical studies must demonstrate the safety of treated blood components and their therapeutic comparability to untreated blood components. In addition, regulatory authorities will weigh INTERCEPT's safety, including potential toxicities of the inactivation compounds, and other risks against the benefits of using the system in a blood supply that has become safer. We have conducted many toxicology studies designed to demonstrate the INTERCEPT Blood System's safety. There can be no assurance that regulatory authorities will not require further toxicology or other studies of our products. Based on discussions with the FDA and European regulatory authorities, we believe that data only from laboratory and animal studies, not data from human clinical studies, will be required to demonstrate the system's efficacy in reducing pathogens. In light of these criteria, our clinical trial programs for the INTERCEPT Blood System consist of studies that differ from typical Phase 1, Phase 2 and Phase 3 clinical studies.

We have relatively little human data supporting our IFC product. Accordingly, prospective blood center manufacturing partners, hospitals or physicians may require additional commercially derived data before choosing to use IFC. Such studies may be timely and require the use of third-party clinical research organizations, or CROs, or data capture methods and may take a considerable amount of time to generate sufficient data before we can achieve broad market acceptance, if ever.

We may be subject to diverse laws and regulations relating to data privacy and security as a result of our employee data or other personal information that we may collect. In addition, if we do collect personal data as part of any clinical trials or other testing, we would be subject to regulatory obligations. This includes, in the U.S., the California Consumer Privacy Act of 2018, or CCPA, and, in the European

Union, or EU, and the European Economic Area, or EEA, the General Data Protection Regulation, or GDPR (Regulation 2016/679) and the related national rules of the individual EU Member States. New privacy rules are being enacted in the U.S. and globally, and existing ones are being expanded, updated and strengthened. Effective May 25, 2018, the GDPR, a broad data protection framework that expands the scope of current EU data protection law to entities that process the personal information of EU subjects, including employee data and clinical trial data that may be processed outside the EU entered into application. The GDPR introduces more stringent operational requirements than its predecessor legislation.

Further, the Court of Justice of the European Union ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the European Union and United States, was invalid and could no longer be used. In September 2020, Switzerland concluded that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. Alternative transfer mechanisms may be used, including the standard contractual clauses, or SCCs, while the authorities interpret the decisions and scope of the invalidated Privacy Shield, but the SCCs have also been called into question in the same ruling that invalidated Privacy Shield. Other states have 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.

Also, in June 2018, the State of California enacted the CCPA, which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA requires covered companies to provide new disclosures to California consumers (as that word is broadly defined in the CCPA), provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches.

Further, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020, election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA.

Further discussion of our regulatory and clinical trial status can be found in "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factors titled *"Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects" and "The red blood cell system is currently in development and may never receive any marketing approvals," as well as generally under the heading "Risks Related to Regulatory Approval and Oversight, and Other Legal Compliance Matters."*

U.S. Health Care Reimbursement and Reform

Our ability to commercialize our products successfully in the U.S. will depend in part on the extent to which coverage and appropriate reimbursement levels for the cost of the products and related treatment are obtained. The INTERCEPT Blood System is currently sold to U.S. based blood collection entities. Because our products are not directly reimbursable by governmental or commercial third-party payors, adoption of the INTERCEPT Blood System will, in part, require coverage and adequate reimbursement to be provided for the procedures and treatments which utilize INTERCEPT-processed blood products. There is no uniform policy of coverage and reimbursement among third-party payors, as such, coverage and reimbursement can differ significantly from payor to payor. Even if favorable coverage and reimbursement status is attained for a particular procedure or treatment, less favorable coverage policies and reimbursement rates may be implemented in the future. If the costs to hospitals for INTERCEPT-processed blood products acquired from blood collection entities cannot be easily, readily, or fully incorporated into the hospital's existing coverage and reimbursement structure, adoption of our products may be negatively affected.

In the U.S., there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and ongoing cost saving efforts may have an impact on our ability to profitably commercialize the INTERCEPT Blood System in the U.S. and elsewhere. The ACA and other health care reform in the U.S. include provisions that place downward pressure on the pricing of medical products which has been delayed, which could further impact our profit margins.

Since its enactment, there have been judicial and Congressional challenges to numerous provisions of the ACA. In addition, President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties as of January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued that 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 that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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 any such challenges and the health care reform measures of the Biden administration will impact the ACA.

In addition, there has been heightened governmental scrutiny to control the rising cost of healthcare. For example, such scrutiny has resulted in several recent congressional inquiries, presidential executive orders, and federal and state legislative activity designed to, among other things, bring more transparency to pricing and reform government program reimbursement methodologies for pharmaceutical products.

Further discussion of the impact of health care reform and laws governing our business practices on our business can be found in "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factors titled "*Legislative, regulatory, or other healthcare reforms may make it more difficult and costly for us to obtain regulatory approval of our products and to produce, market and distribute our products after approval is obtained*" and "*We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business.*"

Human Capital

As of December 31, 2021, we had 294 employees representing at least 35 nationalities which includes 7 dedicated commercial consultants. Approximately 82% of our global employees are women. In addition, of our U.S. employees, approximately 45% identify as non-white.

Below is additional demographic information about our current employee base as of December 31, 2021.

Cerus Employees	**2021**
Salaried workforce	272
Managers and above	72
Part-time employees	13
Average age	45 years
Average length of service in years	5.8 years
Employee turnover rate (voluntary)	9.4%

Our employees are a key factor in our ability to serve our customers and achieve our mission to establish INTERCEPT as the standard of care for transfused blood components globally and to enable our customers to do everything in their power to deliver safe and effective blood products to patients. The ability to hire and retain highly skilled professionals remains key to our success in the marketplace. To attract, maintain and motivate our employees, we offer a challenging work environment, ongoing skills development initiatives, attractive career advancement, opportunities and a culture that rewards entrepreneurial initiative and execution. Our guiding principles of integrity, perseverance, scientific rigor, and urgency are core to who we are and serve as the foundation of our values. Our guiding principles set the tone for how we work together and provide a framework for giving feedback. Service is at the core of our business and our interactions with one another.

Environmental, Social and Governance

As our business continues to grow and develop, we recognize the importance of making responsible business decisions for the benefit of all of our stakeholders, including our stockholders, customers, employees, partners, the communities in which we work and live, as well as the planet. To that end, we are in the process of designing, evaluating, and implementing a corporate Environmental, Social and Governance, or ESG, program and have engaged an outside consultant to help us conduct a materiality assessment and develop a strategy, including short, intermediate and long-term objectives. We anticipate implementing our ESG strategy over the course of 2022 and expect to begin reporting on our progress to our various stakeholders annually commencing in 2023.

Diversity, Equity and Inclusion

A diverse and inclusive workforce is a business imperative and key to our long-term success. Our employees come from numerous countries and bring diversity to our workplace across many critical categories. We believe our company is stronger because of the variety of experiences and backgrounds our employees bring to their work every day. We are committed to creating and maintaining a diverse, inclusive and safe work environment. To continue our efforts to increase diversity in the Cerus workforce, we are developing a strategy

that will look to identify gaps and present suggestions on how we can encourage and cultivate an environment in which all employees feel included and empowered to achieve their best.

Compensation and Benefits

We strive to provide pay, benefits, and services that are competitive to market and create incentives to attract and retain employees globally. Our compensation package includes market-competitive pay, broad-based stock grants and bonuses, health care and retirement benefits, paid time off, and family leave, among others. We are focused on pay equity globally and are striving to close the gap in pay among similar roles and responsibilities throughout our organization.

COVID-19 employee safety and benefits

In light of the ongoing COVID-19 pandemic, we continue to take extra precautions to reduce the risk of virus exposure for all employees. In March 2020, we encouraged all of our employees who were able to work from home to do so. For these newly remote employees, we provided a stipend for IT and/or office equipment to assist our employees in creating an ergonomic home workstation. We allow flexible schedules, and support employee information technology needs. In addition, we have provided training to employees and managers on how to work from home and how to manage remote employees to ensure that our employees are maintaining their physical, mental and emotional wellbeing. For those employees who remain onsite in our laboratories (and those who support those lab workers), we reduced the number of people in the office significantly and allowed the remote work option whenever possible. In addition, we provide personal protective equipment, or PPE, and have put in place new safety protocols. In addition, we required all of our U.S. workforce to be vaccinated for COVID-19 by December 31, 2021.

Communication and Engagement

We strongly believe that Cerus' success depends on employees understanding how their work contributes to our overall strategy. To this end, we utilize a variety of channels to facilitate open and direct communication, including: (i) periodic CEO update emails; (ii) open forums or All Hands Meetings with executives and other leaders; and (iii) regular ongoing update communications.

Health, Wellness and Safety

We are committed to the safety of our employees and communities, from laboratory operations to product development to supplier partnerships. Our goal is to achieve zero serious injuries through continued investment in and focus on our core safety programs and injury-reduction initiatives. We provide access to a variety of innovative, flexible, and convenient health and wellness tools, including annual flu shots for all employees.

Available Information

We maintain a website at *www.cerus.com*. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission. Information contained on or accessible through our websites is not incorporated into, and does not form a part of, this Annual Report or any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

Financial Information

Our financial information including our consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of stockholders' equity, consolidated statements of cash flows, and the related footnotes thereto, can be found under "*Financial Statement Schedules*" in Part IV of this Annual Report on Form 10-K.

Item 1A. ***Risk Factors***

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this annual report on Form 10-K. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business. Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations.

Risks Related to Our Business and Industry

The evolving effects of the COVID-19 pandemic have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which these effects will impact our future results of operations and overall financial performance remains uncertain.

The evolving effects of the COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business related activities have occurred, supply chains have been disrupted, and manufacturing and clinical development activities have been curtailed or suspended. Continued remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the effects of the COVID-19 pandemic has materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses.

Our sales efforts have historically involved significant in-person interaction with potential customers and distributors. With respect to our commercial activities, many of our hospital and blood bank customers continue to have requirements or restrictions on vendors and visitors meeting with their personnel in person, particularly in light of the rise of the Delta and Omicron variants. We have attempted to shift our sales activities to video conferencing and other similar customer interaction models and we have found these alternative approaches to have varying degrees of effectiveness in comparison to in-person sales efforts. As a result, our ability to reinitiate sales and marketing efforts may be slower than expected or may require compliance with new credentialing certifications by our personnel. To the extent that our employees' ability to gain access to hospitals and their personnel remains limited, our commercial and sales interactions with those hospitals and our ability to introduce the INTERCEPT Blood System, including INTERCEPT Fibrinogen Complex, or IFC, may continue to be impaired. We have deferred certain of our customer events and many planned trade shows have been cancelled and we may further defer or cancel additional customer, employee or industry events, or our participation in such events, in the future. In addition, many new customers and prospective customers have been impacted by the COVID-19 pandemic and their ability to on-board, train staff and implement new technologies, including INTERCEPT, has and may continue to be negatively impacted, which may lead such customers to instead choose to utilize other allowable methods with which they have more familiarity. Moreover, we understand that due to the COVID-19 pandemic, many hospitals are consolidating, are laying off workers or are filing for bankruptcy protection, and other hospitals may have such significant budget shortages that they unable to afford pathogen-reduced blood components. Blood products are currently in extremely short supply which is impacting our customers. Customers whose operations have been impacted may have difficulty paying timely, may ask for price reductions or may delay or cancel public tenders. In addition, we understand that use of blood components may at times be negatively impacted due to the COVID-19 pandemic and the resulting deferrals of elective procedures requiring use of blood components, including those treated with INTERCEPT. These events, in turn, may negatively impact our potential product revenues from existing and prospective customers. Conversely, during the pendency of the pandemic, certain existing, new and prospective customers have and may continue to ask for increased utilization of our products beyond what was forecast, and we may not be able to timely satisfy this increase in demand. In addition, while our suppliers have initiated business continuity plans with minimal expected disruption to our supply, we cannot be certain that any prolonged, intensified or worsened effect from the pandemic including the impact of emerging variant strains of the SARS-CoV-2 virus would not negatively impact our supply chain. For example, Fresenius, our primary manufacturing partner for our disposable kits, had to reconfigure production workflow to safely produce INTERCEPT disposable kits and in the future, restrictions and other limitations on Fresenius' ability to conduct business in the ordinary course could negatively impact production of INTERCEPT disposable kits. All of the aforementioned could adversely affect our sales, operating results and overall financial performance.

The COVID-19 pandemic has also negatively impacted our ability to perform many clinical trials, studies and activities, including those covered by our agreement with the Biomedical Advanced Research and Development Authority, or BARDA. Our ongoing and anticipated clinical trials, the post-approval platelet studies, as well as studies to support label expansion for the platelet system in the U.S. have been delayed because of COVID-19. For example, for a brief time, several of the hospital clinical trial sites for our RedeS and ReCePI studies suspended enrollment and several red blood cell production partners for the studies suspended production in order to conserve red blood cells to meet hospital demand during the pandemic. Many hospital sites are proceeding at a reduced capacity. Accordingly, many of the activities expected by BARDA have been delayed and will require an extension of time and/or additional funds under the contract to complete. In addition, as the clinical studies and other activities supported by our BARDA contract get further delayed as a result of the COVID-19 pandemic, we will need to continue to rely on modifications and extensions to the BARDA

agreement to fund the completion of those activities. Should BARDA disallow any modification or extension, we will need to pay for the costs to complete the activities or stop pursuing them altogether. Further delays may recur in the future if patient enrollment sites need to pause participation in our clinical trials and studies and we cannot be certain that further disruption due to the COVID-19 pandemic can be avoided. Should the COVID-19 pandemic persist, continue to worsen, or resurface at locations where we conduct studies or clinical trials, our ability to commence and complete any contemplated studies may be negatively impacted. Furthermore, should we be unable to deploy personnel, derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed under our contract with BARDA, our cash flows would be negatively impacted and/or we may have to initiate furloughs and layoffs, which would prove disruptive to our management and operations. This in turn would impair our ability to complete ongoing studies or commence new studies.

The duration and extent of the impact from the COVID-19 pandemic depends on future developments that cannot be accurately predicted at this time, such as the severity and transmission rate of the virus, including any variants such as Delta and Omicron, and the extent and effectiveness of containment actions. In addition, while the potential economic impact brought by the COVID-19 pandemic may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. As a result of stimulus programs put in place over the past two years, the U.S. and many countries are currently experiencing an inflationary environment. This has led to the U.S. Federal Reserve taking action to raise interest rates which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, our suppliers may raise prices in an inflationary environment, costs to transport our products may increase, availability timeliness of shipping. To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets, plasma and cryoprecipitation in the U.S., and our inability to successfully commercialize the INTERCEPT Blood System in the U.S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business is dependent on our ability to grow and sustain commercialization of the INTERCEPT Blood System in the U.S. Significant product revenue from customers in the U.S. may not occur consistently, if at all if we are unable to demonstrate that our products are economical, safe and efficacious for potential customers. Similar to our experience in foreign jurisdictions, some potential customers in the U.S. have chosen to first validate our technology or conduct other pre-adoption activities prior to purchasing or deciding whether to adopt the INTERCEPT Blood System for commercial use, which may never occur. Further, new hospital customers of any of our blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may further delay customer adoption in the U.S.

On October 1, 2021, all U.S. blood centers had to be compliant with the FDA guidance document, “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion,” or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U.S. blood centers for compliance with the Final Guidance Document, we cannot predict if U.S. customers will continue to adopt INTERCEPT over other options or at what levels. If we are unable to successfully support the commercialization of our platelet system to U.S. customers that have elected to use the INTERCEPT Blood System, then those customers may be required to adopt competing products in order to comply with the Final Guidance Document. Further, U.S. blood centers will be required to change their historical operating practices to conform to our product specifications, or they or their hospital customers may be required to elect more than one option under the Final Guidance Document in order to comply, or they or their hospital customers may choose competing products to comply with the Final Guidance Document. We may be unable to subsequently convert blood centers that chose competing products to the platelet system, which would limit our market potential. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the U.S., we may never generate substantial product revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected.

In any event, our ability to successfully commercialize the INTERCEPT Blood System for platelets, plasma, and cryoprecipitation in the U.S. will depend on our ability to:

- adequately respond in the event of potential increased U.S. customer demand resulting from the implementation of the Final Guidance Document;
- achieve market acceptance and generate product sales through execution of sales agreements on commercially reasonable terms;
- enter into and maintain sufficient manufacturing arrangements for the U.S. market with our third-party suppliers;
- support blood center manufacturing partners in obtaining Biologics License Application, or BLAs, for interstate commerce;
- effectively create market demand for the INTERCEPT Blood System through our education, marketing and sales activities;

- hire, train, deploy, support and maintain a qualified U.S.-based commercial organization and field sales force;
- expand the labeled indications of use for the INTERCEPT Blood System and/or design, develop, test and obtain regulatory approval for new product configurations;
- comply with requirements established by the FDA, including post-marketing requirements and label restrictions; and
- comply with other U.S. healthcare regulatory requirements.

In addition to the other risks described herein, our ability to successfully commercialize the INTERCEPT Blood System for platelets, plasma and cryoprecipitation in the U.S. is subject to a number of risks and uncertainties, including those related to:

- the COVID-19 pandemic and its effect on customers, hospitals, suppliers and our employees;
- the highly concentrated U.S. blood collection market that is dominated by a small number of blood collection organizations;
- availability of donors;
- regulatory and licensing requirements, including the FDA Center for Biologics Evaluation and Research, or CBER, licensing processes and its BLA requirements, that U.S.-based blood centers are required to follow in order to obtain and maintain the required site-specific licenses to engage in interstate transport of blood components processed using the INTERCEPT Blood System;
- changed or increased regulatory restrictions or requirements;
- the amount available for reimbursement pursuant to codes we have obtained under the Healthcare Common Procedure Coding System, or HCPCS, or New Technology Add-On Payment, or NTAP, and pricing for outpatient use of INTERCEPT-treated blood components;
- any supply or manufacturing problems or delays arising with any of our suppliers, many of whom are our sole qualified suppliers for the particular product or component they manufacture, including the ability of our suppliers to maintain FDA approval to manufacture the INTERCEPT Blood System and to comply with FDA-mandated current Good Manufacturing Practice, or cGMP, and Quality System Regulation, or QSR, requirements;
- our and our suppliers ability to produce sufficient quantity of product to meet the growing demand for our products, especially in light of the Final Guidance Document;
- ability of our contracted blood center manufacturing partners to produce IFC at sufficient quantities and at acceptable quality levels;
- dependency upon any third-party manufacturer that supplies products required by blood centers to process and store blood components consistent with our approved specifications and claims, including but not limited to, apheresis collection devices, disposable blood bags and reagents, and platelet additive solution, or PAS;
- our ability to obtain patents, protect trade secrets, prevent others from infringing on our proprietary rights, and operate without infringing the proprietary rights of third parties;
- changes in healthcare laws and policy, including changes in requirements for blood product coverage by U.S. federal healthcare programs; and
- acceptance of the INTERCEPT Blood System as safe, effective and economical from the broad constituencies involved in the healthcare system.

The INTERCEPT Blood System may not achieve broad market adoption.

In order to increase market adoption of the INTERCEPT Blood System and to increase market demand, we must address issues and concerns from broad constituencies involved in the healthcare system, from blood centers to patients, transfusing physicians, key opinion leaders, hospitals, private and public sector payors, regulatory bodies and public health authorities. We may be unable to demonstrate to these constituencies that the INTERCEPT Blood System is safe, effective and economical or that the benefits of using the INTERCEPT Blood System products justify their cost and/or outweigh their risks.

The use of the platelet system results in some processing loss of platelets. As a result, customers or prospective customers may adopt competing solutions if they perceive that:

- the loss of platelets leads to increased costs, or the perception of increased costs for our customers;

- the use of our product in any way constrains the availability of platelets due to platelet loss;
- our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusable unit; or
- our process requires changes in blood center collection processes or clinical regimens to address platelet loss.

Additionally, existing customers may not believe they can justify any perceived operational change or inefficiency either generally or in conjunction with a blood component availability shortage. This concern may be exacerbated during the current blood shortage crisis. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called "corrected count increment") and may be more effective than transfusion of INTERCEPT-treated platelets. Although certain other studies demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, prospective customers may choose not to adopt our platelet system due to considerations relating to corrected count increment or other factors.

The INTERCEPT Blood System does not inactivate all known pathogens, which may limit its market adoption. For example, our products have not been demonstrated to be effective in the reduction of certain non-lipid-enveloped viruses, including hepatitis A and E viruses, and human parvovirus B-19, due to the biology of these viruses. Although we have shown high levels of reduction of a broad spectrum of lipid-enveloped viruses, INTERCEPT's inability to inactivate, or limited reduction, of certain non-lipid-enveloped viruses may negatively impact the decision to adopt by prospective customers. Similarly, although our products have been demonstrated to effectively inactivate spore-forming bacteria, our products have not been shown to be effective in reducing bacterial spores once formed. Furthermore, due to limitations of detective tests, we cannot exclude that a sufficient quantity of pathogen or pathogens beyond the detection limits may still be present in active form, which could present a risk of infection to the transfused patient. Should INTERCEPT-treated components contain detectable levels of pathogens after treatment, the efficacy of INTERCEPT may be called into question, whether or not any remaining pathogens are the result of INTERCEPT's efficacy, the limitations of testing methodologies or other factors. Such uncertainties may limit the market adoption of our products.

We have conducted studies of our products in both *in vitro* and in vivo environments using well-established tests that are accepted by regulatory bodies. However, we cannot be certain that the results of these *in vitro* and *in vivo* studies accurately predict the actual results in humans in all cases. In addition, strains of infectious agents in living donors may be different from those strains commercially available or for which we have tested and for which we have received approval of the inactivation claims for our products. To the extent that actual results in human patients differ, commercially available or tested strains prove to be different, or customers or potential customers perceive that actual results differ from the results of our *in vitro* or *in vivo* testing, market acceptance of our products may be negatively impacted.

If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced or delayed. For example, if adverse events arise from incomplete reduction of pathogens, improper processing or user error, or if testing of INTERCEPT-treated blood samples fails to reliably confirm pathogen reduction, whether or not directly attributable to the INTERCEPT Blood System, customers may refrain from purchasing our products. We have recently learned of instances where, following treatment with INTERCEPT, mishandling of the treated blood components has introduced environmental bacterium. We must help our blood center customers to remain or increase their vigilance in adopting best practices regarding blood component handling. Failure to adequately address this risk may call into question the efficacy of using pathogen reduction.

Furthermore, should customers communicate operational problems or suspected product failure, we will need to investigate and report imputability to the relevant regulatory authorities in a timely manner. We or others may be required to file reports on such complaints or product failure before we have the ability to obtain conclusive data as to imputability which may cause concern with existing and prospective customers or regulators. Should customers feel that INTERCEPT treatment has a negative impact on the number of transfusable platelet units able to be manufactured from available donors, our ability to educate a blood center on the benefits of treating increasing proportions of its platelet units may be negatively impacted. Moreover, there is a risk that further studies that we or others may conduct, including the post-approval studies we are required to conduct as a condition to the FDA approval of the platelet system, will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease using our products. In addition, some hospitals may decide to purchase and transfuse both INTERCEPT-treated blood components and conventional blood components, including IFC which we have no experience selling directly to hospitals. Managing such a dual inventory of blood products may be challenging, and hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination between hospital suppliers, blood centers, or us, which in turn may cause delays in market adoption. In addition, customers may require certain changes to our products for any number of reasons. Complying with such requests may prove costly, and may create complexities surrounding the manufacturing of disposable kits, compliance with regulatory authorities, blood center usage, or inventory management. Conversely, failure to comply with such requests from customers may result in damage to our relationship or the potential loss of customer business.

Market adoption of our products is also affected by blood center and healthcare facility budgets and the availability of coverage and adequate reimbursement from governments, managed care payors, such as insurance companies, and/or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the federal and, in some cases, state levels, regulators, healthcare facilities and third-party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, commercial use of our products may not be covered by governmental or commercial third-party payors for health care services and may never be covered. In addition, the costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third-party payors, the costs and expenses specific to the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. Governmental or third-party payors may change reimbursement rates, year over year, or in reaction to submitted claims for reimbursement of costs and expenses related to blood components treated with INTERCEPT. If the costs to the hospital for INTERCEPT processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, or if reimbursement rates are insufficient or decreased in any given year for blood components treated with INTERCEPT, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products. In addition, even if we are able to achieve market acceptance in the U.S. or newly commercialized markets, we have provided and may in the future provide adoption incentives which may negatively impact our reported sales.

We are exposed to risks associated with the highly concentrated market for the INTERCEPT Blood System.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. Moreover, the market for pathogen reduction systems in the U.S. is highly concentrated and dominated by a small number of blood collection organizations. In the U.S., the American Red Cross represents the largest single portion of the blood collection market. Our existing agreement with the American Red Cross expires in the near-term. Our ability to continue selling product to American Red Cross is dependent on entering into a new sales agreement or amending and extending our existing agreement. We cannot guarantee the long-term volume or timing of commercial purchases that the American Red Cross may make, if any, under our agreement. Furthermore, we cannot assure you that any new or amended agreement with American Red Cross will contain terms that are consistent with or favorable to our existing agreement, if we reach agreement on a new or amended sales agreement at all. Our ability to gain and maintain significant market penetration in the U.S. is largely dependent on utilization of INTERCEPT and distribution of INTERCEPT-treated blood components by the American Red Cross. The American Red Cross is a large organization. Given the large relative size of the American Red Cross and their rapid deployment of the platelet system, our resources may be inadequate to fulfill the American Red Cross' and other customers' demands, which could result in a loss of product revenues or customer contracts, or both.

In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption are made on a regional or even blood center-by-blood center basis, but depend on both local approvals and centralized regulatory approvals from the Paul Ehrlich Institute, or PEI. Obtaining these approvals requires support and coordination from local blood centers, and may take a significant period of time to obtain, if ever. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other parts of the EU and other third countries where we rely on CE Mark approval, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. Following the inclusion of pathogen-inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using our products. The review period for a new MAA can be 12 months or longer following submission and we cannot assure that any of the potential German customers submitting a new MAA will obtain it. Without approvals of MAA applications obtained by potential German customers, our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect our business, results of operations and financial condition. In addition, the reimbursement awarded to INTERCEPT in Germany may not be considered by German blood centers as attractive enough to implement pathogen reduction or cover the entirety of their blood center platelet collections which may in turn limit the market acceptance in Germany. Similar to the U.S., German blood centers will need to successfully market and sell to their hospital customers and understand and assist with the steps that are needed at the hospital level in Germany to administer pathogen-reduced platelets.

While we have entered into agreements with Établissement Français du Sang, or EFS, to supply illuminators and platelet and plasma disposable kits and maintenance services for illuminators to EFS, we cannot provide any assurance that the national deployment of the platelet system in France will be sustainable or that we will be able to secure any contracts subsequent to our existing contract with EFS. If we are unable to continue to successfully support EFS' national adoption of the platelet system, EFS' use of the plasma system, our business, results of operations and financial condition may be adversely impacted. Our contracts with EFS do not contain purchase volume commitments and as such, we may see variability in purchase levels or an altogether cessation. In addition, we understand that EFS is inspecting and testing samples of each lot that they purchase from us prior to accepting the products shipped to fulfill orders. We have little insight into the time to test, testing conditions or ultimate results. Other customers may require similar conditions of purchase. Testing may have a negative impact on our ability to recognize product revenue either due to the time it takes to test and approve the release of a shipment or if the customer experiences problems with testing or if testing results are outside of the customer acceptance criteria.

In Japan, the Japanese Red Cross controls a significant majority of blood transfusions and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. Before the Japanese Red Cross would consider our products, we understand that we may need to commit to making certain product configuration changes, which are currently under development but may not be economically or technologically feasible for us to accomplish.

Significant increases in demand may occur given the concentrated nature of many of the largest potential customers and the potential for a mandate by public health agencies to adopt pathogen reduction technologies. Should those customers choose to adopt and standardize their production on the INTERCEPT Blood System or be required to adopt and standardize on the INTERCEPT Blood System, our ability to meet associated increases in demand will likely be constrained due to a variety of factors, including production capacity at approved manufacturing sites, supply issues, manufacturing disruptions, availability of disposable kits manufactured from the obsolete plastic materials in jurisdictions that have not approved the use of alternate plastics for our disposable kits, or other obsolescence of parts, among others. If we encounter sustained growth or accelerated growth, our production capacity may be strained, at least temporarily or should we encounter disruptions, supply shortages, or shipping delays, we may have to allocate available products to customers, which could negatively impact our business and reputation or cause those customers to adopt competing products.

We may be unable to develop and maintain an effective and qualified U.S. based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our products in the U.S.

Successfully commercializing our products in the U.S. has taken more time than anticipated and has required us to continue to invest in commercialization efforts to build and maintain relationships, additional routine-use data and trust from the industry. We continue to need to attract, retain, train and support sales, marketing and scientific and hospital affairs personnel and other commercial talent. For example, we still need to attract and retain hospital affairs professionals to help educate hospitals and physicians on our products, clinical trial history and publications. Hospital affairs professionals are highly educated and trained professionals and the hiring and employment market for hospital affairs professionals is highly competitive. As such, we need to commit significant additional management and other resources in order to maintain and potentially expand our hospital affairs team and sales and marketing functions. We may be unable to develop and maintain adequate hospital affairs, sales and marketing capabilities for the U.S. market and we also may not be able to devote sufficient resources to the advertising, promotion and sales efforts for the platelet, plasma or cryoprecipitation systems in the U.S. The current labor shortage in the U.S. and in many countries where we have commercialized our products has exacerbated the challenge of attracting and retaining these personnel. In any event, if we are unable to develop and maintain an effective and qualified U.S. based commercial organization in a timely manner or at all, we may fail to realize the full sales potential of our commercial products in the U.S. which would materially and adversely affect our business, financial condition, results of operations and growth prospectus.

We have no prior experience selling directly to hospitals or expertise complying with regulations governing finished biologics, and our inability to successfully commercialize the INTERCEPT Blood System for cryoprecipitation in the U.S would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are just developing an understanding about what may be necessary to market IFC directly to hospitals. We have no prior experience selling directly to hospitals nor do we have prior experience or expertise complying with regulations governing finished biologics. This new business model may contemplate the replacement of expired IFC with new units of IFC at no cost or a reduced cost. We have no experience selling products under this consignment model. The introduction of these new models of doing business require extensive training of our personnel and may lengthen the time it takes for this business unit to be fully operational. In addition, we may sell disposable kits to certain hospitals that have in-house blood center capabilities, blood centers and blood center affiliate organizations for them to self-produce IFC rather than purchase the product from one of our blood center customers may require that we. This may cause conflict with our blood center customers and our initial go-to market approach of selling finished IFC to hospitals. In this regard, our blood center customers may view the sale of biologics directly to hospitals as a competitive threat, which may adversely affect our customer relationships, could negatively impact our business prospects and could result in loss of business and revenue. Conversely, we

may also sell the disposable kits directly to blood centers for the manufacture of IFC for their own account. As a result, we may be directly competing with these blood centers for the sale of IFC. These blood centers have more experience and existing contracts with hospitals and may be able to offer synergies that we cannot, each of which may negatively impact our ability to compete successfully.

In addition, until we are successful in selling INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations or hospitals with in-house blood centers, our ability to commercialize IFC in the U.S. is initially limited to the states of California, Texas, Louisiana, Wisconsin, and Florida. Our ability to directly commercialize finished IFC in other states is dependent on the approval of manufacturing site BLAs by the FDA and we cannot be sure that all of the sites will receive such authorizations in a timely manner, if at all. In addition, in order to market and sell finished IFC to hospital customers throughout the U.S., we will need to identify and validate additional manufacturing partners or sell INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations or hospitals with in-house blood centers. We cannot guarantee that we will be able to successfully negotiate additional agreements with manufacturing partners on terms that are acceptable to us. IFC is a product derived from our INTERCEPT Blood System for plasma. As such, any supply disruptions or failures that could impact our plasma system will have a direct negative impact on the production of IFC. Such supply disruptions could negatively impact our ability to fulfill customer orders, which will have an adverse effect on our business reputation and the successful introduction and adoption of our new products. Further, unless or until we negotiate committed volume purchase agreements with our customers, we can provide no assurance that sales of IFC product will occur in consistent or predictable manner.

If we are unable to successfully market the INTERCEPT Blood System for cryoprecipitation to hospitals or comply with unique regulations governing finished biologics, our ability to monetize and deliver the INTERCEPT Blood System for cryoprecipitation will be negatively impacted which would materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, we may never achieve market acceptance and adoption of IFC by U.S. hospitals to generate product revenue sufficient to cover its costs.

We may be liable and we may need to withdraw our products from the market if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials. Our insurance coverage may be inadequate to offset losses we may incur.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and biologic products. We may be liable if any of our products cause injury, illness or death. Although we complete preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in preclinical and clinical testing could be discovered after a marketing approval or CE Mark approval has been received. For example, in cases where we have obtained regulatory approval or CE Mark approval for our products, we have demonstrated pathogen reduction to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. In addition, even if our products inactivate all pathogens in a blood product, it is often difficult to determine if pathogens are introduced after treatment with INTERCEPT due to blood center or hospital mishandling, shipping or other possibilities. For example, we have recently learned of instances where, following treatment with INTERCEPT, mishandling of the treated blood components has introduced environmental bacterium. We must help our blood center customers to remain or increase their vigilance in adopting best practices regarding blood component handling. Failure to adequately address this risk may call into question the efficacy of using pathogen reduction. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient or was a result of a potential defect or lack of efficacy of our products. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. In addition, should personnel at clinical study sites or ultimately, potential customers, be harmed by amustaline, or believe they have been or could be harmed by amustaline, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. Amustaline is considered a potent chemical and is the active compound of our red blood cell system.

We maintain product liability insurance, but do not know whether the insurance will provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis viruses. Although we believe that our safety procedures for handling and disposing of hazardous materials are adequate and comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result.

A recall of our products, either voluntarily or at the direction of the FDA, the competent authorities of an EU Member State, or another governmental authority, including foreign regulatory authority or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

Any adverse event involving our products, whether in the U.S. or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Under the FDA's reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. We may initiate a product recall under our own initiative if any material deficiency in our product is found, such as a component failure, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues, or withdraw a product to improve device performance or for other reasons. If we do not adequately address problems associated with our products, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. Similar actions and obligations may be imposed by the competent authorities of an EU Member State, or a foreign regulatory authority.

We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future. Such events could impair our ability to supply our products in a cost-effective and timely manner in order to meet our customers' demands.

If our competitors develop products superior to ours, market their products more effectively, or receive regulatory approval before our products, our commercial opportunities could be reduced or be eliminated.

We expect our products will continue to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use and may compete with future products that may be developed by others. Our success depends in part on our ability to respond quickly to customer and prospective customer needs, successfully receive and maintain regulatory approvals, and adapt to medical and technological changes brought about by the development and introduction of new products. Competitors' products or technologies may make our products obsolete or non-competitive. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. If competitive pathogen reduction products experience significant problems, customers and potential customers may question the safety and efficacy of all pathogen reduction technologies, including the INTERCEPT Blood System. Such questions and concerns may impair our ability to market and sell the INTERCEPT Blood System.

Several companies have, or are developing, technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen reduction systems. A number of companies are specifically focusing on alternative strategies for pathogen reduction in platelets and plasma. These alternative strategies may be more effective in reducing certain types of pathogens from blood products, including certain non-lipid-enveloped viruses, such as hepatitis A and E viruses or human parvovirus B-19, which our products have not demonstrated an ability to inactivate or have not demonstrated a high level of inactivation. If our customers determine that competitor's products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community, market adoption of our platelet and plasma products may be adversely impacted. In addition, customers and prospective customers may believe that our competitors' products are safer, more cost effective or easier to implement and incorporate into existing blood processing procedures than INTERCEPT Blood System products. Moreover, regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets.

In addition, while we believe that IFC has many advantages over competitors, traditional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Hospitals may not perceive the advantage of IFC over the competing products, we may be ineffective in selling biological agents directly to hospitals or be unable to demonstrate the economic or patient advantages to customers relative to the competitors. Further, competitors may have more experience marketing and selling products directly to hospitals.

For a discussion of the major competitors to our blood product business, see the discussion under "*Business—Competition*" in Part I, Item 1 of this Annual Report on Form 10-K.

Our platelet and plasma products and product candidates are not compatible with some collection, production and storage methods or combinations thereof. Further, blood centers using INTERCEPT must have access to those certain devices, blood bags, assays or platelet additive solutions that are compatible with our products.

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the U.S. and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet collection device manufacturers may need to modify device collection parameters or software before a prospective customer could use INTERCEPT. If these manufacturers are not cooperative or are resistant to assist their customers or do not assist with making such modifications, the potential market for our products may be limited. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe, and the pooled random donor method, which is used in the U.S. Our platelet system is designed to work with platelets collected and stored in storage solutions, called InterSol and SSP+, and for platelets suspended in 100% plasma. Fresenius is the exclusive manufacturer of InterSol and MacoPharma of SSP+, both widely-used PAS. Many of our customers and prospective customers use InterSol or SSP+ in connection with INTERCEPT treatment. Similarly, some of our customers combine multiple platelet or plasma components before treating the combined product with INTERCEPT. Further, blood centers using INTERCEPT must have access to those certain devices, blood bags, assays or platelet additive solutions that are compatible with our products.

We understand that several third-party manufacturers of pooling sets are planning to discontinue producing pooling sets due to the requirement to comply under the new European Union Regulation (EU) 2017/745, the Medical Device Regulation, or MDR. Our customers' ability to use our INTERCEPT products may be impaired should manufacturers of those products cease production or if our customers are unable to find an alternate pooling set meeting their quality and production requirement for their production of INTERECEPT-treated blood components. In addition, should other manufacturers of collection devices, compatible assays and blood bags, pooling sets or platelet additive solutions fail to obtain or maintain regulatory approval, including CE Mark approval under the MDR, experience unexpected production disruption, or decide to cease distribution of those respective products to customers and prospective customers, or prohibitively increase costs, our ability to sell the INTERCEPT Blood System may be impaired and acceptance which the marketplace could be harmed.

In order to address the entire market in the U.S., Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the U.S., we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. While we have trained many customers to break down such donations to volumes and doses compatible with our products other prospective customers may not want to modify their operating practices and may therefore choose alternative compliant practices. In order to address these customers, we would need to develop future configurations of the platelet system to treat platelet donations with such processing parameters, which is not in our current plans. We estimate that the majority of platelets used in the U.S. are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. In addition, many blood centers may view pooled random donor platelets treated with INTERCEPT as an economically optimal approach. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. In the U.S, our approved labels for the platelet system from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. While we are seeking to generate acceptable data for Amicus collected platelets stored in 100% plasma, we cannot assure you that the data will be acceptable to the FDA or that we will receive timely approval, if ever. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. In addition, given that there is some loss of platelets using our product, blood centers may need to increase collection volumes in order to use our product. Given the current blood component shortage, increased collection volumes may not be achievable or use of INTERCEPT may be considered less efficient than other operating practices. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma systems. In addition, we will need to continue to generate acceptable data in order to conform with the evolving collection practices such as automated whole-blood collection. If we are unable to conform to evolving collection practices our ability to address those portions of the market may be compromised. We may also need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations. In any event, any failures or delays in obtaining FDA, CE Mark and other regulatory approvals for any new configurations would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could materially harm our product revenue and prospects for potential future profitability.

Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We are currently conducting multiple clinical trials for our products and product candidates and plan to commence additional clinical trials of our products and product candidates in the future. We cannot be certain that the design or conduct of, or data collected from, these trials will be sufficient to support FDA, CE Mark or any other regulatory approvals outside the U.S. If we fail to produce positive results in our ongoing or planned clinical trials, the development timeline and regulatory approval and commercialization prospects for our products and our product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, would be materially adversely affected. We do not know whether we will begin or complete clinical trials on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board, ministry of health or ethics committee approval to conduct a study at a prospective clinical site, delays in recruiting subjects to participate in a study, delays in the conduct of the clinical trial by personnel at the clinical site or due to our inability to actively and timely monitor clinical trial sites because of travel restrictions, extreme weather or other natural forces, terrorist activity or general concerns over employee safety. In this regard, we have experienced delays in our RedeS and ReCePI studies related to the COVID-19 pandemic and other factors. For example, in addition to COVID-19 related delays, some clinical sites for the RedeS study are located in areas that are subject to disruption by severe weather such as flooding, hurricanes or other natural forces such as earthquakes, which have delayed enrollment and progress of the RedeS study in the past. In addition, our ReCePI study in complex cardiovascular surgery patients had been slower to enroll due to a variety of factors including low frequency of administering red blood cells to the patient population and reticence to participate in research studies. If we are unable to enroll a sufficient number of patients from the ReCePI study to generate the data needed for licensure, we will need to reach agreement with the FDA on a new pathway to generate sufficient data for the red blood cell system, including the potential for additional Phase 3 clinical trials beyond what is currently contemplated with the RedeS and ReCePI studies. In any event, we cannot be certain that further delays in the RedeS study, the ReCePI study or other clinical trials will not occur because of the COVID-19 pandemic or other factors.

Criteria for regulatory approval in blood safety indications are evolving, reflecting competitive advances in the standard of care against which new product candidates are judged, as well as changing market needs and reimbursement levels. Clinical trial design, including enrollment criteria, endpoints and anticipated label claims are thus subject to change, even if original objectives are being met. As a result, we do not know whether any clinical trial will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical studies and clinical trials and products emerging from any successful trial may not reach the market for several years.

Enrollment criteria for certain of our clinical trials may be quite narrow, further delaying the clinical trial process. For instance, clinical trials previously conducted using INTERCEPT-treated plasma for patients with thrombotic thrombocytopenic purpura lasted approximately four years due in part to the difficulties associated with enrolling qualified patients. In addition, enrollment criteria impacted the speed with which we were able to enroll patients in our European Phase 3 red blood cell system trial in chronic anemia patients, and may impact other studies. Given the need to phenotypically match donations and patients and the existing burden of managing the production and supply to sickle-cell anemia patients, donor recruitment in chronic anemia patients may be difficult or impractical, which may be costly or significantly delay or preclude our ability to obtain any FDA approval of our red blood cell system.

We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later and larger clinical trials or in the results of routine use. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

We have conducted many toxicology studies to demonstrate the safety of the platelet and plasma systems, and we have conducted and plan to conduct toxicology studies for the red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities or Notified Bodies may require further toxicology or other studies to further demonstrate our products' safety, which could delay or preclude regulatory approval and commercialization. Furthermore, any major changes to components used in our products or configuration changes to our products may require additional toxicology studies which may not produce acceptable results. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate a redesign of our product or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. Regulatory agencies weigh the potential risks of using our pathogen reduction products against the incremental benefits, which may be difficult or impossible to quantify.

If any additional product candidates receive approval for commercial sale in the U.S., or if we obtain approval for expanded label claims for the platelet system or plasma system, the FDA may require one or more post-approval clinical or *in vitro* studies as a condition of approval, such as the post-approval clinical study we are conducting in connection with the approval of the platelet system and the additional post-approval study that we are required to conduct on recovery and survival of platelets suspended in 100% plasma in connection with the expanded label claim that we received for the platelet system. In addition, the FDA has required that we successfully complete a recovery and survival study of platelets suspended in platelet additive solutions stored at five days. Each of these studies and any additional studies that the FDA may require could involve significant expense, may require us to secure adequate funding to complete and may not be successful. In addition, enrollment of post-marketing studies may be difficult to complete timely if customers of blood centers are reluctant to accept conventional, non-INTERCEPT-treated products once INTERCEPT products become available to them. Other regulatory authorities or Notified Bodies outside of the U.S. may also require post-marketing studies. Failure to successfully complete post-marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals.

The red blood cell system is currently in development and may never receive any marketing approvals.

While we are in the process of submitting for CE Mark approval of our red blood cell system, it has not been approved for marketing or commercialized anywhere in the world. Significant development and financial resources will be required to progress the red blood cell system into a commercially viable product and to obtain the necessary CE Mark and other regulatory approvals for the product. For instance, regulators or Notified Bodies may require clinical data for our red blood cell system under each collection and processing method using various additive or storage solutions before they would grant approval for any such configuration. The clinical data we have generated thus far and submitted for CE Mark approval does not support multiple configurations of collection processes, storage solutions and kits. If we are required to and are ultimately unable to collect data under each configuration or if we limit our pursuit of certain configurations over others, our market opportunity may be limited. In any event, any failure or further delays in completing the development activities for the red blood cell system would prevent or continue to delay its commercialization, which would materially and adversely affect our business, financial condition, results of operations, growth prospects and potential future market adoption of any of our products, including the red blood cell system.

In some instances, we are relying on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials and development activities for the red blood cell system. We do not control these third parties and, as a result, they may not treat our activities as their highest priority, or in the manner in which we would prefer, which could result in delays, inefficient use of our resources and could distract personnel from other activities. Additionally, if we, our contract research organizations, other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our trials may be deemed unreliable and the FDA or foreign regulatory agencies or Notified Bodies may require us to perform additional clinical trials before approving the red blood cell system for commercialization. We cannot assure you that, upon inspection, regulatory agencies will determine that any of our clinical trials comply with good clinical practices. We must also be able to demonstrate stability of our active compounds manufactured under the FDA's cGMP regulations and similar requirements outside of the U.S. which meets release specifications. If we are unable to demonstrate an ability to manufacture according to our specifications under cGMP with acceptable stability data, we may be unable to satisfy regulatory questions and requirements which could prevent or delay the potential approval of or our ability to commercialize the red blood cell system. In addition, existing lots of these red blood cell compounds manufactured under cGMP may be dispositioned by regulators or ourselves as unsuitable for clinical use which would impact our ability to produce INTERCEPT-treated red blood cells for ongoing and future clinical trials and may require changes to the manufacturing process of our red blood cell compounds or new production of the compounds, all of which would be costly and time consuming and impact our ability to perform under our BARDA contract.

In 2003, we terminated Phase 3 clinical trials evaluating a prior generation of the red blood cell system in acute and chronic anemia patients. The trials were terminated due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients in the 2003 chronic anemia trial. Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. While we successfully completed the European Phase 3 acute anemia clinical trial and the European Phase 3 chronic anemia clinical trial, we cannot assure you that the adverse events observed in the terminated 2003 Phase 3 clinical trials of our earlier red blood cell system will not be observed in current and potential future clinical trials using our modified process. We also cannot assure you that patients receiving INTERCEPT-treated red blood cells will not develop allergic reactions to the transfusion.

We will need to successfully conduct and complete license enabling Phase 3 clinical trials in the U.S. and to generate sufficient chronic anemia data for licensure. Given the need to phenotypically match donations and patients and the existing burden of managing the production and supply to sickle-cell anemia patients, donor recruitment in chronic anemia patients may be difficult or impractical, which could significantly delay or preclude our ability to obtain any FDA approval of our red blood cell system. In any event, there can be no assurance that we will be able to successfully complete these prerequisite Phase 3 clinical trials or otherwise generate sufficient Phase 3 clinical data. In part, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. The FDA

has modified the criteria for a clinical pause in the RedeS and ReCePI studies if we see three or more treatment emergent antibodies with amustaline (S-303) specificity without evidence of hemolysis in patients receiving INTERCEPT-treated red blood cells. If treatment emergent antibody reactions associated with hemolysis are observed in any of our Phase 3 trials, the FDA will require us to place a clinical hold and we will need to investigate the underlying cause. Such investigations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product's reputation and may force us to suspend or terminate development activities related to the red blood cell system in the U.S., which would have a material adverse effect on our business and business prospects. To date, two S-303 antibody events without evidence of hemolysis have been detected in the RedeS study, as well as three similar events in the ReCePI study. We do not yet know if the S-303 antibody events were in the control or test arm, and we cannot provide any assurance that additional S-303 antibody events will not occur, or if they do occur, will not be clinically significant.

We completed our European Phase 3 clinical trials of our red blood cell system for acute anemia patients and separately for chronic anemia patients. We filed our application for CE Mark approval of the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the resubmission of our application under the new MDR. While a relevant competent authority has agreed to review our CE Mark application for the red blood cell system, delays can occur for multiple reasons, including due to clock stops for questions on our CE Mark application or work load for the competent authority. In addition, we are currently in discussions with our sole supplier of key components of the red blood cell system with respect to a dispute over the timing of the termination of our manufacturing and supply agreement with that supplier and its willingness to continue to supply us with such components through an approval decision on our CE Mark application. Because our CE Mark application under the new MDR for the red blood cell system is specific to this supplier's existing manufacturing site and manufacturing processes, if we are unable to reach satisfactory resolution of this dispute, or this supplier is otherwise unable or unwilling to supply us with these components through a CE Mark approval decision using its existing manufacturing site and manufacturing processes, any approval decision on our CE Mark application would be delayed beyond our current expectations, and we may be required to engage and validate a new supplier for these components, which would substantially delay the timing of an approval decision on our CE Mark application, perhaps indefinitely. Accordingly, the timing of the ultimate approval decision on our CE Mark application remains subject to the satisfactory resolution of this dispute, including our current supplier's willingness to continue to supply us with these components using is existing manufacturing site and manufacturing processes through a CE Mark approval decision, or alternatively, the engagement and validation of a new supplier of these key components, and in any event will be based on questions about our CE Mark application and the timing of the responses, and we do not otherwise expect an approval decision will occur for at least another 12 months, if ever. Moreover, we do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to receive CE Mark approval, even if limited to a target patient population having chronic anemia. Furthermore, we do not yet know if the clinical data we have generated will be sufficient to satisfy the stricter standards imposed by the MDR. If such data is deemed insufficient, we may need to generate additional safety data in clinical trials to satisfy the MDR standards. We will likely need to generate additional safety and efficacy data in order to achieve broad label claim or market acceptance. In addition, the European Phase 3 clinical trials in acute, and separately, chronic anemia patients, may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. These data may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate non-inferiority of INTERCEPT red blood cells compared to conventional red blood cells and the significantly lower lifespan for INTERCEPT red blood cells compared to conventional red blood cells may limit our ability to obtain any regulatory approvals in certain countries for the red blood cell system. A number of trial design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials.

If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues, securing commercial manufacturing for sufficient volumes or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our R&D expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. When we experience delays in testing, conducting trials or approvals, our product development costs will increase, which may exceed the budgets or timeframe under our BARDA agreement or which costs may otherwise not be reimbursable to us under the BARDA agreement. Even if we were to successfully complete and receive approval for our red blood cell system, potential blood center customers may object to working with a potent chemical, like amustaline, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system. If the red blood cell system were to face such objections from potential customers, we may choose to pay for capital assets, specialized equipment or personnel for the blood center, which would have a negative impact on any potential contribution margin from red blood cell system sales. Moreover, customers may not accept the manual configuration of the product and require us to develop a more operationally scalable version of the system which would be expensive and may not be successful. Additionally, the use of the red blood cell system may result in some processing loss of red blood cells. If the loss of red blood cells leads to increased costs, or the perception of increased costs for potential customers, or potential customers believe that the loss of red blood cells reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, potential customers may not adopt our red blood cell system, even if approved for commercial sale.

Risks Related to Regulatory Approval and Oversight, and Other Legal Compliance Matters

Our company, our products, and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic and foreign authorities.

Our products, both those sold commercially and those under development are subject to extensive and rigorous regulation by local, state and federal regulatory authorities in the U.S. and by foreign regulatory bodies. Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes in order for the FDA and international regulatory authorities to approve them for commercial use. For our product candidates, we must provide the FDA and international regulatory authorities with preclinical, clinical and manufacturing data demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale. The process of obtaining required regulatory approvals is expensive, uncertain and typically takes a number of years. We may continue to encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all. In addition, our labeling claims may not be consistent across markets. We have developed our products with the aim to standardize the volume of platelets treatable by our system, wherever possible, which may not be accepted by all regulators or customers, may require additional data to support approval or may not produce optimal transfusable blood components. For example, jurisdictions differ in the definition of what constitutes a transfusable unit of platelets and in certain jurisdictions, our approved label claims and the definition of a viable platelet unit for transfusion may allow for a significantly lower or higher platelet count per volume than certain jurisdictions may allow. This variability in platelet count per volume may result in differences in platelet quality once processed and stored using INTERCEPT, and if customers experience sub-optimal platelet quality following INTERCEPT treatment, they may limit their adoption of INTERCEPT or consider adoption of competing blood safety technologies over INTERCEPT.

Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

Outside of the U.S., regulations vary by country, including the requirements for regulatory and marketing approvals or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to CE Mark documentation, countries outside the E.U. may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, Singapore and elsewhere may require in-country clinical trial data, among other requirements, or that our products be widely adopted commercially in Europe and the U.S., or may delay such approval decisions until our products are more widely adopted. In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the U.S., Germany, Canada, Austria, Australia and other countries, applicable to prospective customers of INTERCEPT Blood System products and the blood centers that process and distribute blood and blood products. In those countries, blood centers and other customers are required to obtain approved license supplements from the appropriate regulatory authorities before making available blood products processed with our pathogen reduction systems to hospitals and transfusing physicians. Our customers may lack the resources or capability to obtain such regulatory approvals. Significant product changes or changes in the way customers use our products may require amendments or supplemental approvals to licenses already obtained. Blood centers that do submit applications, supplements or amendments for manufacturing and sale may face disapproval or delays in approval that could further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

In March 2020, we received extensions of our CE Mark approvals for the platelet and plasma systems to 2024 that were issued on the basis of under the MDD; however, we cannot assure you that our products will timely meet the requirements of the new MDR prior to the expirations of the current MDD extensions, and our failure to meet the requirements of the new MDR could materially and adversely affect our business, financial condition, results of operations and growth prospects. We or our customers have received approval for the sale and/or use of INTERCEPT-treated platelets and plasma within Europe in France, Switzerland, Germany and Austria. However, we have recently learned that Swiss regulators will no longer accept CE Mark approval issued on the basis of the MDR for European Union based medical devices. While we are currently in the process of completing the requirements to maintain regulatory approval of our products in Switzerland, we cannot assure you that we will be successful in doing so. In addition, we or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE Mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals due to changes in regulatory law, our inability to maintain compliance with regulations or other factors. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval. If we or our customers are unable to obtain or maintain regulatory approvals for the use and sale or continued sale and use of INTERCEPT-treated platelets or plasma, market adoption of our products will be negatively affected and our business, financial condition, results of operations and growth prospects would be materially and adversely impacted.

As a condition to the initial FDA approval of the platelet system, we were required to submit data from a post-approval clinical study of the platelet system – a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT-treated platelets. While that post marketing study was successful, we are also required to conduct a post-approval recovery and survival clinical study in connection with the label expansion approval for the use of the platelet system to treat platelets suspended in 100% plasma as well as a recovery and survival study of platelets suspended in platelet additive solutions stored at five days. Successful enrollment and completion of these additional post-approval studies will require that we identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers, which we may be unable to do in a timely manner or at all. In addition, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources, which could have an adverse effect on our financial condition and results of operations. In addition, there is a risk that post-approval studies will be unsuccessful or show results inconsistent with our previous studies. Should this happen, potential customers may delay or choose not to adopt the INTERCEPT Blood System and existing customers may cease use of the INTERCEPT Blood System. Failure to successfully complete post-marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals.

We are also required to comply with applicable FDA and other regulatory post-approval requirements relating to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory authorities' requirements, including, in the U.S., ensuring that quality control and manufacturing procedures conform to cGMP and current QSR requirements. We must also comply with requirements concerning advertising and promotion for our products. For example, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, or a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. In addition, our reputation could be damaged and adoption of the products could be impaired.

If a regulatory authority suspects or discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory authority may impose restrictions on use of that product, including requiring withdrawal of the product from the market. Our failure to comply with applicable regulatory requirements could result in enforcement action by regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, seizure, consent decrees and civil penalties;
- repair, replacement, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products and regulatory strategies;
- exclusion from participation in government programs, such as Medicare and Medicaid
- refusal to grant export or import approval for our products or refusal to allow us to enter into government contracts;
- additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance;
- withdrawing or variation in marketing approvals that have already been granted, resulting in prohibitions on sales of our products; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from selling our products and harm our business. In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity.

Should we obtain approval of our red blood cell system, we will likely be required by regulators to collect additional data in patients receiving INTERCEPT-treated red blood cells. In addition, assuming approval, we will be required to develop a registry of patients receiving INTERCEPT-treated red blood cells for future data collection and evaluation. To commence, enroll and complete such a registry, we may incur significant costs. Further, introducing and implementing use of such a registry may face data collection challenges

or resistance from transfusing physicians, hospitals or patients. We cannot ensure that the data collected in such a registry would support continued use of INTERCEPT-treated red blood cells.

In addition, the regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, increased operation costs or lower than anticipated sales. For example, complying with the new MDR will require considerable time, attention and effort by our manufacturers and us and may limit or delay any contemplated changes to our products or expansion of label claims.

If we or our third-party suppliers fail to comply with the FDA's or other regulatory authorities' good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.

In order to be used in clinical studies or sold in the U.S., our products are required to be manufactured in FDA-approved facilities. If any of our suppliers fail to comply with FDA's cGMP regulations or otherwise fail to maintain FDA approval, we may be required to identify an alternate supplier for our products or components. Our products are complex and difficult to manufacture. Finding alternate facilities and obtaining FDA approval for the manufacture of the INTERCEPT Blood System at such facilities would be costly and time-consuming and would negatively impact our ability to generate product revenue from the sale of our platelet, plasma or cryoprecipitation system in the U.S. and achieve operating profitability. Our red blood cell system also needs to be manufactured in FDA-approved facilities, several of which are not currently FDA-approved. Failure of our suppliers to meet cGMP regulations and failure to obtain or maintain FDA approval will negatively impact our ability to achieve FDA approval for our red blood cell system or may require that we identify, qualify and contract with alternative suppliers, if they are available, which would be time consuming, costly and result in further approval delays.

We and our third-party suppliers are also required to comply with the cGMP and QSR requirements, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA and other regulatory authorities audit compliance with cGMP and QSR requirements through periodic announced and unannounced inspections of manufacturing and other facilities. These audits and inspections may be conducted at any time. The manufacturing facility which produces our platelet and plasma systems was recently audited by the FDA. While there were not objectionable conditions observed during the audit, the FDA or other regulatory authorities may inspect and audit facilities manufacturing or products or components at any time. Complying with and resolving any audit findings may result in additional costs, changes to our manufacturers' quality management systems or both. Failure to timely resolve and comply to audit findings, if any, may result in enforcement actions and may result in a disruption to the supply of our products. In any event, if we or our suppliers fail to adhere to cGMP and QSR requirements, have significant non-compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA or other regulatory agency could take enforcement action against us, which could delay production of our products and may include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing or variation of marketing approvals that have already been granted;
- refusal to grant export or import approval for our products; or
- criminal prosecution.

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects.

If we modify our FDA-approved products, we may need to seek additional approvals, which, if not granted, would prevent us from selling our modified products.

Any modifications to the platelet, plasma or cryoprecipitation systems could be determined to significantly affect their safety or effectiveness, including significant design and manufacturing changes, or determined to constitute a major change in their intended use, manufacture, design, components, or technology which would require approval of a new premarket approval application, or PMA, or PMA supplement. Further, any modification to our plasma system may have an impact on the cryoprecipitation system, which may similarly require approval of a new PMA supplement. However, certain changes to a PMA-approved device do not require submission

and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier's decision. The FDA may not agree with our decisions regarding whether new submissions or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, we are redesigning the illuminators used in the platelet and plasma systems and may need to further redesign the illuminator. We will need to obtain regulatory approval of any future redesign of the illuminator before it can be commercialized. Generating data from the new illuminator may be time consuming, expensive or unsuccessful. In addition, in order to address the entire market in the U.S., customers will need to change their operating practices to conform to our product specifications or we will need to obtain approval for additional configurations of the platelet system, as discussed in greater detail above under "*Risks Related to Our Business and Industry—Our platelet and plasma products and product candidates are not compatible with some collection, production and storage methods or combinations thereof*." Should we decide not to pursue or otherwise fail to obtain FDA and foreign regulatory approvals of any new configurations, our ability to generate product revenue from sales of the platelet system may be impaired and our growth prospects may be materially and adversely affected.

In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions, including the option of pathogen reduction technology, when we had not received approval for all operational configurations, the market to which we could sell our products may be limited until we obtain such approvals, if ever, or may be permanently impaired if competing options are more broadly available.

We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business.

We are subject to a number of laws that affect our sales, marketing and other promotional activities by, among other things, limiting the kinds of financial arrangements we may have with hospitals, healthcare providers or other potential purchasers of our products. These laws are often broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. For example, within the E.U., the control of unlawful marketing activities is a matter of national law and regulations in each of the EU Member States. There are a variety of organizations and entities within EU Member States which monitor perceived unlawful marketing activities. We could face civil, criminal and administrative sanctions if it is determined that we have breached our obligations in any EU, Member State in respect of our marketing activities. Industry associations also closely monitor the activities of member companies. If these organizations or authorities name us as having breached our obligations under their regulations, rules or standards, our reputation would suffer and our business and financial condition could be adversely affected.

In addition, there are numerous U.S. federal, state and local healthcare regulatory laws, and equivalent foreign laws, including but not limited to, anti-kickback laws, false claims laws, privacy laws, and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, hospitals, blood centers, physicians, other healthcare providers, and our customers are subject to scrutiny under these laws. Violations of these laws can subject us to significant penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs, including the Medicare and Medicaid programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment of our operations. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce, the referral of an individual for, the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens on behalf of the government, through civil whistleblower or qui tam actions, and the federal civil monetary penalties law, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal payors that are false or fraudulent, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, and which may apply to entities that provide coding and billing advice to customer;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private payors, or making materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses as well as their business associates and their subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections; and
- foreign, or U.S. state or local law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; U.S. state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government or otherwise restrict payments that may be made to healthcare providers; U.S. state and local laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and U.S. state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In addition, there has been a trend of increased U.S. federal, state and local regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payments Sunshine Act, imposes annual reporting requirements on device manufacturers for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS for payments and other transfers of value provided by them, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

We are also subject to domestic and foreign laws and regulations covering data privacy and the protection of health-related and other personal information. Domestic privacy and data security laws are complex and changing rapidly. Many states have enacted laws regulating the online collection, use and disclosure of personal information and requiring that companies implement reasonable data security measures. Laws in all states and U.S. territories also require businesses to notify affected individuals, governmental entities and/or credit reporting agencies of certain security breaches affecting personal information. These laws are not consistent, and compliance with them in the event of a widespread data breach is complex and costly.

In the U.S., the California Consumer Privacy Act of 2018, or CCPA, gives California residents expanded rights related to their personal information, including the right to access and delete their personal information, and receive details about how their personal information is used and shared. These create an additional burden on us, as do the restrictions on "sales" of personal information that allow Californians to opt-out of certain sharing of their personal information. The CCPA prohibits discrimination against individuals who exercise their privacy rights, provides for civil penalties for violations and creates a private right of action for data breaches that is expected to increase data breach litigation. Similarly, the California Privacy Rights Act, or CPRA, when it becomes effective on January 1, 2023, will restrict use of certain categories of sensitive personal information; further restrict the use of cross-contextual advertising techniques; establish restrictions on the retention of personal information; expand the types of data breaches subject to the private right of action; and establish the California Privacy Protection Agency to implement and enforce the new law, as well as impose administrative fines. 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).

In the EU, the General Data Protection Regulation, or GDPR, which is wide-ranging in scope, imposes detailed requirements relating to the control over personal data by individuals to whom the personal data relates, the information that we must provide to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater.

Further, the exit of the United Kingdom, or UK, from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the EU on January 1, 2020, subject to a transition period that ended December 31, 2020. The UK has implemented legislation similar to the GDPR, the UK GDPR, including the UK Data Protection Act, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher. Additionally, the relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear following Brexit, including with respect to regulation of data transfers between EU Member States and the UK. On June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the UK ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the UK. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. We cannot fully predict how the Data Protection Act, the UK GDPR, and other UK data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the UK will be regulated.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU). Existing mechanisms that may facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to provide an adequate level of data privacy and security. The European Commission released a set of "Standard Contractual Clauses" in June 2021 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.

The CCPA, CPRA and similar laws in other states, GDPR and other international privacy laws have increased our responsibility and potential liability in relation to personal data that we process compared to prior law, including in clinical trials and employee data, and we may be required to put in place additional mechanisms to ensure compliance with these laws, which could divert management's attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR and the UK GDPR, we may not be successful either due to various factors within our control or other factors outside our control. It is also possible that local courts and data protection authorities may have different interpretations of applicable law, leading to potential inconsistencies in application of these laws. If we are unable to implement sufficient safeguards to ensure that our transfers of personal information from Europe are lawful, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal information from Europe.

Complying with our obligations under applicable privacy laws, regulations, amendments to or re-interpretations of existing laws and regulations, and contractual or other requirements relating to privacy, data protection, data transfers, data localization, or information security may require us to make changes to our services to enable us or our customers to meet new legal requirements, incur substantial operational costs, modify our data practices and policies, and restrict our business operations. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data security, marketing or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, new regulations, legislative actions or changes in interpretation of existing laws or regulations regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business.

We are also subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti-corruption intent in foreign countries. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement. Any violation of these laws by us or our agents, distributors or joint venture partners could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. We currently operate in many countries where the public sector is perceived as being more or highly corrupt. Our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption activity, such as China, India and Russia. Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly. In addition, failure by us or our agents, distributors or joint venture partners to comply with these laws, rules and regulations could delay our expansion into high-growth markets, could damage market perception of our business and could adversely affect our existing business operations. Increased business in higher risk countries could also subject us and our officers and directors to increased scrutiny and increased liability.

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which have led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Any such investigation or settlement could increase our costs or otherwise have

an adverse effect on our business. In addition, most of these laws apply to not only the actions taken by us, but also actions taken by our distributors and other third-party agents, and healthcare providers with whom we interact. We have limited knowledge and control over the business practices of our distributors and agents, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition.

Legislative, regulatory, or other healthcare reforms may make it more difficult and costly for us to obtain regulatory approval of our products and to produce, market and distribute our products after approval is obtained.

Regulatory guidance and regulations are often revised or reinterpreted by the regulatory agencies in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of, or failure to receive, regulatory approvals for our new products or product configurations would have a material adverse effect on our business, results of operations and financial condition.

Federal and state governments in the U.S. have enacted legislation to overhaul the nation's healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The ACA significantly impacts the medical device industry. Among other things, the ACA:

- established a Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

There have been executive, judicial and Congressional challenges to numerous provisions of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision repealing, 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". 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 that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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 any such challenges and the healthcare reform efforts of the Biden administration will impact ACA and our business. The implementation of new health care legislation could result in significant changes to the health care system, which could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 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 relief support legislation suspended the 2% Medicare sequester 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. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, Congress is considering additional health reform measures.

More recently, there has been heightened governmental scrutiny in the U.S. to control the rising cost of healthcare. For example, such scrutiny has resulted in several recent presidential executive orders, congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to pricing and reform government program reimbursement methodologies for pharmaceutical products. 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. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. State legislatures are also increasingly passing legislation and implementing regulations designed to control the cost of healthcare, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. We expect that additional U.S federal and state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Risks Related to Government Contracts

A significant portion of the funding for the development of the red blood cell system is expected to come from our BARDA agreement, and if BARDA were to eliminate, reduce, delay, or object to extensions for funding of our agreement, it would have a significant, negative impact on our government contract revenues and cash flows, and we may be forced to suspend or terminate our U.S. red blood cell development program or obtain alternative sources of funding.

We anticipate that a significant portion of the funding for the development of the red blood cell system in the United States will come from our agreement with BARDA. The agreement, including its subsequent modifications, provide for reimbursement of certain expenses incurred by us for up to approximately $223.5 million to support the development of the red blood cell system. However, our agreement with BARDA only reimburses certain specified development and clinical activities that have been authorized by BARDA pursuant to the base period and certain options of the agreement and the potential exercise of subsequent option periods. To date, BARDA has exercised approximately $126.5 million under the base period of the agreement and associated options. Accordingly, our ability to receive any of the unexercised $97.0 million in additional funding provided for under the BARDA agreement is dependent on BARDA exercising additional options under the agreement, which it may do or not do at its sole discretion. In addition, BARDA is entitled to terminate our BARDA agreement for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. In addition, activities covered under the base period and exercised options may ultimately take longer than is allowed or cost more than is covered by the BARDA contract. Exercised and unexercised options under the BARDA contract will likely require a longer performance period to complete than is remaining on our agreement; if we are unable to secure additional funding or allow for additional time for completion, we would have to bear the cost to complete the activities or terminate the activities before completion. We have hired and maintain staffing, as well as having entered into agreements with third parties to perform activities associated with the BARDA contract. Should we be unable to fully utilize the personnel or third parties as planned, either because of BARDA funding or time limitations, or other reasons, we may be forced to bear costs that we had anticipated would be covered under the contract. Moreover, the continuation of our BARDA agreement depends in large part on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. BARDA may suspend or terminate the agreement should we fail to achieve key milestones, or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. The uncertainty regarding the duration of the COVID-19 pandemic, and its impact on participating blood centers, hospitals and their patients, severe weather or other natural disaster impacts to sites enrolling our clinical trials may all negatively impact our ability to complete our clinical trials. Our ability to meet the expectations of BARDA under our contract is largely dependent on our ability to attract, hire and retain personnel with competencies that are in short supply. In addition, in many instances we must identify third-party suppliers, negotiate terms acceptable to us and BARDA and ensure ongoing compliance by these suppliers with the obligations covered by our BARDA agreement. If we are unable to provide adequate supplier oversight or if suppliers are unable to comply with the requirements of the agreement, our ability to meet the anticipated milestones may be impaired.

There can also be no assurance that our BARDA agreement will not be terminated, that our BARDA agreement will be extended for existing exercised options or through the exercise of subsequent option periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under our agreement with BARDA. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment and uncertainty associated with the COVID-19 pandemic, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of pathogen reduction technology. While BARDA has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID-19, the availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. Furthermore, funding limitations may require certain activities to slow or be deferred which may be impractical to do. In addition, if we are unable to generate sufficient prerequisite Phase 3 clinical data, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If our BARDA agreement is terminated or suspended, if there is any reduction or delay in funding under our BARDA agreement, or if BARDA determines not to

exercise some or all of the options provided for under the agreement, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, or if we determine that the cost of alternative available capital is too high, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed by BARDA, our cash flows would be negatively impacted, or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. This in turn would impair our ability to complete ongoing studies or commence new studies.

In addition, under the BARDA agreement, BARDA will regularly review our development efforts and clinical activities. Under certain circumstances, BARDA may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such BARDA advice, overall red blood cell program delays and costs associated with additional resources for which we had not planned may result. Also, the costs associated with following such advice may or may not be reimbursed by BARDA under our agreement. Finally, we may decide not to follow the advice provided by BARDA and instead pursue activities that we believe are in the best interests of our red blood cell program and our business, even if BARDA would not reimburse us under our agreement.

Unfavorable provisions in government contracts, including in our contract with BARDA, may harm our business, financial condition and operating results.

U.S. government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our agreement with BARDA, the U.S. government has the power to unilaterally:

- audit and object to any BARDA agreement-related costs and fees on grounds that they are not allowable under the Federal Acquisition Regulation, or FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or grants or extending our existing agreement based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA agreement and may, under certain circumstances involving public health and safety, license such inventions to third parties without our consent;
- cancel, terminate or suspend our BARDA agreement based on violations or suspected violations of laws or regulations;
- terminate our BARDA agreement in whole or in part for the convenience of the government for any reason or no reason, including if funds become unavailable to the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response;
- reduce the scope and value of our BARDA agreement;
- decline to exercise an option to continue the BARDA agreement;
- direct the course of the development of the red blood cell system in a manner not chosen by us;
- require us to perform the option periods provided for under the BARDA agreement even if doing so may cause us to forego or delay the pursuit of other red blood cell program opportunities with greater commercial potential;
- take actions that result in a longer development timeline than expected;
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for the red blood cell program even after it has been funded for an initial period; and
- change certain terms and conditions in our BARDA agreement.

Generally, government contracts, including our agreement with BARDA, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed (plus a portion of the agreed fee) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit recovery of fees. In addition, in the event of termination or upon expiration of our BARDA agreement, the U.S. government may dispute wind-down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. government for denying certain payments under our BARDA agreement, such a challenge could subject us to substantial additional expenses that we may or may not recover. Further, if our BARDA agreement is terminated for convenience, or if

we default by failing to perform in accordance with the contract schedule and terms, a significant negative impact on our cash flows and operations could result.

In addition, government contracts normally contain additional requirements that may increase our costs of doing business and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program;
- mandatory internal control systems and policies; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential liability and to the termination of our BARDA agreement.

Furthermore, we have entered into and will continue to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors, in order to satisfy our contractual obligations under our BARDA agreement. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our BARDA agreement. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our BARDA agreement.

As a result of the unfavorable provisions in our BARDA agreement, we must undertake significant compliance activities. The diversion of resources from our development and commercial programs to these compliance activities, as well as the exercise by the U.S. government of any rights under these provisions, could materially harm our business.

Laws and regulations affecting government contracts, including our agreements with BARDA and the FDA, make it more costly and difficult for us to successfully conduct our business. Failure to comply with laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply with numerous laws and regulations relating to the administration and performance of our agreements. Among the most significant government contracting regulations are:

- the FAR and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Statute, the Procurement Integrity Act, the False Claims Act and the U.S. Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our agreement-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event that the government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, the government would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. In addition, under U.S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal

prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

Risks Related to Our Reliance on Third Parties

We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries.

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain and maintain any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may adversely affect our financial condition and results of operations. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of product revenue and our ability to accurately forecast our product supply needs. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, initial purchases of illuminators or INTERCEPT disposable kits by these third parties may not lead to follow-on purchases of platelet and plasma systems' disposable kits. We have a finite number of illuminators that can be produced under the current approved configuration before a redesigned and approved illuminator is available. Agreements with our distributors typically require the distributor to maintain quality standards that are compliant with standards generally accepted for medical devices. We may be unable to ensure that our distributors are compliant with such standards. Further, we have limited visibility into the identity and requirements of blood banking customers these distributors may have. Accordingly, we may be unable to ensure our distributors properly maintain illuminators sold or provide quality technical services to the blood banking customers to which they sell.

Currently, a fairly concentrated number of distributors contribute a significant portion of our product revenue and we may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations and contractual provisions. In the past, we have experienced weaker than expected growth due to declining performance by certain of our distributors. Periodically, we transition certain territories to new distribution partners or our direct sales force where we believe we can improve performance relative to the distributor. Because new distribution partners or our direct sales force may have limited experience marketing and selling our products in certain territories, or at all, we cannot be certain that they will perform better than the predecessor distributor. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. Termination, loss of exclusivity or transitioning from these distributors may require us to negotiate a transfer of the applicable regulatory approvals to us or new distributors which may be difficult to do in a timely manner, or at all. We expect that our product revenue will be adversely impacted with the loss or transition of one or more of these distributors. If we choose to terminate distributor agreements, we would either need to reach agreement with, qualify, train and supply a replacement distributor or supply and service end-user customer accounts in those territories ourselves. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us, there can be no assurance that this will happen in a timely manner or at all or that the distributor will honor its outstanding commitments to us. In addition, terminated distributors may own illuminators placed at customer sites and may necessitate us to repurchase those devices or require end-user customers to purchase new devices from us. Additionally, we may need terminated distributors to cooperate with us or a new distributor in transitioning sub-distributor relationships and contracts, hospital contracts, public tenders, or regulatory certificates or licenses held in their name. These factors may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense, our working capital is negatively impacted due to longer periods from cash collection from direct sales customers when compared to the timing of cash collection from our former distribution partners and we may be exposed to additional complexity including local statutory and tax compliance. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. In addition, in territories where new distributors are responsible for servicing end-user accounts, there will be a period of transition in order to properly qualify and train these new distributors, which may disrupt the operations of our customers and adversely impact our reputation and operating results. In certain cases where a terminated distributor holds title to illuminators placed in the field, we may choose to buy back the illuminators from the distributor to ensure continuity of service to those customers. If this were to occur, our recognizable product revenue would be negatively impacted.

In February 2021, we entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd. ("ZBK"), to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD. (the "JV") for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood transfusion for platelets and red blood cells in the People's Republic of China. We own 51% of equity in the JV and consolidates the JV. The JV will need to obtain regulatory approval for the INTERCEPT Blood System for Platelets and Red Blood Cells before it can begin commercializing in China. In order to obtain that regulatory approval, the JV may need to run additional clinical studies in China. We cannot assure you the JV will be successful in meeting the endpoint, once defined, or that it will ever receive regulatory approval.

Our manufacturing supply chain exposes us to significant risks.

We do not own our own manufacturing facilities, but rather manufacture our products using a number of third-party suppliers, many of whom are our sole suppliers for the particular product or component that we procure. We rely on various contracts and our relationships with these suppliers to ensure that the sourced products are manufactured in sufficient quantities, timely, to our exact specifications and at prices we agree upon with the supplier. For example, Fresenius is our sole supplier for the manufacture of finished disposable kits for the platelet and plasma systems. We also rely on other third-party suppliers for other components and products that are currently our sole qualified suppliers for such components and products. In the event Fresenius or any of our other sole qualified suppliers refuses or is unable to continue operating under our supply agreements with them, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected. We may also encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. In addition, our product supply chain requires us to purchase certain components in minimum quantities or make last time purchases of obsolete components and may result in a production cycle of more than one year. Significant disruptions to any of the steps in our supply chain process may result in longer productions cycles which could lead to inefficient use of cash or may impair our ability to supply customers with product. Moreover, the price that we pay to some of our suppliers is dependent on the volume of products or components that we order. If we are unable to meet the volume tiers that afford the most favorable pricing, our gross margins will be negatively impacted.

Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons or may unilaterally change the formulations of certain commercially available reagents that we use, causing at least temporary interruptions in supply. In addition, we may need to identify, validate and qualify additional manufacturing capacity with existing or new suppliers. Further, customer demand for our platelet kits is likely to fully utilize the production capacity of our third-party manufacturer(s). As a result, we may need to allocate manufacturing resources such that our supply and mix of platelet kits or plasma kits could be adversely impacted. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill and potentially irreversible loss of momentum in the marketplace. Although we are actively evaluating alternate suppliers and working with suppliers to make the capital investments to operationalize additional sites within our existing supplier's networks for certain components and finished kits, we do not have qualified additional sites or suppliers or capacity beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. In addition, suppliers from whom our contract manufacturers source components and raw materials may cease production or supply of those components to our contract manufacturers. Identification and qualification of alternate suppliers is time consuming and costly, and there can be no assurance that we will be able to demonstrate equivalency of alternate components or suppliers or that we will receive regulatory approval in the U.S. or other jurisdictions. If we conclude that supply of the INTERCEPT Blood System or components from suppliers is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient.

We have purchased a last time build of our current model illuminator, which is being phased out of manufacture due to obsolescence of certain components. As a result, we do not intend to continue manufacturing the current model illuminator. We are currently redesigning the illuminator which is expected to take more than twelve months to complete and obtain regulatory approval. Until such time as we obtain approval for the redesigned illuminator, if ever, the demand for illuminators may be higher than the remaining number of illuminators in inventory, resulting in possible customer allocations or loss of sales. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers, increase production for existing customers or sign up new customers may be negatively impacted. Any failure to, or delays in, receiving regulatory approvals for the redesigned illuminator, or increased costs associated with mitigating any such delays, could materially and adversely affect our business, financial condition, results of operations and growth prospects. Furthermore, we understand that components used in the illuminator are no longer commercially available beyond what we and Nova have stockpiled or to which we have access under final buy transactions or may become unavailable in the current specifications in the near-term. As with our disposable sets, if we conclude that supply of components or spare parts for the illuminators is uncertain, we may choose to purchase and maintain inventories of such components or spare parts, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient. We

are and will need to continue investing in subsequent versions of the illuminator to enhance functionality and manage obsolescence. In addition, our illuminators contain embedded proprietary software that runs on software code we have developed and that we own. Changes to certain components due to obsolescence, illuminator redesign or market demand, may require us to modify the existing software code or to develop new illuminator software. Our ability to develop new illuminator software, correct coding flaws and generally maintain the software code is reliant on third-party contractors who, in some cases, have sole knowledge of the software code. Our ability to develop and maintain the illuminator software may be impaired if we are not able to continue contracting with those key third-party contracted developers or if we are unable to source alternate employees or consultants to do so.

To meet the growing demand for our products, we are likely to invest in manufacturing capacity at existing or alternative manufacturing sites with existing and alternative suppliers, which could be costly and disruptive to our business. In the event that alternate manufacturers or alternate manufacturing sites are identified and qualified, we will need to transfer know-how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers and manufacturing sites; however, certain of our supplier's materials, manufacturing processes and methods are proprietary to them, which will impair our ability to establish alternate sources of supply, even if we are required to do so as a condition of regulatory approval. We may be unable to establish alternate suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all.

Moreover, the inclusion of components manufactured by new suppliers or by alternate sites within our current network of suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms more favorable to us than those that we currently have with our manufacturers. Many of the existing agreements we have with suppliers contain provisions that we have been operating under for an extended period of time, including pricing. Should we enter into agreements or amend agreements with any manufacturer with less favorable terms, including pricing, our results of operations may be impacted, our recourse against such manufacturers may be limited, and the quality of our products may be impacted. Furthermore, we do not have experience working with partners that are producing our products in multiple sites globally. Should we need to oversee our manufacturers producing components or finished goods for our products in multiple global plants, we may be unsuccessful in providing an adequate level of oversight, may be unable to manage the complexity of such operations, including quality, incur additional costs in managing the global supply chain including capital investments in those plants or become less efficient with our use of cash and working capital.

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In the past, non-conformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. Similarly, we have experienced non-conformities and out of specification results in certain component manufacturing needed for clinical use, commercial sale and regulatory submissions. Non-conformities can increase our expenses and reduce gross margins or result in delayed regulatory submissions or clinical trials. Any quality failure in manufacturing by our suppliers may result in a significant write down and impact to our reported gross margins. Should non-conformities occur in the future, we may be unable to manufacture products to support our red blood cell clinical trials, or to meet customer demand for our commercial products, which would result in delays for our clinical programs, or lost sales for our commercial products, and could cause irreparable damage to our customer relationships. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product, manufacturer or facility, including withdrawal of the product from the market.

In addition, we may not receive timely or accurate demand information from distributors or direct customers, or may not accurately forecast demand ourselves for the INTERCEPT Blood System. Should actual demand for our products exceed our own forecasts or forecasts that customers provide, we may be unable to fulfill such orders timely, if at all. Should we be unable to fulfill demand, particularly if mandated by a public health authority or as included in the Final Guidance Document for the U.S., our reputation and business prospects may be impaired.

Further, certain distributors and customers require, and potential future distributors or customers may require, product with a minimum shelf life. If customers requiring minimum shelf-lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf-lives which may lead to increased write-offs and inefficient use of our cash. Should we choose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs and/or reduced gross margins. In order to meet minimum shelf-life requirements, we may need to manufacture sufficient product to meet estimated forecasted demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. Our platelet and plasma systems' disposable kits have 18 to 24 months shelf lives from the date of manufacture. Should we change or modify any of our product configurations or components, such future configurations of our products may not achieve the same shelf life that existing products have. We and our distributors may be unable to ship product to customers prior to the expiration of the product shelf life, a risk that is

heightened if we elect to increase our inventory levels in order to mitigate supply disruptions. We have entered into certain public tenders or may enter into commercial contracts with customers, that call for us to maintain certain minimum levels of inventory. If our suppliers fail to produce components or our finished products satisfactorily, timely, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non-compliance with certain public tenders which may in turn result in penalty fees, permanent harm to our customer relations or loss of customers. In addition, certain large national prospective customers, like those in the U.K. or Japan, may choose to convert all of their operations to INTERCEPT. Should we or our suppliers encounter any manufacturing issues or if we and our suppliers are not able to build more manufacturing capacity, we may not be able to satisfy all of the global demand or may have to allocate available product to certain customers which may force customers to adopt competing products, which could permanently impact our ability to convert those customers to INTERCEPT users and may negatively impact our customers operations and consequently, our competitive position and reputation. Conversely, we may choose to overstock inventory in order to mitigate any unforeseen potential disruption to manufacturing which could consume our cash resources faster than we anticipate and may cause our supply chain to be less efficient.

Until we sell sufficient INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations, expand the number of manufacturing partners producing IFC for us, or more of our manufacturing partners for IFC receive approval of their BLAs, our IFC sales will be limited. Additionally, because IFC are products derived from our INTERCEPT Blood System for plasma, any supply disruptions or failures that could impact our plasma system will have a negative direct impact on the production of IFC. We currently have no experience with customer expectations regarding turnover or inventory levels of IFC held at either our blood center manufacturing partners or at the hospitals themselves. Our IFC product has a shelf life of five days from thaw before it expires. To mitigate product expiration, should hospitals require that we use a consigned inventory model whereby unused product at the hospital at expiration is replaced with fresh product at reduced or no cost to the hospital, we may need to keep additional inventory or manufacture IFC above levels generating an economic return, which could adversely affect our results of operations and financial condition.

Obsolescence or shortage of raw materials, key components of and accessories to the INTERCEPT Blood System, may impact our ability to supply our customers, may negatively impact the operational costs of our customers and may increase the prices at which we sell our products, resulting in slower than anticipated growth or negative future financial performance.

The manufacture, supply and availability of key components of, and accessories to, our products are dependent upon a limited number of third parties and the commercial adoption and success of our products is dependent upon the continued availability of these components or accessories. For example, our customers rely on continued availability of third-party sets, supplied plastics, saline and reagents for processing, storing and manufacturing blood components. If the blood product industry experiences shortages of these components or accessories, or if manufacturers cease production of these components or accessories, the availability and use of our products may be impaired.

With respect to the manufacture of our products, our third-party manufacturers source components and raw materials for the manufacture of the INTERCEPT processing sets. Certain of these components are no longer commercially available, are nearing end-of-life or are available only from a limited number of suppliers. We and our third-party manufacturers do not have guaranteed supply contracts with all of the raw material or component suppliers for our products, which magnify the risk of shortage and obsolescence and decreases our manufacturers' ability to negotiate pricing with their suppliers. For example, a solvent used in the manufacture of the plastic beads for the compound adsorption devices used for our products is no longer available. Accordingly, we purchased all remaining existing material. We will need to qualify plastic beads produced with a new solvent prior to consuming available inventory levels. If we are unable to use all of the raw material produced during the final production run, or if the final material produces suboptimal results, we may require customers to modify their operating practices, or run out of material before an alternate material can be qualified. Moreover, we may be required to impair or write-off the value of any unused last-time-buy raw materials or components. Customers may object to changes in operating practices or changes to the instructions for use, and a potential negative impact on their operations as a result of the use of this material, could impair our reputation or customer acceptance of our products. Any shortage or obsolescence of raw materials, components or accessories or our inability to control costs associated with raw materials, components or accessories, could increase our costs to manufacture our products. Further, if any supplier to our third-party manufacturers is unwilling or unable to provide high quality raw materials in required quantities and at acceptable prices, our manufacturers may be unable to find alternative sources or may fail to find alternative suppliers at commercially acceptable prices, on satisfactory terms, in a timely manner, or at all. Furthermore, we do not yet know whether or not certain components used by blood center operators or used in the production of INTERCEPT will comply with the new standards under the MDR. Failure to comply with the new standards timely may result in a disruption to blood center operations or the manufacture of the INTERCEPT Blood System. If any of these events were to occur, our product quality, competitive position, reputation and business could suffer, we could experience cancellations of customer orders, refusal by customers to accept deliveries or a reduction in our prices and margins to the detriment of our financial performance and results of operations.

Risks Related to Our Financial Condition and Capital Requirements

We expect to continue to generate losses and we may never achieve a profitable level of operations.

Our cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. While our net losses are narrowing, at our expected and guided sales levels of the platelet, plasma and cryoprecipitation systems, and of IFC, our costs to manufacture, distribute, market, sell, support the systems and develop new products are likely to continue to be in excess of our product revenue. We expect to incur additional research and development costs associated with the development of different configurations of existing product candidates and products and our illuminator, development of new products, planning, enrolling and completing ongoing clinical and non-clinical studies, including the post-approval studies or registry studies we are and may be required to conduct in connection with the approvals of the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting in vitro studies and clinical development of our red blood cell system in Europe and the U.S., and completing activities to support a potential CE Mark approval for our red blood cell system in Europe. These costs could be substantial and could extend the period during which we expect to operate at a loss, particularly if we experience any difficulties or delays in completing the activities. In addition, we may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, or to compete favorably with other blood safety interventions or other pathogen reduction technologies, which may reduce or altogether eliminate any gross profit on sales.

If we fail to obtain the capital necessary to fund our future operations or if we are unable to generate positive cash flows from our operations, we will need to curtail planned development or sales and commercialization activities.

Until we are able to generate a sufficient amount of product revenue or limit expenses or capital investments and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on continued access to funds under our BARDA agreement and the public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. While we believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our agreement with BARDA, will be sufficient to meet our working capital requirements for at least the next 12 months, if we are unable to generate sufficient product revenue, or access sufficient funds under our BARDA agreement or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities. In addition, while our stated goal is to achieve profitability in the future, actual results may be different than our forecasted operating plan and may require that we make certain trade-offs to potentially achieve profitability. Such trade-offs may negatively impact our commercial potential or result in deferrals in development activities.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to our Credit, Security and Guaranty Agreement (Term Loan), or the Term Loan Credit Agreement, and our Credit, Security and Guaranty Agreement (Revolving Loan), or the Revolving Loan Credit Agreement, both with MidCap Financial Trust, or MidCap, or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty, political change, and other factors, including uncertainty associated with the COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. As a result of stimulus programs put in place over the past two years, the U.S. and many countries are currently experiencing an inflationary environment. This has led to the U.S. Federal Reserve taking action to raise interest rates, which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, our suppliers may raise prices in an inflationary environment, costs to transport our products may increase, availability timeliness of shipping. If we are unable to raise additional capital when needed, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system if additional studies are necessary for regulatory approval in Europe, which would increase our costs and potentially delay the approval. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may

choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Covenants in our Term Loan Credit Agreement and Revolving Loan Credit Agreement can restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the Term Loan Credit Agreement and Revolving Loan Credit Agreement.

As of December 31, 2021, our total indebtedness under our Term Loan Credit Agreement and Revolving Loan Credit Agreement was approximately $69.4 million. All of our current and future assets, except for intellectual and certain investments in subsidiaries and affiliates, are secured, are secured for our borrowings under the Term Loan Credit Agreement and Revolving Loan Credit Agreement. The Term Loan Credit Agreement and Revolving Loan Credit Agreement require that we comply with certain covenants applicable to us and our subsidiary, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the Term Loan Credit Agreement or the Revolving Loan Credit Agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the Term Loan Credit Agreement or the Revolving Loan Credit Agreement. If we are unable to repay those amounts, the lenders under the Term Loan Credit Agreement or the Revolving Loan Credit Agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these or certain other covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose an exit fee of a percentage of the amount borrowed pursuant to the Term Loan Credit Agreement.

The proposed discontinuation or replacement of the London Inter-Bank Offered Rate, or LIBOR, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Chief Executive of the U.K. Financial Conduct Authority, or FCA, which regulates LIBOR, announced that the FCA intends to phase out the use of LIBOR. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been certain issuances utilizing SOFR, it is unknown whether this or any other alternative reference rate will attain market acceptance as a replacement for LIBOR. The one-month U.S. dollar LIBOR is used as a benchmark rate in our Term Loan Credit Agreement and Revolving Loan Credit Agreement. The FCA had indicated that the one-month U.S. dollar LIBOR reference rate will phase out as of June 30, 2023. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on us are not yet known with certainty. The transition process may involve, among other things, increased volatility and illiquidity in markets for instruments that currently rely on LIBOR and may result in increased borrowing costs and interest rates, the effectiveness of related transactions such as hedges, uncertainty under applicable documentation, including our Term Loan Credit Agreement and Revolving Loan Credit Agreement, or difficult and costly processes to amend such documentation. As a result, our ability to refinance our Term Loan Credit Agreement, Revolving Loan Credit Agreement or other indebtedness or to hedge our exposure to floating rate instruments may be impaired, which could adversely affect our business, financial condition and results of operations.

Risks Related to Managing Our Growth and Other Risks

We operate a complex global commercial organization, with limited experience in many countries. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies. We may be distracted by expansion into new geographies where we do not have experience and we may be unsuccessful in monetizing such opportunities for the benefit of our organization at large.

We are responsible for worldwide sales, marketing, distribution, maintenance and regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties to support us in these areas on a timely basis, our ability to commercialize the INTERCEPT Blood System may be irreparably harmed.

We will need to maintain and may need to increase our competence and size in a number of functions, including sales, deployment and product support, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with U.S., E.U., South American, Asian and local standards and practices, including regulatory, legal and tax requirements, some of which we have limited experience. In this regard, should we obtain regulatory approval in an increased number of geographies, we will need to ensure that we

maintain a sufficient number of personnel or develop new business processes to ensure ongoing compliance with the multitude of regulatory requirements in those territories. Hiring, training and retaining new personnel is costly, time consuming and distracting to existing employees and management. We have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all. In addition, in some cases, the cost of obtaining approval and maintaining compliance with certain regulations and laws may exceed the product revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition. Furthermore, we may choose to seek alternative ways to sell or treat blood components with our products. These may include new business models, which may include selling kits to blood centers, performing inactivation ourselves, staffing blood centers or selling services or other business model changes. We have no experience with these types of business models, or the regulatory requirements or licenses needed to pursue such new business models. We cannot assure you that we will pursue such business models or if we do, that we will be successful. For example, in early 2021, we formed a joint venture with a Chinese entity with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China. Our involvement in the joint venture may be a distraction for our management and impair our ability to successfully and timely manage our other operations. Additionally, the operations of the joint venture may require future capital infusion from us and we may never see a return from our investment in the joint venture.

Adverse market and economic conditions may exacerbate certain risks affecting our business.

Sales of our products are dependent on purchasing decisions of and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including the COVID-19 pandemic, disruptions due to political instability or terrorist attacks, economies and currencies largely affected by declining commodity prices or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for the INTERCEPT Blood System, and of which could adversely affect our business, financial condition, results of operations and growth prospects.

In the past, a meaningful amount of our product revenue has come from sales to distributors for the Russian, other CIS countries, as well as Middle Eastern markets. Weakness and/or instability in worldwide oil demand and/or prices, the ongoing civil, political and economic disturbances in Russia, Ukraine and Turkey, and their spillover effect on surrounding areas, along with the impact of sanctions imposed against Russia by certain European nations and the U.S., may significantly devalue the Russian Ruble and other CIS currencies and have had and may continue to have a negative impact on the Russian and other CIS countries' economies, particularly if sanctions continue to be levied against Russia or are strengthened from those currently in place from either the E.U., U.S. or both, including in connection with Russia's actions with respect to Ukraine. The current unrest among Russia and the U.S., if pushed to a larger conflict, may negatively impact the Russian and Ukrainian economies, which will adversely impact our business in those territories. Additionally, weakness in oil demand and prices resulting from, among other things, the effects of the COVID-19 pandemic, may negatively affect our existing and future business opportunities in oil dependent countries and may cause collection difficulties, declining prices or all of the above. While our agreement with our Russian and other CIS distributors calls for sales, invoicing and collections to be denominated in Euros, if significant sanctions continue or are strengthened, if new sanctions are imposed, the Russian economy and value of the Ruble or other CIS currencies may weaken, perhaps significantly, and our business in Russia and other CIS countries may be negatively impacted further or never recover to historical levels.

Risks associated with our operations outside of the United States could adversely affect our business.

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- complying with diverse and unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- complying with other laws and regulatory requirements to which our business activities abroad are subject, such as the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti-corruption intent in foreign countries (as discussed in greater detail above under "*Risks Related to Regulatory Approval and Oversight, and Other Legal Compliance Matters—We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business*" and "*Risks Related to Our Reliance on Third Parties—We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries*");
- differing payor reimbursement regimes, governmental payors and price controls;
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;

- adverse tax consequences, including changes in applicable tax laws and regulations;
- liabilities for activities of, or related to, our international operations and those of our agents, distributors and joint venture partners;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- economic weakness, including inflation, or political or economic instability in particular economies and markets outside the U.S.;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

For example, product sales of the INTERCEPT Blood System sold outside of the U.S. are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. dollar may materially affect our results of operations. In addition, in a period where the U.S. dollar is strengthening/weakening as compared to Euros and other currencies we transact in, our product revenues and expenses denominated in Euros or other foreign currencies are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility. As our commercial operations grow globally, our operations are exposed to more currencies and as a result our exposure to foreign exchange risk will continue to grow.

Additionally, all of the employees of our subsidiary, Cerus Europe B.V., are employed outside the U.S., including in France, where labor and employment laws are relatively stringent and, in many cases, grant significant job protection to certain employees, including rights on termination of employment. In addition, one of our manufacturing partners that we are dependent on is located in France and may have employees that are members of unions or represented by a works council as required by law. These more stringent labor and employment laws to the extent that they are applicable, coupled with the requirement to consult with the relevant unions or works' councils, could increase our operational costs with respect to our own employees and could result in passed through operational costs by our manufacturing partner. If the increased operational costs become significant, our business, financial condition and results of operations could be adversely impacted, perhaps materially.

Finally, following the result of a referendum in 2016, the U.K. left the E.U. on January 31, 2020, commonly referred to as "Brexit." We may face new regulatory costs and challenges as a result of Brexit that could have a material adverse effect on our operations. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate. Altered regulations could add time and expense to the process by which our product candidates receive regulatory approval in the E.U. Given the lack of comparable precedent, it is unclear what financial, regulatory, trade and legal implications the withdrawal of the U.K. from the E.U. will ultimately have and how such withdrawal will affect us.

If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected.

We are highly dependent upon our executive management team and other critical personnel, including our specialized research and development, regulatory and operations personnel, many of whom have been employed with us for many years and have a significant amount of institutional knowledge about us and our products. We do not carry "key person" insurance. If one or more members of our executive management team or other key personnel were to retire or resign, our ability to achieve development, regulatory or operational milestones for commercialization of our products could be adversely affected if we are unable to replace them with employees of comparable knowledge and experience. In addition, we may not be able to retain or recruit other qualified individuals, and our efforts at knowledge transfer could be inadequate. If knowledge transfer, recruiting and retention efforts are inadequate, significant amounts of internal historical knowledge and expertise could become unavailable to us. We also rely on our ability to attract, retain and motivate skilled and highly qualified personnel in order to grow our company. Competition for qualified personnel in the medical device and pharmaceutical industry is very intense. Labor shortages of qualified personnel is expected to persist for the foreseeable future and has required that we broaden our searches and change the way we operate. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, ability to perform under our BARDA agreement, or results of operations and growth prospects could be adversely affected. Even if we are able to identify and hire qualified personnel commensurate with our growth objectives and opportunities, the process of integrating new employees is time consuming, costly and distracting to existing employees and management. Such disruptions may have an adverse impact on our operations, our ability to service existing markets and customers, or our ability to comply with regulations and laws.

Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from a single site that may be subject to lengthy business interruption in the event of a severe earthquake. We also may suffer loss of computerized information and may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems.

Virtually all of our research and development activities and the significant portion of our general and administrative activities are performed in or managed from our facilities in Concord, California, which are within an active earthquake fault zone. Should a severe earthquake occur, we might be unable to occupy our facilities or conduct research and development and general and administrative activities in support of our business and products until such time as our facilities could be repaired and made operational. Our property and casualty and business interruption insurance in general does not cover losses caused by earthquakes. While we have taken certain measures to protect our scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us. We have also taken measures to limit damage that may occur from the loss of computerized data due to power outage, system or component failure or corruption of data files. However, we may lose critical computerized data, which may be difficult or impossible to recreate, which may harm our business. We may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems, which may subject us to fines or adverse consequences, up to and including loss of our ability to conduct business.

Significant disruptions of information technology systems or actual or alleged breaches of data security could adversely affect our business.

Our business is increasingly dependent on complex and interdependent information technology systems, including internet-based systems, databases and programs, to support our business processes as well as internal and external communications. These include those that are used directly by our operations and those used by critical service providers and suppliers, including our manufacturing partners. As use of information technology systems has increased, deliberate attacks, attempts to gain unauthorized access to computer systems and networks, and unintentional actions or inactions that expose us to security vulnerabilities and incidents have increased in frequency and sophistication. Our and our supplier's information technology, systems and networks are potentially vulnerable to breakdown, ransomware, supply chain attacks, malicious intrusion and computer viruses which may result in the impairment of production and key business processes or loss of data or information. We and our suppliers are also potentially vulnerable to data security breaches-whether by (a) intentional or accidental actions or inactions or (b) employees or others-which may expose sensitive data to unauthorized persons. For example, we have in the past and may in the future be subject to "phishing" attacks in which third parties send emails purporting to be from reputable sources. Phishing attacks may attempt to obtain personal information, infiltrate our systems to initiate wire transfers or otherwise obtain proprietary or confidential information. Although we have not experienced any losses as a result of such attacks or any other breaches of data security, such breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others.

We may be subject to contractual, regulatory, or legal requirements that obligate us to use industry-standard or reasonable security measures to safeguard personal information. A security breach could lead to claims by our customers or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages, and in some cases our customer agreements do not limit our remediation costs or liability with respect to data breaches.

Litigation resulting from security incidents may adversely affect our business. Actual or alleged unauthorized access to our platform, systems, networks, or physical facilities, or those of our vendors, could result in litigation with our customers or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our products and/or platform capabilities in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur, and the confidentiality, integrity, or availability of personal information was disrupted, we could incur significant liability, or our platform, systems, or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

We know that certain of our suppliers have been successfully attacked by certain malware aimed at extracting a ransom. Should such ransomware breaches occur in the future, production may be impacted, information exfiltrated or other records and information compromised or lost. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures designed to protect our data security and information technology systems, such measures may not prevent such events. Notifications and follow-up actions related to a security breach of one of our suppliers could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs.

Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations. Further, the costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these problems may not be successful, and these problems could result in interruptions, delays, cessation of service, negative publicity, loss of customer trust, less use of our products and services as well as other harms to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses, which may result in potential regulatory inquiries, litigation or other investigations, and can affect our financial and operational condition.

While we have attempted to limit our liability in our contracts, there can be no assurance that contractual limitations of liability are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

Our ability to use our federal and state net operating loss, or NOL, carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards (if any), and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. Under current law, U.S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax 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 federal tax laws. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research and development credit carryforwards) to offset its post-change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. Although we have completed studies to provide reasonable assurance that an ownership change limitation would not apply, we cannot be certain that a taxing authority would reach the same conclusion. If, after a review or audit, an ownership change limitation were to apply, utilization of our domestic NOL and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being utilized to reduce future income tax liabilities. 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. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Risks Related to Our Intellectual Property

We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.

Our commercial success will depend, in part, on obtaining and maintaining patent protection on our products and successfully defending our products against third-party challenges. Our technology will be protected from unauthorized use only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to:

- obtain patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, we are aware of an expired U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to have infringed any valid claim of this patent, we may, among other things, be required to pay damages. Our patents expire at various dates between 2022 and 2038. In

addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2022 and 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products.

Our patents do not cover all of the countries in which we are selling, and planning to sell, our products. We will not be able to prevent potential competitors from using our technology in countries where we do not have patent coverage. Further, the laws of some foreign countries may not protect intellectual property rights to the same extent as the laws of the U.S., including the CIS countries, China and other jurisdictions where we are currently expanding or seeking to expand our commercialization efforts through distributors or otherwise. For example, we recently formed a joint venture with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China. The prosecution of intellectual property infringement and trade secret theft in China is more difficult and unpredictable than in the United States, and we may also have limited legal recourse in the event our intellectual property rights are infringed. In any event, our inability to adequately enforce or protect our intellectual property rights to INTERCEPT in China and other foreign jurisdictions where we are currently expanding or seeking to expand our commercialization efforts could adversely impact our potential commercial success and harm our business.

In certain countries, including European Union countries, China and India, compulsory licensing laws exist that may be used to compel a patent owner to grant licenses to third parties, for reasons such as non-use of the patented subject matter within a certain period of time after patent grant or commercializing in a manner that is cost-prohibitive in the country. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license for the INTERCEPT Blood System to a third-party, which could materially diminish the value of such patents. This could adversely impact our potential product revenue opportunities.

We may face litigation requiring us to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings before the U.S. Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights. We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees, consultants and contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know-how and inventions.

General Risk Factors

We are obligated to develop and maintain proper and effective internal control over financial reporting. In the future, we may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weakness identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting.

Complying with Section 404 requires a rigorous compliance program as well as adequate time and resources. As a result of expanding our commercialization efforts, developing, improving and expanding our core information technology systems as well as implementing new systems to support our sales, supply chain activities and reporting capabilities, all of which require significant management time and support, we may not be able to complete our internal control evaluation, testing and any required remediation in a timely fashion. For example, with respect our joint venture formed with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China, we had no prior experience designing and maintaining effective internal control over financial reporting for joint ventures or for economic entities in China. Failure to adequately maintain an effective internal control structure over the joint venture's financial results may result in significant deficiencies or material weaknesses in our internal control over financial reporting. Additionally, if we identify one or more material weaknesses in our internal control over financial reporting,

we will not be unable to assert that our internal controls are effective. Should our internal controls be deemed ineffective, our ability to obtain additional financing, or obtain additional financing on favorable terms, could be materially and adversely affected which, in turn, could materially and adversely affect our business, our financial condition and the value of our common stock. If we are unable to assert that our internal control over financial reporting is effective in the future, or if our independent registered public accounting firm is unable to express an opinion or expresses an adverse opinion on the effectiveness of our internal controls in the future, investor confidence in the accuracy and completeness of our financial reports could be further eroded, which would have a material adverse effect on the price of our common stock.

Provisions of our charter documents, our compensatory arrangements and Delaware law could make it more difficult for a third-party to acquire us, even if the offer may be considered beneficial by our stockholders.

Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti-takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third-party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third-party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine. In addition, our executive employment agreements, change of control severance benefit plan and equity incentive plans and agreements thereunder provide for certain severance benefits in connection with a change of control of us, including single-trigger equity vesting acceleration benefits with respect to outstanding stock options, which could increase the costs to a third-party acquirer and/or deter such third-party from acquiring us.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

Our corporate headquarters, which includes our principal executive offices, is located in Concord, California. We lease this facility, which includes 84,631 square feet and includes laboratory space for blood safety research and supports general administrative, marketing and technical support functions. We also lease an office facility in Amersfoort, the Netherlands, which is used for selling and administrative functions. We believe that our current and future facilities will be adequate for the foreseeable future.

Item 3. ***Legal Proceedings***

None.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Our common stock is traded on the Nasdaq Global Market under the symbol "CERS". On February 8, 2022, we had 124 holders of record of our common stock.

Dividends

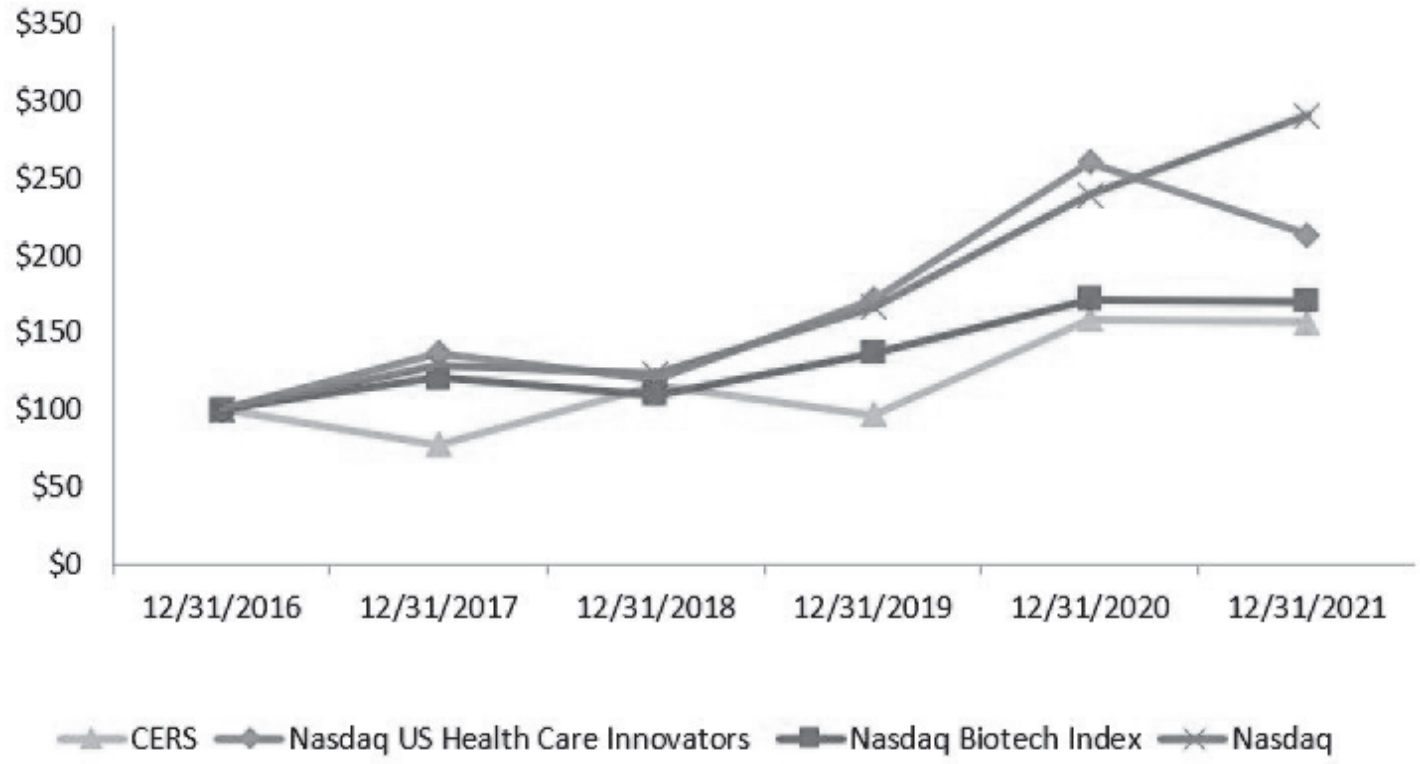
We have not declared or paid dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future.

Stock Performance Graph [(1)]

The following graph shows the total stockholder return of an investment of $100 in cash (and the reinvestment of any dividends thereafter) on December 31, 2016, and tracked the performance through December 31, 2021, for (i) our common stock, (ii) the US Health Care Innovators Index, and (iii) the Nasdaq Stock Market (United States) Index. Our stock price performance shown in the graph below is based upon historical data and is not indicative of future stock price performance.

The Nasdaq Biotechnology Index, used in prior years as a specific industry index to compare to our stock performance, has been modified and we are no longer included in such index. Accordingly, we replaced it with the Nasdaq US Health Care Innovators Index, which is comprised of us and companies with operations similar to ours that are in our industry. Accordingly, we believe that including this new index provides a more appropriate comparison of our stock performance. In this transition year, we have retained the Nasdaq Biotechnology Index for comparison purposes, but will not include that index in our stock performance graph going forward.

Comparison of 5-year Cumulative Total Return on Investment



	December 31,					
	2016	2017	2018	2019	2020	2021
Cerus Corporation	$ 100.00	$ 77.70	$ 116.55	$ 97.01	$ 159.08	$ 156.55
Nasdaq US Health Care Innovators	100.00	136.98	119.54	171.70	260.55	213.16
Nasdaq Biotech Index	100.00	121.06	109.77	136.56	171.64	170.55
Nasdaq	100.00	128.24	123.26	166.68	239.42	290.63

(1) The graph and the other information furnished in this section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by references to any filing of Cerus Corporation under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

Item 6. ***Reserved***

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

This discussion and analysis should be read in conjunction with our audited consolidated financial statements and the accompanying notes thereto included in this Annual Report on Form 10-K for the year ended December 31, 2021. Operating results for the year ended December 31, 2021, are not necessarily indicative of results that may occur in future periods.

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of the INTERCEPT Blood System. Our INTERCEPT Blood System is intended for use with blood components and certain of their derivatives: plasma, platelets, red blood cells and to produce INTERCEPT Fibrinogen Complex, or IFC, and pathogen reduced plasma, cryoprecipitate reduced. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals, including but not limited to U.S. Food and Drug Administration, or FDA, approval in the U.S., and Class III CE Marks in the European Union and other jurisdictions that recognize CE Mark approval, and are being marketed and sold in a number of countries around the world, including the U.S., certain countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East, and Latin America and selected countries in other regions of the world. Additionally, we have received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. In addition, the INTERCEPT Blood System for Cryoprecipitation is used to produce pathogen reduced plasma, cryoprecipitate reduced. We currently sell the platelet and plasma systems and the INTERCEPT Blood System for Cryoprecipitation using our direct sales force and through distributors and sell IFC or disposable kits to manufacture IFC in the U.S. using our direct sales force.

The platelet system is approved in the U.S. for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in 100% plasma or InterSol in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease or TA-GVHD. As part of the FDA's approval of the platelet system, we are required to successfully conduct and complete two post-approval studies - a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT-treated platelets; and a recovery study of platelets treated with the platelet system that is currently in progress. The haemovigilance study was successfully completed in 2021. The plasma system is approved in the U.S. for ex vivo preparation of pathogen-reduced, whole blood derived or apheresis plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion, and as an alternative to gamma irradiation for prevention of TA-GVHD.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development and has not been commercialized anywhere in the world. We filed our application for CE Mark approval of the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the resubmission of our application under the new European Medical Device Regulation, or MDR. However, we do not expect an approval decision will occur for at least another 12 months, if ever. See also the risk factor entitled "*The red blood cell system is currently in development and may never receive any marketing approvals" under "Item 1A—Risk Factors*" of this Annual Report on Form 10-K for additional information with respect timing of the ultimate approval decision on our CE Mark application. In 2017, we initiated a Phase 3 clinical, double-blind study in the U.S., known as the RedeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional, red blood cells. Also in 2017, we received investigational device exemption, or IDE, approval from the FDA to initiate a Phase 3 clinical trial, known as the ReCePI study that is designed to evaluate the efficacy and safety of INTERCEPT-treated red blood cells in patients requiring transfusion for acute blood loss during surgery. Due to the COVID-19 pandemic, many of the hospital sites conducting our RedeS and ReCePI studies suspended enrollment to focus on their response to the pandemic. Should the COVID-19 pandemic persist or heighten, we could see renewed or further delays to trial enrollment. In addition, we will need to generate acceptable Phase 3 clinical data from chronic anemia patients in the U.S. before the FDA will consider our red blood cell system for approval. We also understand that one or more additional *in vitro* studies will be required to be successfully completed and submitted to the FDA. There can be no assurance that we will be able to successfully complete any such *in vitro* studies, nor can there be any assurance that we will successfully complete our Phase 3 trial in chronic anemia patients. In part, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. We must demonstrate to the FDA an ability to define, test and meet acceptable specifications for our current Good Manufacturing Practice and ISO standards for the manufactured compounds used to prepare INTERCEPT-treated red blood cells before we can submit and seek regulatory approval of our red blood cell system from the FDA. In addition, we do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to receive CE Mark approval, even if limited to a target patient population having chronic anemia and, we may need to generate additional safety data from commercial use in order to achieve broader market acceptance. In addition, these trials may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and the significantly

lower lifespan for INTERCEPT-treated red blood cells compared to conventional red blood cells may limit our ability to obtain any regulatory approvals in certain countries for the red blood cell system. As part of our development activities, we will need to successfully complete a number of *in vitro* studies prior to receiving any regulatory approvals in Europe and certain additional activities, including successfully completing the RedeS and ReCePI studies and an additional Phase 3 clinical trial for chronic anemia patients, including sickle-cell anemia patients, in the U.S., prior to receiving any regulatory approvals in the U.S. Successful completion of these activities may require capital beyond that which we currently have or that may be available to us under our agreement with BARDA, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. In addition, if we are unable to obtain from our suppliers sufficient clinical quantities of the active compounds for our red blood cell system meeting defined quality and regulatory specifications, if our suppliers are not able to maintain regulatory compliance or if we experience additional delays in enrollment for the RedeS and ReCePI studies because of the COVID-19 pandemic or any other reason, we may experience delays in testing, conducting trials or obtaining approvals, and our product development costs would likely increase.

In June 2021, we extended our agreement with BARDA, part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, through December 2023. The agreement provides funding from BARDA to support the development of our red blood cell system, including clinical and regulatory development programs in support of potential licensure, and development, manufacturing and scale-up activities, as well as activities related to broader implementation of all three INTERCEPT systems in areas of emerging pathogens. The RedeS and ReCePI and other studies are being funded as part of our agreement with BARDA. Under the contract, BARDA reimburses us for allowable direct contract costs, as such costs are incurred, and for allowable indirect costs. See the discussion under "BARDA" below for more information.

In November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. Beginning in 2021, we began supplying INTERCEPT Blood System for Cryoprecipitation to select blood centers that manufacture IFC for us, and in 2021, we completed our first sale of IFC to a hospital customer. We plan to sell the finished IFC made by our manufacturing blood center partners directly to hospitals. Similar to our platelet and plasma products, any blood center manufacturing IFC will need to complete their process validations and obtain site-specific licenses from CBER before we or they can sell finished IFC to hospital customers outside of the states producing IFC. While one of our manufacturing partners received its BLA from CBER in 2021, we plan to continue working with our other U.S.-based blood centers manufacturing partners to support these activities and any delay in obtaining these licenses would adversely impact the nationwide availability of our finished IFC in the U.S. In addition, we have entered into certain agreements with blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation kits which will allow those blood centers and blood center affiliate organizations to produce finished IFC for their own sales efforts to hospitals.

We have borrowed and, in the future, may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to the Credit, Security and Guaranty Agreement (Term Loan), or the Term Loan Credit Agreement, and Credit, Security and Guaranty Agreement (Revolving Loan), or the Revolving Loan Credit Agreement, as described below, or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty, political change, and other factors, including uncertainty associated with the COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. As a result of stimulus programs put in place over the past two years, the U.S. and many countries are currently experiencing an inflationary environment. This has led to the U.S. Federal Reserve taking action to raise interest rates, which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, we expect that the costs of our business will increase as suppliers raise prices in an inflationary environment, transportation costs increase, and global supply chain constraints impact availability of our products. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time our existing operations provide sufficient cash flow to conduct these trials.

Although we received FDA approval of our platelet and plasma systems in December 2014, our U.S. commercial efforts continue to be largely focused on enabling blood centers that are using INTERCEPT to optimize production and increase the number of platelet and

plasma units produced and made available to patients and continuing to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. In addition, to address the entire market in the U.S., customers will need to modify their operating practices, or we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. On October 1, 2021, all U.S. blood centers had to be compliant with the FDA guidance document, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U.S. blood centers for compliance, we cannot predict if U.S. customers will continue to adopt INTERCEPT over other options or at what levels. Should we be unable to manufacture INTERCEPT in sufficient quantities in a timely manner, or have adequate resources to assist customers with implementing the INTERCEPT Blood System, U.S. blood centers may be forced to use alternate options allowed by the guidance document, which could permanently impact our ability to convert those blood centers to INTERCEPT users. Hospitals in regions seeing a surge in COVID-19 cases may disallow access to their sites or personnel which will delay our ability to market and sell our products, including IFC. Should the COVID-19 pandemic persist or heighten, customers may not be able to implement new technologies such as INTERCEPT and may instead choose to utilize other allowable methods with which they may have more familiarity.

Outside of the U.S., we recognize product revenues from the sale of our platelet and plasma systems in a number of countries around the world including those in Europe, the Commonwealth of Independent States, or CIS, and the Middle East. We utilize both our direct sales organization and regional distributors to market and sell our platelet and plasma systems in these international markets. Our commercial efforts outside the U.S. are focused on increasing market adoption with our existing customer relationships and building demand in new geographies.

Generally, we enter into customer agreements for a specified term and varying options or extensions beyond the initial term. We cannot assure that all customers will use our products at historical levels or at all since securing long-term purchase volume commitments is not always possible, given the unpredictable nature of blood collection and usage. We also cannot provide any assurance that we will be able to secure any subsequent contracts with our customers or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contracts.

If we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including the U.S., we will have difficulties achieving profitability. In order to commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products and product candidates, which, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

In addition to the anticipated product revenues from sales of our platelet and plasma systems and sales of IFC, we anticipate that we will continue to recognize revenue from our government contracts. We recognize government contract revenue associated with the government contracts as qualified costs are incurred for reimbursement over the performance period.

Fresenius

Fresenius Kabi AG, or Fresenius, manufactures and supplies the platelet and plasma systems to us under a supply agreement, or the Supply Agreement. Fresenius is obligated to sell, and we are obligated to purchase, finished disposable kits for our platelet, plasma and red blood cell systems. The Supply Agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are defined through 2021. In response to public health directives in France similar to local orders issued in the U.S. to respond to the COVID-19 pandemic, in 2020 Fresenius reconfigured production workflow to ensure employee safety and to comply with local requirements for social distancing and continues to operate under those local requirements. For a discussion of the risks presented to our supply chain by the COVID-19 pandemic, see "Item 1A—Risk Factors" of this Annual Report on Form 10-K.

See Note 12, *Development and License Agreements*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for further information regarding the Supply Agreement with Fresenius.

Government contracts

In June 2016, we entered into an agreement with BARDA to support our development and implementation of pathogen reduction technology for platelet, plasma, and red blood cells, including access to funding that could potentially support various activities, including funding studies necessary to support a potential premarket approval application submission to the FDA for the red blood cell system, and acceleration of commercial scale up activities to facilitate potential adoption of the red blood cell system by U.S. blood centers.

The agreement with BARDA provides for the reimbursement of certain amounts incurred by us in connection with our satisfaction of certain contractual milestones. Under the agreement, we are reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits,

overhead and general and administrative expenses. As of December 31, 2021, BARDA has committed to reimburse certain of our expenses related to the clinical development of the red blood cell system during a base period, or the Base Period, and under exercised option periods, or Option Periods, in an aggregate amount of up to $126.5 million. If we satisfy subsequent milestones and BARDA were to exercise additional Option Periods, the total funding opportunity under the BARDA agreement could reach up to $223.5 million through December 31, 2023. If exercised by BARDA in its sole discretion, each subsequent Option Period would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of emerging pathogens, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. If certain additional Option Periods are exercised by BARDA, we could be responsible for $9.6 million of co-investment. See Note 12, *Development and License Agreements*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for further information regarding the agreement with BARDA.

In September 2020, we entered into a five-year agreement with the FDA for the development of next-generation compounds to optimize pathogen reduction treatment of whole blood to reduce the risk of transfusion-transmitted infections. Under the agreement, we are reimbursed and will recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. The total potential contract value is $11.1 million. See Note 12, *Development and License Agreements*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for further information regarding the agreement with FDA.

Equity Agreements

See Note 9, *Stockholders' Equity*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for further information regarding the Controlled Equity Offering^{SM} Sales Agreement with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated, or the Sales Agreement, for the issuance and sale of our common stock.

Debt Agreement

See Note 7, *Debt,* in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

COVID-19

The current COVID-19 pandemic has affected and will continue to affect economies and business around the world. To date, various governmental authorities and private enterprises have implemented numerous measures to contain the pandemic, such as travel bans and restrictions, quarantines, shelter-in-place orders and non-essential business shutdowns, which have led to severe disruptions to the global and U.S. economies that may continue for a prolonged duration and has triggered a recession or a period of economic slowdown. We do not yet know the full extent of potential impacts on our product revenues, business operations, clinical trials, or overall financial projections. Should our employees, notably laboratory-based personnel, see a surge in infections, our ability to complete research and development activities may be impaired. As such, certain studies and trials may be delayed for an extended period of time. Furthermore, key deployment and technical service personnel, if infected, will not be able to support customers timely or effectively which could negatively impact our ability to support customers looking to begin INTERCEPT use or those experiencing any operational difficulties. The extent and duration of the pandemic is highly uncertain and difficult to predict. We are actively monitoring and managing our response and assessing actual and potential impacts to our operating results and financial condition, which could also impact trends and expectations as described in more detail below.

Comparability

This Management's Discussion and Analysis of Financial Condition and Results of Operations generally discusses December 31, 2021 and December 31, 2020 items and year-to-year comparisons between 2021 and 2020. Discussions of 2019 items and year-to-year comparisons between 2020 and 2019 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on February 25, 2021.

Critical Accounting Policies and Management Estimates

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to product revenue recognition and government contract revenue. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies require us to make significant judgments and estimates used in the preparation of our financial statements:

• **Revenue**—Revenue is recognized in accordance with Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers", by applying the following five steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The main source of our revenue is product revenue from sales of the INTERCEPT Blood System for platelets and plasma, or the platelet and plasma systems or disposable kits, UVA illumination devices, or illuminators, spare parts, storage solutions, maintenance services of illuminators, and IFC. We sell the platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. We sell IFC directly to hospital customers in the U.S. using a direct sales force, though we may in the future sell INTERCEPT Blood System for Cryoprecipitation disposable kits to strategic blood centers that are not manufacturing partners for our distribution and sale of IFC. For all sales of our INTERCEPT Blood System products, we use a binding purchase order or signed sales contract as evidence of a contract and satisfaction of our policy. For all sales of IFC, our customers place orders in Bloodhub, and our manufacturing partners fulfill orders and ship orders to our customers. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. The contracts with customers can include various combinations of products, and to a lesser extent, services. We must determine whether products or services are capable of being distinct and accounted for as separate performance obligations, or are accounted for as a combined performance obligation. We must allocate the transaction price to each performance obligation on a relative standalone selling price, or SSP basis, and recognize the revenue when the performance obligation is satisfied. We determine the SSP by using the historical selling price of the products and services. If the amount of consideration in a contract is variable, we estimate the amount of variable consideration that should be included in the transaction price. Product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration that we expect to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, spare parts, storage solutions and IFC are recognized upon the transfer of control of the products to the customer. Product revenue from maintenance services is recognized ratably on a straight-line basis over the term of maintenance as customers simultaneously consume and receive benefits. Freight costs charged to customers are recorded as a component of product revenue. Taxes invoiced to our customers and remitted to governments are recorded on a net basis, which excludes such tax from product revenue.

• **Government contract revenue**—Revenue related to the cost reimbursement provisions under our government contract agreements is recognized as the allowable direct contract costs plus allowable indirect costs are incurred based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. Direct costs incurred under cost reimbursable contracts are recorded as research and development expenses or general and administrative expenses. Payments to us pursuant to our government contract agreements are provisional payments subject to adjustment upon audit by the government. These audits could result in an adjustment to revenue previously reported, which adjustments potentially could be significant. We believe that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

Results of Operations

Years Ended December 31, 2021, 2020 and 2019

Revenue

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2021	2020	2019	2021 to 2020	2020 to 2019
Product revenue	$ 130,859	$ 91,920	$ 74,649	42%	23%
Government contract revenue	28,659	22,329	19,125	28%	17%
Total revenue	$ 159,518	$ 114,249	$ 93,774	40%	22%

Product revenue increased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily due to year-over-year sales volume growth in disposable platelet system kit sales in the U.S. Also contributing to the increase was a strengthened Euro compared to the U.S. dollar during the year ended December 31, 2021, as compared to the year ended December 31, 2020. We anticipate product revenue for INTERCEPT disposable kits will increase in future periods driven by the expected continued expansion of U.S. sales, increased market acceptance of the INTERCEPT Blood System and adoption of the INTERCEPT Blood System in geographies where commercialization efforts are underway. In addition, we expect to see IFC product revenue increase in future periods, in part due to the impact of our sales efforts to U.S. hospital customers. However, a deterioration of the Euro relative to the U.S. dollar has in the past, and could in the future, have a material impact on our product revenues, as a significant portion of our product revenue is still expected to come from Euro denominated markets over the near term. As a result of these and other factors, the historical results may not be indicative of INTERCEPT Blood System product revenue in the future.

Government contract revenue increased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily due to increased activities under our government contracts, resulting from the reimbursement of the direct and indirect contract costs incurred under our government contracts. Given the ongoing effects that the COVID-19 pandemic has on our BARDA funded activities, we do not anticipate that government contracts revenue will materially change from historical trends.

Cost of Product Revenue

Our cost of product revenue consists of the cost of the INTERCEPT Blood System sold, provisions for obsolete, slow-moving and unsaleable product, certain order fulfillment costs, to the extent applicable and costs for idle facilities. Inventory is accounted for on a first-in, first-out basis.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2021	2020	2019	2021 to 2020	2020 to 2019
Cost of product revenue	$ 63,475	$ 41,157	$ 33,419	54%	23%

Cost of product revenue increased during the year ended December 31, 2021, compared to the year ended December 31, 2020. The increase was primarily due to increased sales, and, to a lesser extent, the impact of foreign exchange rates.

Our gross margin on product sales was 51% during the year ended December 31, 2021, compared to 55% during the year ended December 31, 2020. The decrease in gross margin on product sales was primarily due to unfavorable product mix with U.S. customers primarily from platelet kits used to produce a single therapeutic dose which contribute to a lower gross margin percentage relative to platelet kits used to produce more than one therapeutic dose. Changes in our gross margin on product sales are affected by various factors, including the volume of product manufactured and the relative per unit pricing in our Supply Agreement with Fresenius, the timing of inventory purchases related to the underlying exchange rate of the Euro relative to the U.S. dollar, manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which products are sold. Furthermore, we expect that our suppliers will raise prices in an inflationary environment, resulting in increased costs to produce our product, increased transportation costs and an adverse impact on the efficiency of our supply chain. Additionally, we may encounter unforeseen manufacturing difficulties, including those related to the COVID-19 pandemic, which, at a minimum, may lead to higher than anticipated costs, scrap rates, delays in manufacturing products, or lower production levels of manufacturing than would be needed to meet demand. We may also decide to make investments with our manufacturing partners to identify longer-term efficiencies, but result in near-term increased costs. In addition, we may face competition which may limit our ability to maintain existing selling prices for our products which in turn would negatively affect our reported gross margins on product sales. Our gross margins on product sales may be impacted in the future based on all of these and other criteria.

We expect to build inventory levels that will be sufficient to meet forecasted demand. While our suppliers have initiated business continuity plans with minimal disruption to our supply to date, we cannot be certain that any prolonged, intensified or worsened effect from the COVID-19 pandemic would not significantly impact our supply chain. At times, we may purchase quantities of materials, components or finished products that are expected to be on-hand for longer than one year. We may procure and carry this inventory to mitigate obsolescence, supply chain disruption and for business continuity reasons.

Research and Development Expenses

Our research and development expenses include salaries and related expenses for our scientific personnel, non-cash stock-based compensation, payments to consultants, costs to prepare and conduct preclinical and clinical trials, third-party costs for development activities, certain regulatory costs, costs associated with our facility related infrastructure, and laboratory chemicals and supplies.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2021	2020	2019	2021 to 2020	2020 to 2019
Research and development	$ 63,691	$ 64,410	$ 60,376	(1%)	7%

Research and development expenses slightly decreased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily due to completion of work for certain post-market platelet and IFC studies, largely offset by increased costs associated with work associated with new product development.

We expect to incur additional research and development costs associated with inflationary pressures on labor and study costs, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., completing activities to support our CE Mark submission for our red blood cell system in Europe, new product development and product enhancements, including potential new label claims, design efforts on our illuminator, and costs associated with performing the activities under our government contracts. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to,

intense and changing government regulation, the impact of the COVID-19 pandemic, uncertainty of future preclinical studies and clinical trial results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under "Item 1A—*Risk Factors*" in Part I of this Annual Report on Form 10-K.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, non-cash stock-based compensation, expenses for our commercialization efforts in a number of countries around the world including those in U.S., Europe, the CIS and the Middle East, Asia, Latin America, and expenses for accounting, tax, internal control, legal, and facility and infrastructure related expenses, and insurance premiums. We expect to incur additional Selling, general and administrative costs associated with inflationary pressures on labor and vendor costs.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2021	2020	2019	2021 to 2020	2020 to 2019
Selling, general and administrative	$ 81,288	$ 67,015	$ 66,205	21%	1%

Selling, general, and administrative expenses increased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily driven by stock-based and incentive compensation as well as investments associated with the commercial launch of IFC.

Non-Operating Income (Expense), Net

Non-operating expense, net consists of foreign exchange gains and losses, interest charges incurred on our debt, and other non-operating gains and losses, including interest earned from our short-term investment portfolio, and gains and losses due to changes in fair value of certain investments.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2021	2020	2019	2021 to 2020	2020 to 2019
Foreign exchange (loss) gain	$ (572)	$ 793	$ (86)	(172%)	(1,022%)
Interest expense	(4,923)	(3,746)	(6,065)	31%	(38%)
Other income, net	374	1,713	1,396	(78%)	23%
Total non-operating expense, net	$ (5,121)	$ (1,240)	$ (4,755)	313%	(74%)

Foreign Exchange Gain (Loss)

We had foreign exchange losses during the year ended December 31, 2021, compared to foreign exchange gains during the year ended December 31, 2020, which was primarily due to less favorable foreign exchange variations between the Euro and the U.S. dollar.

Interest Expense

Interest expense increased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily due to the higher underlying balance per our Term Loan Credit Agreement driven by our borrowing of Tranche 2, of $15.0 million on March 29, 2021.

Other Income, Net

Other income, net decreased during the year ended December 31, 2021, compared to the year ended December 31, 2020, primarily due to the decrease of interest income from our investments in marketable securities.

Provision for Income Taxes

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2021	2020	2019	2021 to 2020	2020 to 2019
Provision for income taxes	$ 319	$ 284	$ 263	12%	8%

The tax expenses were primarily a result of our Cerus Europe B.V. subsidiary's operating profit.

Due to our history of cumulative operating losses, management has concluded that, after considering all of the available objective evidence, it is not likely that all our net deferred tax assets as of December 31, 2021, will be realized. Accordingly, substantially all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of December 31, 2021.

Liquidity and Capital Resources

In recent years, our sources of capital have primarily consisted of public issuance of common stock, debt instruments, and to a lesser extent, cash from product sales and reimbursements under our government agreements.

At December 31, 2021 and December 31, 2020, we had the following cash and cash equivalents, short-term investments and restricted cash (in thousands):

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 48,759	$ 36,594
Short-term investments	80,600	97,000
Restricted cash	2,285	2,309
Total	$ 131,644	$ 135,903

Excess cash is typically invested in highly liquid instruments of short-term investments with high-quality credit rated corporate and government agency fixed-income securities in accordance with our investment policy.

At December 31, 2021 and December 31, 2020, we had the following indebtedness (in thousands):

	December 31, 2021	December 31, 2020
Debt – current	$ 14,697	$ 8,516
Debt – non-current	54,724	39,588
Total	$ 69,421	$ 48,104

Operating Activities

	Year Ended	
(in thousands)	**December 31, 2021**	**December 31, 2020**
Net cash used in operating activities	$ (33,922)	$ (41,811)

The decrease in net cash used in operating activities was primarily related to increased product sales and underlying gross profit, revenue from our BARDA agreement and the timing of payments, partially offset by increased inventory build during the year ended December 31, 2021, compared to the same period in 2020.

Investing Activities

	Year Ended	
(in thousands)	**December 31, 2021**	**December 31, 2020**
Net cash provided by (used in) investing activities	$ 12,688	$ (49,558)

The change period over period was primarily the result of higher purchases of investments from the proceeds associated with our January 2020 public offering of our common stock during the year ended December 31, 2020, as compared to higher proceeds from the maturity and sale of our investments to support operations, during the year ended December 31, 2021.

Financing Activities

	Year Ended	
(in thousands)	**December 31, 2021**	**December 31, 2020**
Net cash provided by financing activities	$ 34,294	$ 91,783

The decrease in net cash provided by financing activities for the year ended December 31, 2021, was primarily due to the net proceeds of approximately $62.7 million received from our January 2020 public offering of our common stock, and net proceeds of approximately $13.9 million received from the shares sold under the agreement with Cantor Fitzgerald & Co. during the year ended December 31, 2020. This was partially offset by borrowings under our Term Loan Credit Agreement of $15.0 million and net increased borrowings under our Revolving Loan Credit Agreement of $2.7 million, and net proceeds of approximately $3.1 million received from the shares sold under the Sales Agreement during the year ended December 31, 2021. See *Note 7, Debt,* in Part I of this Annual Report on Form 10-K for more information.

Working Capital

(in thousands)	**December 31, 2021**	**December 31, 2020**
Working capital	$ 108,546	$ 123,457

Working capital decreased as of December 31, 2021, compared to December 31, 2020, primarily due to continued overall use of cash from operations to support the increased costs associated with product enhancements, initiatives for expanded platelet label claims,

preliminary design efforts on our next generation illuminator, and investments associated with the commercial launch of IFC, offset by proceeds from increased product sales and collections, proceeds from the borrowings under our Term Loan Credit Agreement and Revolving Loan Credit Agreement, and proceeds from the shares sold under the Sales Agreement the during the year ended December 31, 2021.

Capital Requirements

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with developing and commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercialization of our platelet, plasma systems and IFC, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval studies we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., costs associated with performing the agreed-upon activities under our government agreements, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities, required post-approval studies, market preparedness and product launch activities for any of our product candidates and products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to funds under our government contracts and the public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations, if at all, and interest income earned on the investment of our cash balances. While we believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our agreement with government contracts, will be sufficient to meet our capital requirements for at least the next 12 months, if we are unable to generate sufficient product revenue, or access sufficient funds under our government contracts or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to the Term Loan Credit Agreement and Revolving Loan Credit Agreement, or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

In December 2020, we entered into the Sales Agreement under which we may issue and sell up to $100.0 million of our common stock through or to Cantor Fitzgerald & Co. or Stifel, Nicolaus & Company, Incorporated, as sales agent or principal. To date, we have sold 0.4 million shares of our common stock under the Sales Agreement for net proceeds of $3.1 million.

While we expect to receive significant funding under our agreement with BARDA, our ability to obtain the funding we expect to receive under this agreement is subject to various risks and uncertainties, with respect to BARDA's ability to terminate the agreement for convenience at any time and our ability to achieve the required milestones under this agreement, including with respect to the conduct of the RedeS and ReCePI studies, enrollment for which has been suspended or slowed at many of the hospital sites due to the COVID-19 pandemic. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment and uncertainty associated with the COVID-19 pandemic, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreement, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed by BARDA, our cash flows would be negatively impacted or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. In addition, if we are unable to generate sufficient prerequisite Phase 3 clinical data, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have.

Furthermore, while BARDA has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID-19, the availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If alternative sources of funding are not available, or if we determine that the cost of alternative available capital is too high, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

We do not currently enter into any hedging contracts to normalize the impact of foreign exchange fluctuations. As a result, our future results could be materially affected by changes in these or other factors.

As a result of economic conditions, general global economic uncertainty, political change, global pandemics, natural disasters, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our government agreements, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Other Information

See *Note 9, Stockholders' Equity*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for further information regarding the public offering of our common stock.

Commitments

See *Note 7, Debt,* in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

See *Note 8, Commitments and Contingencies*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for more information on our operating leases.

We did not have any off-balance sheet arrangements as of December 31, 2021.

Financial Instruments

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our available-for-sale securities related to corporate debt and U.S. government agency securities are classified as Level 2 in the fair value hierarchy, which uses observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. We did not record any credit losses for the years ended December 31, 2021, 2020 and 2019. Adverse global economic conditions have had, and may continue to have, a negative impact on the market values of potential investments.

New Accounting Pronouncements

See *Note 2, Summary of Significant Accounting Policies,* in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for more information on new accounting pronouncements.

Item 7A. *Quantitative and Qualitative Disclosures about Market Risk*

Interest Rate Risk

At December 31, 2021, we held cash, cash equivalents, short-term investments and investments in marketable equity securities of $129.4 million. We do not believe our exposure to interest rate risk to be material given we held cash in interest-bearing accounts with financial institutions and the short-term nature of our investment portfolio consisted of highly liquid money market instruments and corporate debt and U.S. government agency securities with short-term maturities. The weighted average interest rates of our cash and cash equivalents at December 31, 2021, were 1.19%

Our exposure to market rate risk for changes in interest rates relates primarily to our money market instruments, corporate debt securities and the amounts borrowed pursuant to the Term Loan Credit Agreement and Revolving Loan Credit Agreement. We do not use derivative financial instruments. By policy, we may place investments with high quality debt security issuers, limit the amount of credit exposure to any one issuer and limit duration by restricting the term for single securities and for the portfolio as a whole. Our investments are held and managed by a third-party capital management adviser that in turn, utilizes a combination of active market quotes and where necessary, proprietary pricing models as well as a subscribed pricing service, in order to estimate fair value. While we believe that we will be able to recognize the fair value of our money market instruments when they mature or are sold, or if we purchase investments in securities in the future, there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these securities are with will be able to meet their debt obligations.

With respect to the Term Loan Credit Agreement and Revolving Loan Credit Agreement, we are exposed to risks associated with changes in interest rates in connection with our related borrowings. Based on our indebtedness under the Term Loan Credit Agreement of $55.0 million and Revolving Loan Credit Agreement of $14.7 million as of December 31, 2021, and the interest rate on such borrowings then in effect, a hypothetical 100 basis point increase in interest rates could increase our net interest expense in 2021 by approximately $0.7 million subject to certain limitations in each agreement.

Foreign Currency Risk

Our international operations are subject to risks typical of an international business, including, among other factors: differing political, economic, and regulatory climates, different tax structures, and foreign exchange volatility. We do not currently enter into any hedging contracts to normalize the impact of foreign exchange fluctuations. As a result, our future results could be materially impacted by changes in these or other factors.

Product sales for our blood safety products are predominantly made in Europe and generally are invoiced to customers in Euro. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems. These inventory purchases and operating expenses are generally paid in Euro and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of non-operating income (expense), net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. An unfavorable 10% change in foreign currency exchange rates for our cash, accounts receivable, accounts payable and accrued liabilities that are denominated in foreign currencies at December 31, 2021, would have negatively impacted our annual financial results by $0.6 million. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

Item 8. *Financial Statements and Supplementary Data*

Our consolidated financial statements, together with related notes and reports of Ernst & Young LLP, independent registered public accounting firm, are listed in Item 14(a) and included herein.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act, Rule 13a–15(e) and 15d-15(e)), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our CEO and CFO have concluded that as of December 31, 2021, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2021, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which is included below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act which occurred during our fiscal quarter ended December 31, 2021, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerus Corporation

Opinion on Internal Control over Financial Reporting

We have audited Cerus Corporation's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Cerus Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 22, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Ernst & Young LLP

Redwood City, California
February 22, 2022

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 since we intend to file our definitive proxy statement for our 2022 annual meeting of stockholders, or the Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required by this item is to be included in our 2022 Proxy Statement as follows:

- The information relating to our executive officers is to be included in the section entitled "Executive Officers;"
- The information relating to our directors and nominees for directors is to be included in the section entitled "Proposal No. 1—Election of Directors;"
- The information relating to our audit committee and audit committee financial expert is to be included in the section entitled "Information Regarding the Board of Directors and Corporate Governance;" and
- If required, the information regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is to be included in the section entitled "Delinquent Section 16(A) Reports."

Such information will be included in the Proxy Statement and is incorporated herein by reference.

Code of Ethics

We have adopted the Cerus Corporation Code of Business Conduct and Ethics, or Ethics Code, that applies to all of our officers, directors and employees. The Ethics Code is available on our website at www.cerus.com on the "Corporate Governance" page of the section titled "Investors." If we make any substantive amendments to the Ethics Code or grant any waiver from a provision of the Ethics Code to any executive officer or director, we intend to promptly disclose the nature of the amendment or waiver as required by applicable laws. To satisfy our disclosure requirements, we may post any waivers of or amendments to the Ethics Code on our website in lieu of filing such waivers or amendments on a Form 8-K.

Our employees are required to report any conduct that they believe in good faith to be an actual or apparent violation of the Ethics Code. The Audit Committee of our Board of Directors has established procedures to receive, retain and address complaints regarding accounting, internal accounting controls or auditing matters and to allow for the confidential and anonymous submission by employees of related concerns.

Item 11. *Executive Compensation*

The information required by this item is to be included in our Proxy Statement under the sections entitled "Executive Compensation," "Director Compensation," "Information Regarding the Board of Directors and Corporate Governance—Information Regarding Committees of the Board of Directors—Compensation Committee Interlocks and Insider Participation" and "Information Regarding the Board of Directors and Corporate Governance—Information Regarding Committees of the Board of Directors—Compensation Committee Report" and is incorporated herein by reference.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this item with respect to equity compensation plans is to be included in our Proxy Statement under the section entitled "Securities Authorized for Issuance Under Equity Compensation Plans—Equity Compensation Plan Information" and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and in each case is incorporated herein by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is to be included in our Proxy Statement under the sections entitled "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance—Independence of the Board of Directors" and is incorporated herein by reference.

Item 14. ***Principal Accountant Fees and Services***

The information required by this item is to be included in our Proxy Statement under the section entitled "Proposal 4— Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are being filed as part of this Annual Report on Form 10-K:

(a) *The following documents are being filed as part of this Annual Report on Form 10-K:*

(1) Financial Statements.

(2) Financial Statement Schedules.

Financial statement schedules have been omitted in this Annual Report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) Exhibits

Exhibit Number	Description of Exhibit
3.1(12)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(12)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(16)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.4(35)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(2)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(29)	Description of securities registered under Section 12 of the Exchange Act of 1934.
	Supply and/or Manufacturing Agreements
10.1(17)†	Amended and Restated Supply Agreement, dated April 21, 2014, by and between Cerus Corporation and Purolite Corporation.
10.2(33)	First Amendment to Amended and Restated Supply Agreement, dated December 1, 2020, by and between Cerus Corporation and Purolite Corporation.
10.3(23)†	Amended and Restated Supply and Manufacturing Agreement, dated April 1, 2017, by and between Cerus Corporation and Porex Corporation.
10.4(26) †	First Amendment to Supply and Manufacturing Agreement, by and between Cerus Corporation and Porex Corporation, dated June 22, 2018.
10.5(34) †	Letter Agreement, by and between Cerus Corporation and Porex Corporation, dated January 6, 2021.
10.6††	Second Amendment to Supply and Manufacturing Agreement by and between Cerus Corporation and Porex Corporation, dated December 21, 2021.

10.7(19)†	Amended and Restated Manufacturing and Supply Agreement, dated October 19, 2015, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.8(26) †	Amendment to Amended and Restated Manufacturing and Supply Agreement, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH, effective as of August 10, 2018.
10.9(30) ††	Side Letter to Supply Agreement, dated January 14, 2020, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.10(33)††	Amendment #2 to the Amended and Restated Manufacturing and Supply Agreement, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH, dated December 23, 2020.
10.11(3)†	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.12(20)†	Amendment #1 to the Manufacturing and Supply Agreement, dated March 15, 2016, by and between NOVA Biomedical Corporation and Cerus Corporation.
10.13(10)†	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.14(14)†	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
	Loan and Security Agreements
10.15(28) †	Credit, Security and Guaranty Agreement (Term Loan), dated March 29, 2019, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.16(33)	Amendment No. 1 to Credit, Security and Guaranty Agreement (Term Loan), dated December 31, 2020, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.17(36)	Amendment No. 2 to Credit, Security and Guaranty Agreement (Term Loan), dated September 30, 2021, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.18(28) ††	Credit, Security and Guaranty Agreement (Revolving Loan), dated March 29, 2019, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.19(33) ††	Amendment No. 1 to Credit, Security and Guaranty Agreement (Revolving Loan), dated December 31, 2020, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.20 ††	Amendment No. 2 to Credit, Security and Guaranty Agreement (Revolving Loan), dated December 23, 2021, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
	Real Estate Lease Agreements
10.21(24) †	Lease, dated February 16, 2018, between Cerus Corporation and 1200 Concord LLC.
10.22(25)	First Amendment to Lease, dated May 11, 2018, between Cerus Corporation and 1200 Concord LLC.
10.23(26)	Second Amendment to Lease, dated August 10, 2018, between Cerus Corporation and 1200 Concord LLC.
10.24(27)	Third Amendment to Lease, dated October 5, 2018, between Cerus Corporation and 1200 Concord LLC.
10.25(27)	Fourth Amendment to Lease, dated November 30, 2018, between Cerus Corporation and 1200 Concord LLC.

Employment Agreements or Offer Letters

10.26(9)*	Employment Letter, by and between Cerus Corporation and William M. Greenman, dated May 12, 2011.
10.27(13)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.28(25)*	Amendment to Employment Letter, by and between Cerus Corporation and William M. Greenman, dated April 17, 2018.
10.29(15)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.30(8)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.31(6)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.32(25)*	Amendment to Employment Letter, by and between Cerus Corporation and Kevin Green, dated April 17, 2018.
10.33(13)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.34(15)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
10.35(18)*	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPath, dated May 12, 2015.
10.36(22)*	Employment Letter, by and between Cerus Corporation and Vivek Jayaraman, dated May 31, 2016.

Stock Plans and Related Forms

10.37(31)*	Amended and Restated 1996 Employee Stock Purchase Plan, effective June 3, 2020.
10.38(35)*	Amended and Restated 2008 Equity Incentive Plan, effective June 2, 2021.
10.39(11)*	Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.
10.40(11)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.
10.41(11)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
10.42(21)*	Cerus Corporation Inducement Plan.
10.43(21)*	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Cerus Corporation Inducement Plan.
10.44(21)*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Cerus Corporation Inducement Plan.
10.45(25)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan, amended as of April 17, 2018.
10.46(25)*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the Amended and Restated 2008 Equity Incentive Plan, amended as of April 17, 2018.

Other Compensatory Plans or Agreements

10.47(13)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.48(25)*	Cerus Corporation Change of Control Severance Benefit Plan, amended as of April 17, 2018.

10.49(5)*	Form of Severance Benefits Agreement.
10.50(35)*	Amended and Restated Non-Employee Director Compensation Policy, effective February 22, 2021.
10.51(30)*	2019 and 2020 Executive Officer Compensation Arrangements.
10.52(34)*	2020 and 2021 Executive Officer Compensation Arrangements.
10.53(31)*	Nonqualified Plan Service and Expense Agreement, by and between Cerus Corporation and Principal Life Insurance Company, dated May 21, 2020.
10.54(31)*	The Executive Nonqualified Excess Plan Adoption Agreement, dated May 21, 2020.
	Other Material Agreements
10.55(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.56(4)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.57(32)	Controlled Equity Offering^{SM} Sales Agreement, dated December 11, 2020, by and among Cerus Corporation, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated.
10.58(7)†	License Agreement, dated as of February 2, 2005, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare S.A. and Baxter Healthcare Corporation).
21.1	List of Registrant's subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
31.1	Certification of the Principal Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(37)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document. – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Certain portions of this exhibit are subject to a confidential treatment order.

†† Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

* Compensatory Plan.

(1) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.

(2) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 19, 2008.

(3) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2008.

(4) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on April 30, 2009.

(5) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 1, 2009.

(6) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.

(7) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2009.

(8) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on March 8, 2010.

(9) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2011.

(10) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2011.

(11) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2012.

(12) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2012.

(13) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2012.

(14) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2013.

(15) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2013.

(16) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2014.

(17) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2014.

(18) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2015.

(19) Incorporated by reference to the like-described exhibit to Registrant's Annual Report on Form 10-K, for the year ended December 31, 2015.

(20) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2016.

(21) Incorporated by reference to the like-described exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on August 31, 2016.

(22) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2016.

(23) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2017.

(24) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2018.

(25) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2018.

(26) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2018.

(27) Incorporated by reference to the like-described exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.

(28) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2019.

(29) Incorporated by reference to the like-described exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2019.

(30) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

(31) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

(32) Incorporated by reference to the like-described exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 11, 2020.

(33) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2020.

(34) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021.

(35) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021.

(36) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021.

(37) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of the Registrant's 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.

Item 16. ***Form 10-K Summary***

None.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerus Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cerus Corporation (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 22, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Revenue Recognition

Description of the Matter

In the year ended December 31, 2021, the Company recognized $130.9 million of product revenue. As discussed in Note 2 to the consolidated financial statements, product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration which the Company expects to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, spare parts and storage solutions are recognized upon the transfer of control of the products to the customer.

Auditing the Company's revenue recognition was challenging due to variability in the terms and conditions within certain customer contracts and, as certain customer contracts include multiple products and/or services requiring management to apply judgment to determine whether the products and services are distinct performance obligations or should be accounted for as a combined performance obligation. Customer contracts must be carefully evaluated for terms that might affect the timing or measurement of revenue recognition.

How We Addressed the Matter in Our Audit

We obtained an understanding of, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process, including management's assessment of performance obligations.

Our audit procedures over the determination of the distinct performance obligations and the timing of revenue recognition included, among others, obtaining an understanding of the terms of new revenue contracts by reading both the Company's summary documentation and the corresponding contract for a sample of new revenue agreements. We also confirmed with a sample of customers the terms and conditions of certain contracts via direct correspondence with customers.

For a sample of individual sales transactions, we inspected the executed contract and purchase order to identify the contract, identified the performance obligation(s) in the contract to compare to those identified by management, and calculated the transaction price. We evaluated the Company's allocation of the transaction price to the performance obligations, and inspected third-party evidence of transfer of control of the goods or services to the customer.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1991.

Redwood City, California
February 22, 2022

CERUS CORPORATION

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,759	$ 36,594
Short-term investments	80,600	97,000
Accounts receivable	25,129	21,166
Current inventories	26,793	23,254
Prepaid and other current assets	5,821	5,417
Total current assets	187,102	183,431
Non-current assets:		
Property and equipment, net	12,208	13,867
Operating lease right-of-use assets	12,971	13,122
Goodwill	1,316	1,316
Restricted cash	2,285	2,309
Other assets	21,617	7,370
Total assets	$ 237,499	$ 221,415
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 35,608	$ 24,213
Accrued liabilities	25,673	24,753
Debt – current	14,697	8,516
Operating lease liabilities – current	1,905	1,915
Deferred product revenue	673	577
Total current liabilities	78,556	59,974
Non-current liabilities:		
Debt – non-current	54,724	39,588
Operating lease liabilities – non-current	16,260	16,873
Other non-current liabilities	2,342	1,174
Total liabilities	151,882	117,609
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized, issuable in series; zero shares issued and outstanding at December 31, 2021 and 2020, respectively		
Common stock, $0.001 par value; 400,000 and 225,000 shares authorized; 173,670 and 168,170 shares issued and outstanding at December 31, 2021 and 2020, respectively	174	168
Additional paid-in capital	1,048,936	1,012,932
Accumulated other comprehensive (loss) income	(149)	674
Accumulated deficit	(964,342)	(909,968)
Total Cerus Corporation stockholders' equity	84,619	103,806
Noncontrolling interest	998	—
Total liabilities and stockholders' equity	$ 237,499	$ 221,415

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year Ended December 31,		
	2021	2020	2019
Product revenue	$ 130,859	$ 91,920	$ 74,649
Cost of product revenue	63,475	41,157	33,419
Gross profit on product revenue	67,384	50,763	41,230
Government contract revenue	28,659	22,329	19,125
Operating expenses:			
Research and development	63,691	64,410	60,376
Selling, general and administrative	81,288	67,015	66,205
Total operating expenses	144,979	131,425	126,581
Loss from operations	(48,936)	(58,333)	(66,226)
Non-operating expense, net:			
Foreign exchange (loss) gain	(572)	793	(86)
Interest expense	(4,923)	(3,746)	(6,065)
Other income, net	374	1,713	1,396
Total non-operating expense, net	(5,121)	(1,240)	(4,755)
Loss before income taxes	(54,057)	(59,573)	(70,981)
Provision for income taxes	319	284	263
Net loss	(54,376)	(59,857)	(71,244)
Net loss attributable to noncontrolling interest	(2)	—	—
Net loss attributable to Cerus Corporation	$ (54,374)	$ (59,857)	$ (71,244)
Net loss per share attributable to Cerus Corporation			
Basic and diluted	$ (0.32)	$ (0.37)	$ (0.51)
Weighted average shares outstanding:			
Basic and diluted	171,279	163,949	139,831

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Net loss	$ (54,376)	$ (59,857)	$ (71,244)
Other comprehensive (loss) income			
Unrealized (losses) gains on available-for-sale investments, net of taxes	(823)	560	395
Comprehensive loss	(55,199)	(59,297)	(70,849)
Comprehensive loss attributable to noncontrolling interest	—	—	—
Total comprehensive loss attributable to Cerus Corporation	$ (55,199)	$ (59,297)	$ (70,849)

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2018	136,853	$ 136	$ 863,531	$ (281)	$ (778,867)	$ —	$ 84,519
Issuance of common stock from public offering, net of offering costs	5,648	6	26,854	—	—	—	26,860
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	1,790	2	3,208	—	—	—	3,210
Stock-based compensation	—	—	13,312	—	—	—	13,312
Other comprehensive income	—	—	—	395	—	—	395
Net loss	—	—	—	—	(71,244)	—	(71,244)
Balance at December 31, 2019	144,291	144	906,905	114	(850,111)	—	57,052
Issuance of common stock from public offering, net of offering costs	19,338	19	76,253	—	—	—	76,272
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	4,541	5	11,745	—	—	—	11,750
Stock-based compensation	—	—	18,029	—	—	—	18,029
Other comprehensive income	—	—	—	560	—	—	560
Net loss	—	—	—	—	(59,857)	—	(59,857)
Balance at December 31, 2020	168,170	168	1,012,932	674	(909,968)	—	103,806
Issuance of common stock from public offering, net of offering costs	400	1	3,068	—	—	—	3,069
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	5,100	5	9,365	—	—	—	9,370
Stock-based compensation	—	—	23,571	—	—	—	23,571
Other comprehensive loss	—	—	—	(823)	—	—	(823)
Equity contribution from noncontrolling interest	—	—	—	—	—	1,000	1,000
Net loss	—	—	—	—	(54,374)	(2)	(54,376)
Balance at December 31, 2021	173,670	$ 174	$ 1,048,936	$ (149)	$ (964,342)	$ 998	$ 85,617

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Operating activities			
Net loss	$ (54,376)	$ (59,857)	$ (71,244)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,148	3,109	2,403
Stock-based compensation	23,571	18,029	13,312
Non-cash operating lease cost	1,422	1,435	1,566
Changes in valuation of warrant investment	(148)	(422)	—
Net (gain) loss on sale of available-for-sale securities	(21)	234	—
Loss on disposal of property and equipment	—	—	15
Impairment of long-lived assets	387	274	—
Unrealized gain on investments	(267)	—	—
Non-cash interest expense	1,248	478	386
Foreign currency remeasurement loss (gain)	511	(887)	367
Changes in operating assets and liabilities:			
Accounts receivable	(4,215)	(4,125)	(8,075)
Inventories	(19,610)	(4,030)	(6,043)
Other assets	2,738	(597)	1,802
Accounts payable	12,204	1,984	4,939
Accrued liabilities and other non-current liabilities	(610)	2,557	1,335
Manufacturing and development obligations	—	—	(6,334)
Deferred product revenue	96	7	72
Net cash used in operating activities	(33,922)	(41,811)	(65,499)
Investing activities			
Capital expenditures	(910)	(1,615)	(8,935)
Purchases of investments	(52,066)	(98,793)	(43,907)
Proceeds from maturities and sale of investments	65,664	50,850	81,027
Net cash provided by (used in) investing activities	12,688	(49,558)	28,185
Financing activities			
Net proceeds from equity incentives	9,370	11,750	3,210
Net proceeds from public offerings	2,743	76,534	26,931
Net proceeds on revolving line of credit	6,181	3,499	5,017
Proceeds from loans	15,000	—	39,433
Repayment of loans	—	—	(31,104)
Contribution from noncontrolling interest	1,000	—	—
Net cash provided by financing activities	34,294	91,783	43,487
Effect of exchange rates on cash, cash equivalents, and restricted cash	(919)	1,068	(339)
Net increase in cash, cash equivalents and restricted cash	12,141	1,482	5,834
Cash, cash equivalents and restricted cash, beginning of period	38,903	37,421	31,587
Cash, cash equivalents and restricted cash, end of period	$ 51,044	$ 38,903	$ 37,421
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 4,181	$ 3,269	$ 3,077
Cash paid for income taxes	278	265	229
Non-cash investing activities:			
Non-cash leasehold improvements	—	—	2,949

See accompanying Notes to Consolidated Financial Statements.

Note 1. Nature of Operations and Basis of Presentation

Cerus Corporation (the "Company") was incorporated in September 1991 and is developing and commercializing the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen reduction. The Company has worldwide commercialization rights for the INTERCEPT Blood System for platelets, plasma, red blood cells, and cryoprecipitation.

The Company sells its INTERCEPT platelet and plasma systems in North America, Europe, Middle East and Africa, and other regions around the world. Also in the U.S., the INTERCEPT Blood System for Cryoprecipitation is approved for the production of INTERCEPT Fibrinogen Complex, a therapeutic product for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. The Company conducts significant research, development, testing and regulatory compliance activities on its product candidates that, together with anticipated selling, general, and administrative expenses, are expected to result in substantial additional losses, and the Company may need to adjust its operating plans and programs based on the availability of cash resources. The Company's ability to achieve a profitable level of operations will depend on successfully completing development, obtaining additional regulatory approvals and achieving widespread market acceptance of its products. There can be no assurance that the Company will ever achieve a profitable level of operations.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include those of Cerus Corporation, its subsidiary, and its variable interest entity in which the Company is the primary beneficiary in accordance with the consolidation accounting guidance, after elimination of all intercompany accounts and transactions (together with Cerus Corporation, hereinafter "Cerus" or the "Company"). These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Immaterial Correction of an Error

The Company determined the historical classification of the effects of foreign currency movements on the Company's period-end foreign denominated cash balances was incorrectly presented as a component of the Company's net cash used in operating activities as opposed to being presented separately as effect of exchange rates on cash. The Company determined that the impact of the error to previously issued financial statements was not material and has corrected the immaterial error in the comparative period within these financial statements. The impact of this correction for the twelve months ended December 31, 2020 and 2019, was an increase (decrease) to net cash used in operating activities of $1.1 million and ($0.4 million) with corresponding amounts presented separately as the effect of exchange rates on cash, cash equivalents, and restricted cash, for each of the periods corrected.

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, including those related to the nature and timing of satisfaction of performance obligations, the timing when the customer obtains control of products or services, the standalone selling price ("SSP") of performance obligations, variable consideration, the collectability of accounts receivable, inventory reserves, fair values of investments, the allowance for credit losses, stock-based compensation, intangible assets and goodwill, useful lives of intangible assets and property and equipment, income taxes, accrued liabilities, and incremental borrowing rate, among others. The Company bases its estimates on historical experience, future projections, and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

Revenue is recognized by applying the following five steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company's main source of revenue is product revenue from sales of the INTERCEPT Blood System for platelets and plasma ("platelet and plasma systems" or "disposable kits"), UVA illumination devices ("illuminators"), INTERCEPT Fibrinogen Complex ("IFC"), spare parts and storage solutions, and maintenance services of illuminators. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. The Company sells its

IFC to hospitals and blood banks. The Company uses a binding purchase order or signed sales contract as evidence of a contract and satisfaction of its policy. Generally, the Company's sales contracts for disposable kits and illuminators with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. The contracts with customers can include various combinations of products, and to a lesser extent, services. The Company must determine whether products or services are capable of being distinct and accounted for as separate performance obligations, or are accounted for as a combined performance obligation. The Company must allocate the transaction price to each performance obligation on a relative SSP basis, and recognize the product revenue when the performance obligation is satisfied. The Company determines the SSP by using the historical selling price of the products and services. If the amount of consideration in a contract is variable, the Company estimates the amount of variable consideration that should be included in the transaction price using the most likely amount method, to the extent it is probable that a significant future reversal of cumulative product revenue under the contract will not occur. Product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration to which the Company expects to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, IFC, spare parts and storage solutions are recognized upon the transfer of control of the products to the customer. Product revenue from maintenance services are recognized ratably on a straight-line basis over the term of maintenance as customers simultaneously consume and receive benefits. Freight costs charged to customers are recorded as a component of product revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

The Company receives reimbursement under its U.S. government contracts that support research and development of defined projects. The contracts generally provide for reimbursement of approved costs incurred under the terms of the contracts. Revenue related to the cost reimbursement provisions under the Company's U.S. government contracts is recognized as the qualified direct and indirect costs on the projects are incurred. The Company invoices under its U.S. government contracts using the provisional rates in the government contracts and thus is subject to future audits at the discretion of the government. The Company believes that government contract revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. However, these audits could result in an adjustment to government contract revenue previously reported, which adjustments could be potentially significant. Costs incurred related to services performed under the contracts are included as a component of research and development or selling, general and administrative expenses in the Company's consolidated statements of operations. The Company's use of estimates in recording accrued liabilities for government contract activities (see "Use of Estimates" above) affects the revenue recorded from development funding and under the government contracts.

Disaggregation of Product Revenue

Product revenue by geographical locations of customers during the years ended December 31, 2021, 2020 and 2019, was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Product revenue:			
North America	$ 68,968	$ 32,380	$ 20,936
Europe, Middle East and Africa	60,124	57,427	52,499
Other	1,767	2,113	1,214
Total product revenue	$ 130,859	$ 91,920	$ 74,649

Contract Balances

The Company invoices its customers based upon the terms in the contracts, which generally requires payment 30 to 60 days from the date of invoice. Accounts receivable are recorded when the Company's right to the consideration are determined to be unconditional. The Company had no contract assets at December 31, 2021 and December 31, 2020.

Contract liabilities mainly consist of deferred product revenue related to maintenance services, unshipped products, and uninstalled illuminators. Maintenance services are generally billed upfront at the beginning of each annual service period and recognized ratably over the service period. The Company applies an optional exemption to not disclose the value of unsatisfied performance obligations for contracts that have an original expected duration of one year or less.

Research and Development Expenses

Research and development ("R&D") expenses are charged to expense when incurred, including cost incurred pursuant to the terms of the Company's U.S. government contract. Research and development expenses include salaries and related expenses for scientific and regulatory personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of R&D facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

The Company's use of estimates in recording accrued liabilities for R&D activities (see "Use of Estimates" above) affects the amounts of R&D expenses recorded from development funding. Actual results may differ from those estimates under different assumptions or conditions.

Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be classified as cash equivalents. These investments primarily consist of money market instruments, and are classified as available-for-sale.

Investments

Investments with original maturities of greater than three months primarily include corporate debt and U.S. government agency securities that are designated as available-for-sale and classified as short-term investments. Available-for-sale securities are carried at estimated fair value. The Company views its available-for-sale portfolio as available for use in its current operations. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities were recorded in "Unrealized gains (losses) on available-for-sale investments, net of taxes" on the Company's consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale investments, if any, were determined on a specific identification method, and were recorded in "Other income, net" on the Company's consolidated statements of operations. The costs of securities sold are based on the specific identification method, if applicable. The Company reported the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews its available-for-sale securities on a regular basis to evaluate whether any security in an unrealized loss position has expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. Expected credit losses, if any, are recorded in "Other income, net" on the Company's consolidated statements of operations.

Deferred Compensation Plan

The Company's deferred compensation plan, pursuant to which compensation deferrals began in 2020, is a nonqualified deferred compensation plan that allows highly compensated employees to defer up to 80 percent of their base salary and up to 100 percent of their variable compensation each plan year. The Company may make discretionary contributions to each participant in an amount determined each year. To fund the deferred compensation plan's long-term liability, the Company purchases Company-owned life insurance contracts on certain employees. The insurance serves as an investment source for the funds being set aside. Participants in the deferred compensation plan select the mutual funds in which their compensation deferrals are deemed to be invested as a component of the insurance contracts. As of December 31, 2021 and December 31, 2020, $1.1 million and $0.2 million, respectively, were included in "Other assets" on the Company's consolidated balance sheets, which represents the cash surrender value of the associated life insurance policies, and $1.2 million and $0.2 million, respectively, were included in "Other non-current liabilities" on the Company's consolidated balance sheets, which represents the carrying value of the liability for deferred compensation. Gains and losses on the investments related to the nonqualified deferred compensation plan are included in "Other income (expense), net", on the Company's consolidated statements of operations, and corresponding changes in their deferred compensation liability are included in operating expenses.

Restricted Cash

As of December 31, 2021 and December 31, 2020, the Company's "Restricted cash" consisted primarily of a letter of credit relating to an office building lease. As of December 31, 2021 and December 31, 2020, the Company also had certain non-U.S. dollar denominated deposits recorded as "Restricted cash" in compliance with certain foreign contractual requirements.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, available-for-sale securities and accounts receivable.

Pursuant to the Company's investment policy, substantially all of the Company's cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company's investments carry high credit quality ratings, which is in accordance with its investment policy. At December 31, 2021, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

Concentrations of credit risk with respect to accounts receivable exist. On a regular basis, including at the time of sale, the Company performs credit evaluations of its significant customers that it expects to sell to on credit terms. Generally, the Company does not require collateral from its customers to secure accounts receivable. To the extent that the Company determines specific invoices or customer accounts may be uncollectible, the Company establishes an allowance for doubtful accounts against the accounts receivable on its consolidated balance sheets and records a charge on its consolidated statements of operations as a component of selling, general and administrative expenses.

The Company had two customers and three customers that accounted for more than 10% of the Company's outstanding trade receivables at both December 31, 2021 and December 31, 2020, respectively. These customers cumulatively represented approximately 48% and 51% of the Company's outstanding trade receivables at December 31, 2021 and December 31, 2020, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At December 31, 2021 and December 31, 2020, inventory consisted of raw materials, work-in-process and finished goods. Finished goods include INTERCEPT disposable kits, illuminators, and certain replacement parts for the illuminators. Platelet and plasma systems' disposable kits generally have 18 to 24 month shelf lives from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Raw materials and work-in-process includes certain components that are manufactured over a protracted length of time before being sold to, and ultimately incorporated and assembled by Fresenius Kabi Deutschland GmbH or Fresenius, Inc. (with their affiliates, "Fresenius") into the finished INTERCEPT disposable kits. It is not customary for the Company's production cycle for inventory to exceed 12 months, however, in certain circumstances the Company purchases inventory components it expects to consume beyond 12 months. The Company uses its best judgment to factor in lead times for the production of its raw materials, work-in-process and finished units to meet the Company's forecasted demands. Additionally, from time-to-time, the Company may engage in strategic longer-range inventory purchases due to concentration of supplier risk, obsolescence of materials or components, or simply as safety stock to mitigate disruption to supply. Based upon estimated production needs and current inventory levels, the Company determines the amount of inventory necessary for the next 12 months. Any amounts in excess of this 12 month rolling projection are classified as Other assets in the consolidated balance sheets. Changes to those estimates could potentially impact amounts recorded as current or non-current.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or net realizable value. The Company uses judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded within "Cost of product revenue" on the Company's consolidated statements of operations. At December 31, 2021 and December 31, 2020, the Company had $0.2 million and less than $0.1 million, respectively, recorded for potential obsolete, expiring or unsalable product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, leasehold improvements, construction-in-progress, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated on a straight-line basis over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements. During the twelve months ended December 31, 2021 and 2020, the Company had non-cash purchases of capital expenditures of $0.1 million and $0.5 million, respectively.

Goodwill

Goodwill is not amortized, but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Such impairment analysis is performed on August 31 of each fiscal

year, or more frequently if indicators of impairment exist. The test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative goodwill impairment test. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative impairment test; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The quantitative goodwill impairment test compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates in one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not impaired. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess, limited to the carrying amount of goodwill in the Company's one reporting unit.

During the year ended December 31, 2021, 2020 and 2019, the Company did not dispose of, impair or recognize additional goodwill.

Long-lived Assets

The Company evaluates its long-lived assets for impairment by continually monitoring events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets.

Foreign Currency Remeasurement

The functional currency of the Company's foreign subsidiary is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using historical exchange rates. Product revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded within "Foreign exchange (loss) gain" on the Company's consolidated statements of operations.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant-date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

See Note 10 for further information regarding the Company's stock-based compensation assumptions and expenses.

Consolidated Variable Interest Entity

In February 2021, the Company entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd. ("ZBK"), to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD. (the "JV") for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood transfusion for platelets and red blood cells in the People's Republic of China. The Company owns 51% of the outstanding equity in the JV and consolidates the JV as it has determined that the investment is a variable interest entity ("VIE") and that the Company is the primary beneficiary.

For the year ended December 31, 2021, the Company contributed certain intangible intellectual property rights with zero recorded cost basis and recognized the $1.0 million equity funding contributed by ZBK as cash and as Noncontrolling interest in the Stockholders' equity section of the consolidated balance sheet. Operating expenses for the JV were de minimis for the period presented.

Income Taxes

The provision for income taxes is accounted for using an asset and liability approach, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company does not recognize tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant

information. Use of a valuation allowance is not an appropriate substitute for derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's U.S. federal tax returns for years 2001 through 2020, California tax returns for years through 2020, and Netherlands tax returns for years 2017 through 2019 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a valuation allowance on substantially all of its net deferred tax assets.

Net Loss Per Share attributable to Cerus Corporation

Basic net loss per share attributable to Cerus Corporation is computed by dividing net loss attributable to Cerus Corporation by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to Cerus Corporation gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options, employee stock purchase plan rights and restricted stock units, which are calculated using the treasury stock method.

For the years ended December 31, 2021, 2020 and 2019, all potentially dilutive securities outstanding have been excluded from the computation of dilutive weighted average shares outstanding because such securities have an antidilutive impact due to losses reported.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per share for the years ended December 31, 2021, 2020 and 2019 (in thousands, except per share amounts):

	Year Ended December 31,		
	2021	2020	2019
Numerator for Basic and Diluted:			
Net loss attributable to Cerus Corporation	$ (54,374)	$ (59,857)	$ (71,244)
Denominator:			
Basic weighted average number of shares outstanding	171,279	163,949	139,831
Effect of dilutive potential shares	—	—	—
Diluted weighted average number of shares outstanding	171,279	163,949	139,831
Net loss per share attributable to Cerus Corporation:			
Basic and diluted	$ (0.32)	$ (0.37)	$ (0.51)

The table below presents potential shares that were excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the years ended December 31, 2021, 2020 and 2019 (shares in thousands):

	Year Ended December 31,		
	2021	2020	2019
Weighted average number of anti-dilutive potential shares:			
Stock options	16,345	17,692	17,401
Restricted stock units	6,798	5,485	3,361
Employee stock purchase plan rights	153	32	72
Total	23,296	23,209	20,834

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the Company's consolidated balance sheets. As of December 31, 2021 and December 31, 2020, the Company did not have finance leases.

ROU assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The ROU asset also includes any lease payments made and excludes lease incentives. The lease

terms may include options to extend or terminate the lease when it is reasonably certain to be exercised. Operating leases are recognized on a straight-line basis over the lease term.

Guarantee and Indemnification Arrangements

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements that the Company is a party to contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company's technology infringes the intellectual property rights of a third-party or claims that the sale or use of the Company's products have caused personal injury or other damage or loss. The Company has not received any such requests for guarantees and indemnifications under these provisions and has not been required to make material payments pursuant to these provisions.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at December 31, 2021 and December 31, 2020.

Fair Value of Financial Instruments

The Company applies the provisions of fair value relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of its debt approximates their carrying amounts. The Company measures and records certain financial assets and liabilities at fair value on a recurring basis, including its available-for-sale securities. The Company classifies instruments within Level 1 if quoted prices are available in active markets for identical assets, which include the Company's cash accounts and money market funds. The Company classifies instruments in Level 2 if the instruments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. These instruments include the Company's corporate debt and U.S. government agency securities holdings. The available-for-sale securities are held by a custodian who obtains investment prices from a third-party pricing provider that uses standard inputs (observable in the market) to models which vary by asset class. The Company classifies instruments in Level 3 if one or more significant inputs or significant value drivers are unobservable. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

See Note 3 for further information regarding the Company's valuation of financial instruments.

Note 3. Available-for-sale Securities and Fair Value on Financial Instruments

Available-for-sale Securities

The following is a summary of available-for-sale securities at December 31, 2021 (in thousands):

	December 31, 2021				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Allowance for Credit Loss	Fair Value
Money market funds	$ 7,170	$ —	$ —	$ —	$ 7,170
United States government agency securities	25,761	1	(77)	—	25,685
Corporate debt securities	52,611	105	(156)	—	52,560
Mortgage-backed securities	2,377	—	(22)	—	2,355
Total available-for-sale securities	$ 87,919	$ 106	$ (255)	$ —	$ 87,770

The following is a summary of available-for-sale securities at December 31, 2020 (in thousands):

	December 31, 2020				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Allowance for Credit Loss	Fair Value
Money market funds	$ 6,203	$ —	$ —	$ —	$ 6,203
United States government agency securities	29,570	66	—	—	29,636
Corporate debt securities	66,756	611	(3)	—	67,364
Total available-for-sale securities	$ 102,529	$ 677	$ (3)	$ —	$ 103,203

Available-for-sale securities at December 31, 2021 and December 31, 2020, consisted of the following by contractual maturity (in thousands):

	December 31, 2021		December 31, 2020	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$ 44,873	$ 44,952	$ 64,857	$ 65,117
Greater than one year and less than five years	43,046	42,818	37,672	38,086
Total available-for-sale securities	$ 87,919	$ 87,770	$ 102,529	$ 103,203

The following tables show all available-for-sale marketable securities in an unrealized loss position for which an allowance for credit losses has not been recognized and the related gross unrealized losses and fair value, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position (in thousands):

	December 31, 2021					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 27,909	$ (153)	$ 998	$ (3)	$ 28,907	$ (156)
United States government agency securities	18,367	(75)	1,019	(2)	19,386	(77)
Mortgage backed securities	2,355	(22)	0	0	2,355	(22)
Total	$ 48,631	$ (250)	$ 2,017	$ (5)	$ 50,648	$ (255)

	December 31, 2020					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 5,105	$ (3)	$ —	$ —	$ 5,105	$ (3)

The Company typically invests in highly-rated securities, and its investment policy limits the amount of credit exposure to any one issuer. The policy generally requires investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for expected credit losses, the Company reviews factors such as the length of time and extent to which fair value has been below its cost basis, the financial condition of the issuer and any changes thereto, changes in market interest rates, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's cost basis. The Company also regularly reviews its investments in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the years ended December 31, 2021, 2020 and 2019, the Company did not recognize any expected credit losses. The Company has no current requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held.

The Company recorded less than $0.1 million, less than $0.1 million, and zero of gross realized gains from the sale or maturity of available-for-sale investments during the year ended December 31, 2021, 2020 and 2019, respectively. The Company recorded zero, $0.3 million and zero of gross realized losses from the sale or maturity of available-for-sale investments during the year ended December 31, 2021, 2020 and 2019, respectively.

Fair Value Disclosures

The Company uses certain assumptions that market participants would use to determine the fair value of an asset or liability in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritized the inputs into three broad levels as follows:

- Level 1: Quoted prices in active markets for identical instruments
- Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)
- Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

To estimate the fair value of Level 2 debt securities as of December 31, 2021, the Company's primary pricing service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

To estimate the fair value of Level 3 warrant investments as of December 31, 2021, the Company uses a standard Black-Scholes option pricing model, using a class volatility consistent with the seniority and preference rights of the underlying preferred stock. Key assumptions used in the valuation include the privately held company's preferred stock price, warrant exercise price, equity volatility, expected term of warrant, risk-free interest rates, and details specific to the warrant. The Company recognizes the changes in the fair value of this warrant in "Other income, net" on the Company's consolidated statements of operations.

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2021 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 7,170	$ 7,170	$ —	$ —
United States government agency securities	Short-term investments	25,685	—	25,685	—
Corporate debt securities	Short-term investments	52,560	—	52,560	—
Mortgage-backed securities	Short-term investments	2,355	—	2,355	—
Total short-term investments		87,770	7,170	80,600	—
Warrants	Other assets	570	—	—	570
Total financial assets		$ 88,340	$ 7,170	$ 80,600	$ 570

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2020 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 6,203	$ 6,203	$ —	$ —
United States government agency securities	Short-term investments	29,636	—	29,636	—
Corporate debt securities	Short-term investments	67,364	—	67,364	—
Total short-term investments		103,203	6,203	97,000	—
Warrants	Other assets	422	—	—	422
Total financial assets		$ 103,625	$ 6,203	$ 97,000	$ 422

The Company did not have any transfers among fair value measurement levels during the years ended December 31, 2021 and December 31, 2020.

The following table provides a summary of the total gain recognized in the Company's consolidated statements of operations due to changes in the fair value of the warrant (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Gain from changes in the fair value of level 3 investments	$ 148	$ 422	$ —

Note 4. Inventories

Inventories at December 31, 2021 and December 31, 2020, consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$ 15,664	$ 647
Work-in-process	5,044	4,450
Finished goods	22,129	18,157
Total inventories	42,837	23,254
Less: non-current inventories	16,044	—
Total current inventories	$ 26,793	$ 23,254

Non-current inventories, which primarily consists of work-in-process, is included in Other assets in the consolidated balance sheet.

Note 5. Property and Equipment, net

Property and equipment, net at December 31, 2021 and December 31, 2020, consisted of the following (in thousands):

	December 31,	
	2021	2020
Construction-in-progress	$ -	$ 292
Machinery and equipment	3,987	3,446
Computer equipment and software	3,828	3,425
Furniture and fixtures	2,065	2,065
Leasehold improvements	12,814	12,802
Consigned equipment	1,364	1,416
Total property and equipment, gross	24,058	23,446
Accumulated depreciation and amortization	(11,850)	(9,579)
Total property and equipment, net	$ 12,208	$ 13,867

Depreciation and amortization expense related to property and equipment, net was $2.5 million, $2.2 million and $2.2 million for the years ended December 31, 2021, 2020 and 2019, respectively. As part of the Company's 2020 review of property and equipment, $0.3 million was recorded to impairment of long-lived assets for machinery and equipment associated with a terminated agreement in "Research and development" on the Company's consolidated statements of operations. No such impairment charges were incurred for the years ended December 31, 2021 and 2019.

Note 6. Accrued Liabilities

Accrued liabilities at December 31, 2021 and December 31, 2020, consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Accrued compensation and related costs	$ 18,506	$ 15,999
Accrued professional services	3,942	3,020
Other accrued expenses	3,225	5,734
Total accrued liabilities	$ 25,673	$ 24,753

Note 7. Debt

Debt at December 31, 2021, consisted of the following (in thousands):

	Principal	Unamortized Discount	Total
Term Loan Credit Agreement	$ 55,000	$ (276)	$ 54,724
Less: current portion of term loan	—	—	—
Non-current portion of term loan	$ 55,000	$ (276)	$ 54,724

Debt at December 31, 2020, consisted of the following (in thousands):

	Principal	Unamortized Discount	Net Carrying Value
Term Loan Credit Agreement	$ 40,000	$ (412)	$ 39,588
Less: current portion of term loan	—	—	—
Non-current portion of term loan	$ 40,000	$ (412)	$ 39,588

Principal, interest and fee payments on the Term Loan Credit Agreement (as defined below) at December 31, 2021, are expected to be as follows (in thousands):

Year ended December 31,	Principal	Interest and Fees	Total
2022	$ —	$ 4,182	$ 4,182
2023	41,250	3,134	44,384
2024	13,750	1,826	15,576
Total	$ 55,000	$ 9,142	$ 64,142

Loan Agreements

On March 29, 2019, the Company entered into a Credit, Security and Guaranty Agreement (Term Loan) (the "Term Loan Credit Agreement") with MidCap Financial Trust ("MidCap") to borrow up to $70 million in three tranches (collectively "2019 Term Loan"), with a maturity date of March 1, 2024. The first advance of $40.0 million ("Tranche 1") was drawn by the Company on March 29, 2019, with the proceeds used in part to repay in full the outstanding term loans and fees under a prior loan agreement. The second advance of $15.0 million ("Tranche 2") was drawn by the Company on March 29, 2021. The third advance of $15.0 million ("Tranche 3") expired on December 31, 2021. The borrowings under the 2019 Term Loan bear interest at the sum of a fixed percentage spread and the greater of (i) 1.8% or (ii) one month LIBOR. At December 31, 2021, the effective interest rate on the Term Loan was approximately 7.50%. This debt requires interest-only payments through March 1, 2023, followed by 12 months of payments with interest and equal payment of principal. Prepayments of the 2019 Term Loan under the Term Loan Credit Agreement, in whole or in part, will be subject to early termination fees which decline each year until the fourth anniversary of the applicable funding date, at which time there is no early termination fee. Upon the final payment, the Company must also pay an exit fee calculated based on a percentage of the aggregate principal amount of all tranches advanced to the Company. The Company uses the effective interest method to recognize the final payment over the term of the debt.

The Company also maintains a Credit, Security and Guaranty Agreement (Revolving Loan) (the "Revolving Loan Credit Agreement") with MidCap. The borrowing limit under the Revolving Loan Credit Agreement is $15.0 million. The amount borrowed under the Revolving Loan Credit Agreement can be increased, upon request by the Company, by up to an additional $5.0 million, subject to agent and lender approval and the satisfaction of certain conditions. The Revolving Loan Credit Agreement has a maturity date of March 1, 2024. Amounts drawn under the Revolving Loan Credit Agreement bear interest at the sum of a fixed percentage spread and the greater of (i) 1.80% or (ii) one-month LIBOR. There are also fractional fees based on the amounts either drawn or undrawn. If the Revolving Loan Credit Agreement is terminated before maturity or the funding obligation is permanently reduced, there are termination fees which decline each anniversary until the third anniversary, at which time there is no termination fee. As of December 31, 2021 and December 31, 2020, the Company had borrowed $14.7 million and $8.5 million under the Revolving Loan Credit Agreement, respectively, which is included in "Debt – current" in the Company's consolidated balance sheets.

The Term Loan Credit Agreement and Revolving Loan Credit Agreement contain certain financial and non-financial covenants, with which the Company was in compliance at December 31, 2021. Additionally, both agreements are secured by substantially all of the Company's assets, with some exclusions.

Note 8. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment and automobiles under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2030, with certain of the leases providing for renewal options, provisions for adjusting future lease payments based on the consumer price index, and the right to terminate the lease early. The Company does not assume renewals in determination of the lease term unless the renewals are deemed to be reasonably assured at lease commencement. The Company recorded the lease right-of-use asset and obligation at the present value of lease payments over the lease term. The rates implicit in the Company's leases are generally not readily determinable. The Company must estimate its incremental borrowing rate to discount the lease payments to present value. Operating lease assets also include lease incentives.

Supplemental cash flow information related to operating leases is as follows (dollars in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cash payments for operating leases	$ 3,390	$ 3,400	$ 3,204
Right-of-use assets obtained in exchange for operating lease obligations	1,311	344	13,417

	December 31, 2021	December 31, 2020
Weighted-average remaining lease term	7.4 years	8.5 years
Weighted-average discount rate	8.7%	9.0%

Future minimum non-cancelable payments under operating leases as of December 31, 2021, were as follows (in thousands):

	Operating Leases
2022	$ 3,436
2023	3,291
2024	3,087
2025	2,746
2026	2,798
Thereafter	10,539
Total future lease payments	25,897
Less imputed interest	7,732
Present value of lease liabilities	$ 18,165

During the years ended December 31, 2021, 2020 and 2019, the Company recorded operating lease expenses of $3.2 million, $3.3 million and $3.4 million, respectively. As of December 31, 2021, the Company had no leases that have not yet commenced.

Purchase Commitments

The Company is party to agreements with certain providers for certain components of the INTERCEPT Blood System. Certain of these agreements require minimum purchase commitments from the Company. As of December 31, 2021, the Company had $27.7 million of short-term purchase commitments and $2.7 million of long-term purchase commitments, which are not recorded in the Company's consolidated balance sheets.

Note 9. Stockholders' Equity

Common Stock

In June 2021, the Company's stockholders approved a certificate of amendment of the Company's Amended and Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of common stock from 225 million shares to 400 million shares.

Sales Agreements

On December 11, 2020, the Company entered into the Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated (each a "Sales Agent" and collectively, the "Sales Agents"), under which the Company may issue and sell from time to time up to $100.0 million of the Company's common stock through or to the Sales Agents, as sales agent or principal. Under the Sales Agreement, each Sales Agent receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of the Company's common stock. The issuance and sale of these shares by the Company pursuant to the Sales Agreement are deemed an "at-the-market" offering and are registered under the Securities Act of 1933, as amended. During the year ended December 31, 2021, 0.4 million shares of the Company's common stock were sold under the Sales Agreement for net proceeds of $3.1 million. At December 31, 2021, the Company had approximately $96.8 million of common stock available to be sold under the Sales Agreement.

Note 10. Stock-Based Compensation

Employee Stock Plans

Employee Stock Purchase Plan

The Company maintains an Employee Stock Purchase Plan (the "Purchase Plan"), which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. Under the Purchase Plan eligible employee participants may purchase shares of common stock of the Company at a purchase price equal to 85% of the lower of the fair market value per share on the start date of the offering period or the fair market value per share on the purchase date. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. In June 2020, the Company's stockholders approved an amendment and restatement of the Purchase Plan that increased the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 1.5 million shares. At December 31, 2021, the Company had 1.6 million shares available for future issuance.

2008 Equity Incentive Plan and Inducement Plan

The Company also maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan and its subsequent amendments (collectively, the "Amended 2008 Plan"). The Amended 2008 Plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units ("RSUs"), stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. In June 2019, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 11.8 million shares. In June 2020, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 5.0 million shares. In June 2021, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 7.6 million shares. Option awards under the Amended 2008 Plan generally have a maximum term of ten years from the date of the award. The Amended 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Options granted by the Company to employees generally vest over four years. RSUs are measured based on the fair market value of the underlying stock on the date of grant. RSUs granted by the Company to employees generally vest over three to four years. Performance-based stock granted under the Amended 2008 Plan are limited to 500,000 shares of common stock per calendar year. Performance-based cash awards granted under the Amended 2008 Plan are limited to $1.0 million per recipient per calendar year. At December 31, 2021, 659,000 performance-based stock awards were outstanding.

At December 31, 2021, the Company had approximately 32.7 million shares of its common stock subject to outstanding options or unvested RSUs, or remaining available for future issuance under the Amended 2008 Plan, of which approximately 15.1 million shares and 6.7 million shares were subject to outstanding options and unvested RSUs, respectively, and approximately 10.9 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options or vesting of RSUs.

Activity under the Company's equity incentive plans related to stock options is set forth below (in thousands except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balances at December 31, 2020	16,306	$ 4.71
Granted	1,475	6.40
Exercised	(2,552)	3.79
Forfeited/canceled	(137)	5.97
Balances at December 31, 2021	15,092	5.02

Activity under the Company's equity incentive plans related to RSUs is set forth below (in thousands except per share amounts):

	Number of RSUs Unvested	Weighted Average Grant Date Fair Value per Share
Balances at December 31, 2020	5,739	$ 5.24
Granted [(1)]	3,861	6.46
Vested [(1)]	(2,538)	5.24
Forfeited [(1)]	(372)	6.03
Balances at December 31, 2021	6,690	5.90

(1) Includes shares issuable under performance-based restricted stock unit awards.

The total fair value of RSUs as of their respective vesting dates, for the years ended December 31, 2021, 2020, and 2019, were $16.1 million, $6.8 million and $5.6 million, respectively.

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2021, was as follows (in thousands except weighted average exercise price and contractual term):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances at December 31, 2021				
Stock options outstanding	15,092	$ 5.02	5.14	$ 27,194
Stock options vested and expected to vest	14,986	5.01	5.11	27,116
Stock options exercisable	12,161	4.84	4.32	24,076

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the stock option and the Company's closing stock price on the last trading day of each respective fiscal period.

The total intrinsic value of options exercised for the years ended December 31, 2021, 2020 and 2019, was $7.5 million, $7.9 million and $1.6 million, respectively. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of the Company's common stock as of the close of the exercise date.

Stock-based Compensation Expense

Stock-based compensation expense recognized on the Company's consolidated statements of operations for the years ended December 31, 2021, 2020 and 2019, was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Research and development	$ 4,950	$ 3,739	$ 2,472
Selling, general and administrative	18,621	14,290	10,840
Total stock-based compensation expense	$ 23,571	$ 18,029	$ 13,312

Stock-based compensation expense in the above table does not reflect any income taxes as the Company has experienced a history of net losses since its inception and has a nearly full valuation allowance on its deferred tax assets. In addition, there was neither income tax benefits realized related to stock-based compensation expense nor any stock-based compensation costs capitalized as part of an asset during the years ended December 31, 2021, 2020 and 2019.

As of December 31, 2021, the Company expects to recognize the remaining unamortized stock-based compensation expense of $7.2 million and $23.7 million, respectively, related to non-vested stock options and RSUs, net of estimated forfeitures, over an estimated remaining weighted average period of 2.3 years and 1.7 years, respectively.

Valuation Assumptions for Stock-based Compensation

The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options and employee stock purchase plan rights. The Black-Scholes option-pricing model is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables, which include the expected term of the grants, actual and projected employee stock option exercise behaviors, including forfeitures, the Company's expected stock price volatility, the risk-free interest rate and expected dividends. The Company recognizes the grant-date fair value of the stock award as stock-based compensation expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures.

The expected life of the stock options is based on observed historical exercise patterns. Groups of employees having similar historical exercise behavior are considered separately for valuation purposes. The Company estimates stock option forfeitures based on historical data for employee groups. The total number of stock options expected to vest is adjusted by actual and estimated forfeitures.

The expected volatility is estimated by using historical volatility of the Company's common stock. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term commensurate with the expected term of the option. The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero.

The weighted average assumptions used to value the Company's stock-based awards for the years ended December 31, 2021, 2020 and 2019, was as follows:

	Year Ended December 31,		
	2021	2020	2019
Stock Options:			
Expected term (in years)	6.97	6.89	5.59
Estimated volatility	55%	52%	50%
Risk-free interest rate	1.16%	0.94%	2.32%
Expected dividend yield	0%	0%	0%
Employee Stock Purchase Plan Rights:			
Expected term (in years)	0.74	0.72	0.80
Estimated volatility	56%	53%	46%
Risk-free interest rate	0.07%	0.86%	2.04%
Expected dividend yield	0%	0%	0%

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2021, 2020 and 2019, was $3.51 per share, $2.71 per share and $2.73 per share, respectively. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2021, 2020 and 2019, was $2.21 per share, $1.71 per share and $1.84 per share, respectively.

Note 11. Retirement Plan

The Company maintains a defined contribution savings plan (the "401(k) Plan") that qualifies under the provisions of Section 401(k) of the Internal Revenue Code and covers eligible U.S. employees of the Company. Under the terms of the 401(k) Plan, eligible U.S. employees may make pre-tax dollar or post-tax (Roth) contributions of up to 60% of their eligible pay up to a maximum cap established by the IRS. The Company may contribute a discretionary percentage of qualified individual employee's salaries, as defined, to the 401(k) Plan. In 2019, the Company began providing a 401(k) match, subject to certain limitations. Under the 401(k) match, the Company matches 50% of the first 6% of each employee's 401(k) contribution, up to an annual maximum of $5,000. The employer match will vest immediately.

Note 12. Development and License Agreements

Agreements with Fresenius

Fresenius Kabi AG ("Fresenius") manufactures and supplies the platelet and plasma systems to the Company under a supply agreement (the "Supply Agreement"). Fresenius is obligated to sell, and the Company is obligated to purchase, finished disposable kits for the Company's platelet and plasma systems and the Company's red blood cell system product candidate (the "RBC Sets"). The Supply

Agreement permits the Company to purchase platelet and plasma systems and RBC Sets from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms per unit were initially fixed and declined at specified annual production levels, and are subject to certain adjustments after the initial pricing term. Under the Supply Agreement, the Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying consolidated balance sheets until such time as Fresenius makes payment to the Company.

The initial term of the Supply Agreement extends through July 1, 2025 (the "Initial Term") and is automatically renewed thereafter for additional two-year terms (each, a "Renewal Term"), subject to termination by either party upon (i) two years written notice prior to the expiration of the Initial Term or (ii) one year written notice prior to the expiration of any Renewal Term. Under the Supply Agreement, the Company has the right, but not the obligation, to purchase certain assets and assume certain liabilities from Fresenius.

Government contracts

In June 2016, the Company entered into an agreement with Biomedical Advanced Research and Development Authority ("BARDA") to support the Company's development and implementation of pathogen reduction technology for platelet, plasma, and red blood cells.

The agreement with BARDA and its subsequent modifications include a base period (the "Base Period") and option periods (each, an "Option Period"). The agreement includes committed funding for clinical development of the INTERCEPT Blood System for red blood cells (the "red blood cell system"). In June 2021, BARDA committed an additional $9.6 million raising the committed funding to up to $126.5 million as of December 31, 2021, and the potential for the exercise by BARDA of subsequent Option Periods that, if exercised by BARDA and completed, would bring the total funding opportunity to $223.5 million through December 31, 2023. If exercised by BARDA, subsequent Option Periods would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of emerging pathogens, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. The Company could be responsible for $9.6 million of co-investment if certain Option Periods are exercised. BARDA will make periodic assessments of the Company's progress and the continuation of the agreement is based on the Company's success in completing the required tasks under the Base Period and each exercised Option Period. BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate the agreement for convenience at any time.

As of December 31, 2021 and December 31, 2020, $4.7 million and $4.6 million, respectively, of unbilled amounts were included in accounts receivable on the Company's consolidated balance sheets related to BARDA.

In September 2020, the Company entered into a five-year agreement with the U.S. Food and Drug Administration for the development of next-generation compounds to optimize pathogen reduction treatment of whole blood to reduce the risk of transfusion-transmitted infections. The total potential contract value is $11.1 million. As of December 31, 2021 and December 31, 2020, $0.2 million and less than $0.1 million, respectively, of billed and unbilled amounts were included in accounts receivable on the company's consolidated balance sheets related to FDA.

Note 13. Income Taxes

U.S and foreign components of consolidated loss before income taxes for the years ended December 31, 2021, 2020 and 2019, was as follows (in thousands):

	2021	2020	2019
Loss before income taxes:			
U.S.	$ (54,757)	$ (61,246)	$ (71,946)
Foreign	700	1,673	965
Loss before income taxes	$ (54,057)	$ (59,573)	$ (70,981)

The provision for income taxes for the years ended December 31, 2021, 2020 and 2019, was as follows (in thousands):

	2021	2020	2019
Provision for income taxes:			
Current:			
Foreign	$ 274	$ 274	$ 255
Federal	—	—	—
State	—	—	2
Total current	274	274	257
Deferred:			
Foreign	—	—	—
Federal	23	6	4
State	22	4	2
Total deferred	45	10	6
Provision for income taxes	$ 319	$ 284	$ 263

The difference between the provision for income taxes and the amount computed by applying the federal statutory income tax rate to loss before taxes for the years ended December 31, 2021, 2020 and 2019, was as follows (in thousands):

	2021	2020	2019
Federal statutory tax	$ (11,352)	$ (12,510)	$ (14,906)
Federal research credits	(2,159)	(1,630)	(1,857)
State research credits	(767)	(749)	(821)
Expiration of federal carryovers	4,651	9,200	5,472
Change in valuation allowance	10,482	6,738	13,059
Compensation related items	460	978	158
State taxes	(1,294)	(1,921)	(1,111)
Other	298	178	269
Provision for income taxes	$ 319	$ 284	$ 263

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 at the enacted rates. The significant components of the Company's deferred tax assets and liabilities at December 31, 2021, 2020 and 2019, were as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 150,523	$ 141,176
Research and development credit carryforwards	29,411	28,892
Capitalized research and development	8,406	10,756
Compensation related items	11,951	10,957
Operating leases	4,125	4,214
Other	8,218	6,051
Total deferred tax assets	212,634	202,046
Valuation allowance	(209,524)	(199,042)
Net deferred tax assets	$ 3,110	$ 3,004
Deferred tax liabilities:		
Right-of-use assets	$ 2,895	$ 2,892
Other	313	163
Total deferred tax liabilities	$ 3,208	$ 3,055

The valuation allowance increased by $10.5 million for the year ended December 31, 2021, compared to the increase of $6.7 million and $13.1 million for the years ended December 31, 2020 and 2019, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for

regulatory approval of the Company's products prior to commercialization and expected near-term future losses. The Company expects to maintain a valuation allowance until circumstances change.

For the year ended December 31, 2021, the Company reported pretax net losses on its consolidated statement of operations and calculated taxable losses for both federal and state taxes. The difference between reported net loss and taxable loss are due to differences between book accounting and the respective tax laws.

The Company's tax losses and credits are subject to varying carryforward periods. The gross amounts and dates of expiration of the significant carryforwards are as follows:

	Total	Expires 2022-2024	Expires 2025-2031	Expires 2032-2041	No Expiration
Federal losses carryovers	$ 676,762	$ 76,223	$ 183,062	$ 185,571	$ 231,906
California loss carryovers	80,227	—	41,407	38,820	—
Other state loss carryovers	53,967	620	870	52,477	
Federal research credits	19,001	6,180	1,539	11,282	—
California research credits	13,178	—	—	—	13,178
Federal foreign tax credits	610	—	610	—	—

The Company's ability to utilize net operating loss and research and development credit carryforwards is limited by (a) its ability to generate future taxable income, (b) varying apportionment and allocation rules, and (c) limitations pursuant to the ownership change rules in accordance with Section 382 of the Internal Revenue Code of 1986 and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions.

The Company's unrecognized tax benefits relate to federal and California research tax credits. These tax credits have not been utilized on any tax return and currently have no impact on the Company's tax expense due to the Company's operating losses and the related valuation allowances.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits (in thousands):

	December 31, 2021	December 31, 2020
Unrecognized tax benefits at beginning of period	$ 10,110	$ 10,842
Decreases related to expired carryforwards	(1,296)	(1,171)
Increases related to prior year tax positions	112	
Increases related to current year tax positions	440	439
Unrecognized tax benefits at end of period	$ 9,366	$ 10,110

The Company will recognize accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties.

Note 14. Segment, Customer and Geographic Information

The Company continues to operate in only one segment, blood safety. The Company's chief executive officer is the chief operating decision maker who evaluates performance based on the net revenues and operating loss of the blood safety segment. The Company considers the sale of all of its INTERCEPT Blood System products to be similar in nature and function, and any revenue earned from services is minimal.

The Company's operations outside of the U.S. include a wholly-owned subsidiary headquartered in Europe. The Company's operations in the U.S. are responsible for the R&D and global and domestic commercialization of the INTERCEPT Blood System, while operations in Europe are responsible for the commercialization efforts of the platelet and plasma systems in Europe, the Commonwealth of Independent States and the Middle East. Product revenues are attributed to each region based on the location of the customer, and in the case of non-product revenues, on the location of the collaboration partner.

The Company had the following significant customers that accounted for more than 10% of the Company's total product revenue, during the years ended December 31, 2021, 2020 and 2019 (in percentages):

	Year Ended December 31,		
	2021	2020	2019
American Red Cross	30%	20%	14%
Établissement Français du Sang	16%	21%	27%

Revenues by geographical location were based on the location of the customer during the years ended December 31, 2021, 2020 and 2019, and was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Product revenue:			
United States	$ 67,498	$ 31,517	$ 20,611
France	20,887	19,404	20,075
Other countries	42,474	40,999	33,963
Total product revenue	130,859	91,920	74,649
Government contract revenue:			
United States	28,659	22,329	19,125
Total government contract revenue	28,659	22,329	19,125
Total revenue	$ 159,518	$ 114,249	$ 93,774

Long-lived assets by geographical location at December 31, 2021 and December 31, 2020, were as follows (in thousands):

	December 31,	
	2021	2020
U.S. and territories	$ 11,931	$ 13,559
Europe & other	277	308
Total long-lived assets	$ 12,208	$ 13,867

SIGNATURES

Pursuant to the requirement of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Concord, State of California, on the 22nd day of February, 2022.

CERUS CORPORATION

By: /s/ WILLIAM M. GREENMAN

William M. Greenman
President and Chief Executive Officer

Each person whose signature appears below constitutes and appoints William M. Greenman and Kevin D. Green, his or her true and lawful attorney-in-fact and agent, each acting alone, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to the Annual Report on Form 10-K and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s WILLIAM M. GREENMAN **William M. Greenman**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 22, 2022
/s/ KEVIN D. GREEN **Kevin D. Green**	Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 22, 2022
/s/ DANIEL N. SWISHER, JR. **Daniel N. Swisher, Jr.**	Director and Chair of the Board of Directors	February 22, 2022
/s/ ERIC H. BJERKHOLT **Eric H. Bjerkholt**	Director	February 22, 2022
/s/ ANN LUCENA **Ann Lucena**	Director	February 22, 2022
/s/ TIMOTHY L. MOORE **Timothy L. Moore**	Director	February 22, 2022
/s/ JAMI NACHTSHEIM **Jami Nachtsheim**	Director	February 22, 2022
/s/ GAIL SCHULZE **Gail Schulze**	Director	February 22, 2022
/s/ FRANK WITNEY, PH.D. **Frank Witney, Ph.D.**	Director	February 22, 2022

Exhibit 31.1

CERTIFICATION

I, William M. Greenman, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: February 22, 2022

/s/ WILLIAM M. GREENMAN

William M. Greenman
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Kevin D. Green, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: February 22, 2022

/s/ KEVIN D. GREEN

Kevin D. Green
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), William M. Greenman, the Chief Executive Officer of Cerus Corporation (the "Company") and Kevin D. Green, the Chief Financial Officer of the Company, hereby certify that, to the best of their knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 22nd day of February, 2022.

/s/ WILLIAM M. GREENMAN	/s/ KEVIN D. GREEN
William M. Greenman	**Kevin D. Green**
Chief Executive Officer	**Chief Financial Officer**
(Principal Executive Officer)	**(Principal Financial Officer)**

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 Cerus Corporation 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.