

**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, 2020

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-21937

**CERUS CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
1220 Concord Avenue, Suite 600,  
Concord, California  
(Address of principal executive offices)

68-0262011  
(I.R.S. Employer  
Identification No.)

94520  
(Zip Code)

(925) 288-6000

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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, 2020, 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 \$928 million. <sup>(1)</sup>

As of February 10, 2021, there were 168,220,090 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 2021 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, 2020 incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of \$6.60 per share on June 30, 2020. Excludes 3.6 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, 2020.



FORM 10-K

For the Fiscal Year Ended December 31, 2020

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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 Pathogen Reduced Cryoprecipitated Fibrinogen Complex, or PRCFC, 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, 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 third parties to manufacture 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 effects of the COVID-19 pandemic have materially affected how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which this will impact our future results of operations and overall financial performance remains uncertain.
- The COVID-19 pandemic has negatively impacted our ability to perform many clinical trials, studies and activities, including those covered by our agreement with Biomedical Advanced Research and Development Authority, or BARDA.
- We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets and plasma in the United States, and our inability to successfully commercialize the INTERCEPT Blood System in the United States 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 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.
- If our competitors develop products superior to ours, market their products more effectively than we market our products, or receive regulatory approval before our products, our commercial opportunities could be reduced or eliminated.
- 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 products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities.
- 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.
- If BARDA were to eliminate, reduce or delay funding from our agreement, this could 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.

- Laws and regulations affecting government contracts, including our agreements with BARDA and the U.S. Food and Drug Administration, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.
- 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.
- 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 may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.
- Our stock price is volatile and your investment in our common stock may suffer a decline in value.

## **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: plasma, platelets, red blood cells and to produce PRCFC 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, in November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce PRCFC 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 both the platelet and plasma systems using our direct sales force and through distributors and plan to sell PRCFC directly to hospital customers 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 began submitting for CE Mark approval under the Medical Device Regulation, or MDR, in September 2020. We do not expect an approval decision under the MDR until 2022, 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 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 loss, 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 and red blood cell 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:

<u>Product or Product Candidate Under Development</u>	<u>Product or Development Status</u>
INTERCEPT Blood System—Platelets	<ul style="list-style-type: none"> <li>• 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</li> <li>• Refiling for CE Mark under MDR commencing in 2021</li> <li>• U.S. post-approval haemovigilance study enrolling patients</li> </ul>
INTERCEPT Blood System—Plasma	<ul style="list-style-type: none"> <li>• 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</li> <li>• Refiling for CE Mark under MDR expected to commence in 2021</li> <li>• Received FDA approval of the premarket approval supplement, or PMA, to produce PRCFC in 2020</li> </ul>
INTERCEPT Blood System—Red Blood Cells	<ul style="list-style-type: none"> <li>• Phase 1 clinical trial completed in 2010</li> <li>• U.S. Phase 2 recovery and lifespan study completed in 2014</li> <li>• U.S. Phase 3 clinical trial, known as the RedeS study, enrolling patients</li> <li>• U.S. Phase 3 acute anemia clinical trial, known as the ReCePI study, enrolling patients</li> <li>• Additional U.S. studies also planned</li> <li>• European Phase 3 acute anemia clinical trial completed in 2014; European Phase 3 chronic anemia clinical trial completed in 2017</li> <li>• European CE Mark under MDR commenced in 2020; expected submission in 2021</li> </ul>
INTERCEPT Blood System—Cryoprecipitation	<ul style="list-style-type: none"> <li>• FDA approval in November 2020</li> <li>• U.S. agreement with certain blood center manufacturing partners to manufacture extended-storage cryoprecipitate</li> <li>• Limited commercialization in the U.S. is expected to commence in 2021; broader national commercialization rollout in the U.S. expected to commence in 2022</li> </ul>

*INTERCEPT Blood System for Platelets and Plasma*

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 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 to potentially reduce the risk of transfusion-associated graft versus host disease. 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 discussion with FDA. The first patient enrolled in the haemovigilance study in December 2015. 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. In 2018, the FDA granted Breakthrough Device Designation to our proposed extended-storage cryoprecipitate after treatment with the plasma system and in November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce PRCFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce pathogen reduced plasma, cryoprecipitate reduced. Our commercial efforts in 2021 will largely be 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 preparing for the commercial launch of the INTERCEPT Blood System for Cryoprecipitation. 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 INTERCEPT-treated products 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 making INTERCEPT-treated blood products available to their interstate hospital customers. Several blood centers have submitted and received their interstate licenses, or BLAs. Until BLAs are obtained, U.S. blood centers are limited to sell the applicable INTERCEPT-treated blood components to hospital customers within the state in which the INTERCEPT-treated platelets or plasma are processed. Further, the hospital customers of these blood centers may need 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, in order to address the entire market in the U.S., we will need to develop, test and obtain FDA approval of 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, or triple doses. Although available in Europe, we will need to provide additional data to the FDA for a triple dose configuration of the platelet system to treat platelet donations with such processing parameters. 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 premarket application, or PMA, supplement. 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. Our failure to obtain FDA and foreign regulatory approvals of these new configurations could significantly 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 donated 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 MDD and in September 2020, we began the process to resubmit our application under the new MDR. We do not expect to receive any regulatory approvals of our red blood cell system before 2022, if ever.

In January 2015, we announced that the completed European Phase 3 clinical trial of RBCs treated with the INTERCEPT Blood System for acute anemia in cardiovascular surgery subjects 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, in January 2018, we 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 may need to generate additional safety data from commercial use in order to achieve broad market acceptance or our label claims may be limited if ever approved. As part of our development and chemistry, manufacturing and control, or CMC, activities, we will need to successfully complete validation studies on sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe.

In the U.S., we successfully completed a Phase 2 recovery and lifespan study in 2014. In 2017, 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. 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. 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 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 over the past twelve months. Several participating institutions implemented policies that limited clinical research activities and some eligible subjects have rejected participation because of the need for follow up. 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. The current COVID-19 pandemic has resulted in delays in enrollment for our clinical trials. Should the 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, 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 factor titled "*Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country's regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue in that country. Our investigational red blood cell system requires extensive additional testing and development.*"

Information regarding our revenues for the years ended December 31, 2020, 2019 and 2018 can be found in "Item 7— Management's Discussion and Analysis of Financial Condition and Results of Operations", and "Financial Statement Schedules—Financial Statements" of this Annual Report on Form 10-K.

## ***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 PRCFC 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 devices, 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 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 additional 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 renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach. Pricing under the agreement is established through 2021, therefore new pricing will need to be agreed 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 as of January 1, 2020, for an additional two years. 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 Brotech Corporation d/b/a Purolite Company, or Purolite, for the supply of raw materials used to make the compound adsorption devices. The amended supply agreement expires in April 2022 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. In 2020, we entered into an agreement with Purolite for the purchase of raw materials that may become obsolete, and therefore agreed to make deposits and purchase manufactured raw materials to be used in our compound adsorption devices, with manufacturing and delivery expected during 2021.

Pursuant to a contract that we and Nova Biomedical Corporation, or Nova, entered into in September 2008, Nova is manufacturing illuminators for us. The term of our agreement with Nova automatically renews for successive one-year terms each September in the event neither party delivers written notice of its intent to terminate twelve months prior to each September renewal date. We currently do not have plans to terminate our agreement with Nova and we have not been notified by Nova of their intention to terminate the agreement. In February 2019, we entered into an agreement with Nova for the purchase of components that may become obsolete and for other components to build illuminators. We agreed to prepay for certain of such components before they are converted into finished illuminators over a protracted period.

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 incurred these maintenance fees in the past. The term of the amended manufacturing and supply agreement with Ash Stevens automatically extended at the end of 2019 and now continues until December 31, 2021, 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, including Fresenius and Nova, 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. In September 2019, the FDA issued a final 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. The guidance document requires all blood collection facilities to comply with the options available under the guidance document, which includes the INTERCEPT Blood System, for all platelet collections, no later than October 1, 2021. 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 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. 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 up to 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-treat 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 July 2017, we entered into new agreements with EFS to supply illuminators, platelet and plasma disposable kits. The agreement for supply of illuminators and platelet disposable kits provided for a base term of two years, with two options for EFS to extend for one year each, both of which have been exercised by EFS. 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. 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 contract. 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. More recently, the National Blood Service has implemented the INTERCEPT Blood System for platelets in one of its centers for validation of the technology. In July 2015, the

National Blood Service issued a public tender to solicit bids for both pathogen inactivation and bacterial detection, to which we responded. In December 2015, the National Blood Service announced that it had terminated the potential tender for 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.

In 2018, the FDA granted Breakthrough Device Designation to our proposed extended-storage INTERCEPT-treated cryoprecipitate, and in November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce PRCFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and pathogen reduced plasma, cryoprecipitate reduced. We have entered into manufacturing agreements with certain blood centers to produce PRCFC for us. In order to successfully commercialize PRCFC, we will need to influence the market and sell directly to hospital users of cryoprecipitate and have begun to add resources to our existing commercial teams to commercialize PRCFC. We do not know if PRCFC will be perceived as economically attractive to hospital customers or at what price, if any, or if the investment needed to sell PRCFC will be sustainable. We may choose to sell kits to produce PRCFC to blood centers instead of using manufacturing partners. Should we choose to sell kits to produce PRCFC, we may alienate our contracted manufacturing partners, put pressure on the pricing for PRCFC in the marketplace or be unsuccessful in commercializing PRCFC in the U.S. to its full potential.

Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, and/or other third-party payors. 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 U.S. federal and 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 the U.S., 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. The Centers for Medicare & Medicaid Services published a separate reimbursement code and premium pricing for pathogen-reduced platelet and plasma components under the Healthcare Common Procedure Coding System, or HCPCS. The reimbursement pricing for our platelet and plasma products under HCPCS is driven by actual costs charged to hospitals for INTERCEPT-treated components. While we have applied for a New Technology Add On Payment, or NTAP, for PRCFC, we cannot assure you that we will receive approval or at what amount. Even though platelet and plasma blood components treated with our products are approved for reimbursement by governmental or commercial third-party payors, including under HCPCS codes, the costs and expenses related to use of the INTERCEPT Blood System are not directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products, including PRCFC, cannot be easily, readily, or fully incorporated into the existing reimbursement structure, 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 PRCFC 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.

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 distributor's ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements account for 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 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 our government contract revenue and other financial information for the years ended December 31, 2020, 2019 and 2018. 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 or delay funding from our contract, this could 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*" 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 PRCFC has many advantages over competitors, traditional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Hospitals may not perceive the advantage of PRCFC 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 S.A., 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 recently 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.

Further discussion of the major competitors to our blood product business can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled "*If our competitors develop products superior to ours, market their products more effectively than we market our products, or receive regulatory approval before our products, our commercial opportunities could be reduced or eliminated.*"

### **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, 2020, we owned nine issued or allowed U.S. patents and approximately 77 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2021 and 2037. 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 2021 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 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 components, held as work-in-process on our consolidated balance sheets, may potentially take over one year to 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. 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. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year or conversely, may be insufficient to meet an increase in demand for our products. 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 significant 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 PRCFC 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 may also sell the INTERCEPT Blood System for Cryoprecipitation directly to blood centers that are not contracted with us as manufacturing partners. We may encounter pricing challenges and competition between the direct to hospital sales model and kit sale to blood center model should we decide to sell INTERCEPT Blood System for Cryoprecipitation kits to blood centers for their own production and sale to hospitals.

## Research and Development Expenses

A significant portion of our operating expenses is related to research and development and we intend to maintain a strong commitment to our research and development efforts. As we look ahead, we anticipate that the regulatory submission processes related to planned PMA supplements for the platelet and plasma systems in the U.S. will require continued investment in research and development activities, as will our ongoing clinical, development and 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, 2020, 2019 and 2018.

## 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, of the European Union. Medical devices, including INTERCEPT will need to be re-registered and approved under a new MDR.

The European Union requires that medical devices affix the CE Mark, an international symbol of adherence to quality assurance standards and compliance with the MDD and ultimately, the MDR. We initially received the 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 we currently received an extension of registration under the MDD, we cannot assure you that our products will timely meet the requirements of the new MDR prior to the expiration of the MDD extension. 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 Medical Device Directive, or MDD, and in September 2020, we began the process to resubmit our application under the new MDR. While we have begun filing for CE Mark approval of our red blood cell system, we do not expect an approval decision will occur until 2022, 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 PRCFC 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. to include, among others, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections.

As a condition to the FDA approval of the platelet system, we are 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. We are currently evaluating the results from this completed study. Should the results of this study reveal unacceptable safety risks, we could be required to perform additional studies, which may be costly, and even lose U.S. marketing approval of the platelet and/or plasma systems. 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. For example, due to the obsolescence of certain parts, we have redesigned the illuminator 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. 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 platelets triple dose collections and 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. We understand that the manufacturing facility which produces our platelet and plasma systems will be audited by the FDA. We and our contract manufacturers will need to satisfactorily resolve and comply with adverse findings of the audit, if any. 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.

We are also required to report certain adverse events and production problems, if any, to the FDA and foreign regulatory authorities, when applicable, and FDA 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 determines that our promotional materials or training constitute 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, 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 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 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. Prior to broader customer adoption in the U.S., U.S.-based blood centers need to complete their process validations and obtain site-specific licenses from CBER before making 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 a U.S.-based blood center customer has obtained. Additionally, the hospital customers of ours or of any of our new 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 result in further delay of customer adoption in the U.S. We plan to continue working with hospitals and U.S.-based blood centers to support these activities as any delay would adversely impact our ability to sell products in the U.S.

We plan to supply the INTERCEPT Blood System for Cryoprecipitation to select blood centers that will manufacture PRCFC for us. We plan to sell the finished PRCFC made by our manufacturing blood center partners directly to hospitals. Similar to our platelet and plasma products, our blood center manufacturing partners producing PRCFC will need to complete their process validations and obtain site-specific licenses from CBER before we can make PRCFC available to hospital customers outside of the states producing PRCFC. We plan to continue working with U.S.-based blood centers manufacturing partners to support these activities and any delay in obtaining these licenses would adversely impact our ability to sell products in the U.S.

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 PRCFC product. Accordingly, prospective blood center manufacturing partners, hospitals or physicians may require additional commercially derived data before choosing to use PRCFC. 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). 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 EU implemented 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. The GDPR implements 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.

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 factor titled: *“Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country’s regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate product revenue in that country. Our investigational red blood cell system requires extensive additional testing and development.”*

## **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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, or the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unclear when a decision will be made. It is unclear how the Supreme Court ruling, other such litigation, 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 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, 2020, we had approximately 270 employees representing at least 28 nationalities which includes 4 dedicated commercial consultants. Approximately 63% of our global employees are women. In addition, of our U.S. employees, approximately 41% identify as non-white.

Below is additional demographic information about our current employee base as of December 31, 2020.

<b>Cerus Employees</b>	<b>2020</b>
Salaried workforce .....	246
Managers and above.....	76
Part-time employees.....	8
Average age .....	46 years
Average length of service in years .....	5.8 years
Employee turnover rate (voluntary).....	5.4%

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.

***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 COVID-19 pandemic, Cerus took 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 labs and office significantly with the remote work option whenever possible. In addition, we provide personal protective equipment, put in place new safety protocols, and we test all onsite lab employees once per week.

***Communication and Engagement***

We strongly believe that Cerus’ success depends on employees understanding how their work contributes to the Company’s 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](http://www.cerus.com); however, information found on our website is not incorporated by reference into this report. 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.

## **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 effects of the COVID-19 pandemic have materially affected how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which this will impact our future results of operations and overall financial performance remains uncertain.*

In December 2019, a novel coronavirus disease, or COVID-19, was reported and in January 2020, the World Health Organization, or the WHO, declared it a Public Health Emergency of International Concern. On February 28, 2020, the WHO raised its assessment of the COVID-19 threat from high to very high at a global level due to the continued increase in the number of cases and affected countries, and on March 11, 2020, the WHO characterized COVID-19 as a pandemic. The COVID-19 pandemic, and any potential future significant outbreak of epidemic, pandemic, or contagious diseases in the human population that results in a widespread health crisis, could continue to adversely affect the broader economies, financial markets, our ability to make meaningful progress with many of our development programs and result in disruption and impact on existing and prospective customers.

Although we are currently deemed to be a critical business by national, state and local governments, out of an abundance of caution for our employees and to minimize the spread of COVID-19, we have put restrictions on employee travel and working from our facilities in the United States and Europe. These restrictions have negatively impacted and disrupted at least certain aspects of our business and delayed some of our timelines. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our global and domestic operations, including providing training and technical support, resulting in disruptions in our sales and marketing efforts. Moreover, the pandemic has severely restricted the level of economic activity in affected areas and may continue to adversely impact demand for, and sales of, our products. 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 implement new technologies, including INTERCEPT, has and may continue to be negatively impacted. Furthermore, our ability to gain access to customers during the COVID-19 pandemic may continue to be negatively impacted and may limit our ability to prepare customers and sell product. Conversely, during this 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. Furthermore, the COVID-19 pandemic has in the past and may continue to limit access to hospitals which could disrupt blood center interaction with those hospitals and the introduction of the INTERCEPT Blood System. In addition, should hospital access be restricted, our ability to sell pathogen reduced cryoprecipitate fibrinogen complex, or PRCFC, directly to hospitals may be impaired. 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, 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 crisis would not negatively impact our supply chain. All of the aforementioned could adversely affect our sales, operating results and overall financial performance.

Our primary manufacturing partner for our disposable kits is located in France where restrictive government and private enterprise measures were implemented in response to the COVID-19 pandemic. To ensure employee safety and comply with local requirements for social distancing, we understand that Fresenius Kabi Deutschland GmbH, or Fresenius, had to reconfigure production workflow to safely produce INTERCEPT disposable kits. A renewed spike in the pandemic in France could increase employee absenteeism at the manufacturing site and is a potential risk that could negatively impact production, the magnitude of which depends, in part, on the length and severity of the restrictions and other limitations on their ability to conduct business in the ordinary course.

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, the extent and effectiveness of containment actions, and an effective rollout of a vaccination program. In the event one or more of our laboratory employees is exposed to or becomes ill with COVID-19, our ability to complete research and development activities may be impaired and dependent studies and trials may be delayed as a result. We cannot guarantee that the resumption of these activities will be expeditious or that the resulting delays will not be for an extended period of time. Furthermore, if key deployment and/or technical service personnel are exposed to or become ill with COVID-19, our ability to effectively support our customers on a timely basis could be negatively impacted and our ability to support customers looking to implement INTERCEPT may be impaired.

In addition, while the potential economic impact brought by COVID-19 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. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. 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.

***The COVID-19 pandemic has negatively impacted our ability to perform many clinical trials, studies and activities, including those covered by our agreement with BARDA.***

Beyond the commercial impact that the COVID-19 pandemic may have on our operations, our clinical and development programs have been adversely affected. Our ongoing and anticipated clinical trials, the post-approval platelet studies, as well as studies to support label expansion for our platelet program in the U.S. have been delayed because of COVID-19. Many hospital sites suspended enrollment and have not yet resumed enrollment while others are proceeding at a reduced capacity. Further delays may occur in the future if patient enrollment sites need to pause participation in our clinical trials and studies. 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 the Biomedical Advanced Research and Development Authority, or BARDA, our cash flows would be negatively impacted and/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 recommence and complete studies if and when the COVID-19 crisis subsides.

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. As the clinical studies and other activities supported by our BARDA contract get further delayed as a result of the COVID-19 pandemic, we must rely on modifications and extensions to the BARDA agreement to fund the completion of those activities. If we are unable to get approval for those modifications or extensions, we may need to fund the completion of those studies and activities ourselves. If BARDA were to eliminate, reduce or delay funding under our agreement, or if we are otherwise required to self-fund the activities covered by the BARDA agreement, this could have a significant negative impact on the programs associated with such funding, including the discontinuation of those programs, and could have a significant negative impact on our revenues and cash flows. In addition, certain activities expected to be performed under our BARDA agreement have been significantly delayed. Should BARDA disallow extensions of time to perform the contemplated activities, we would have to either fund the completion of the activities ourselves or discontinue pursuit. 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.

***We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets, plasma and cryoprecipitation in the United States, or 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.***

We have invested a significant portion of our efforts and financial resources on the development of the INTERCEPT Blood System for platelets, plasma, and cryoprecipitation for the U.S. market. As a result, our business is substantially dependent on our ability to



successfully commercialize the INTERCEPT Blood System in the U.S. in a timely manner. In September 2019, the FDA issued a final guidance document, “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion,” or Final Guidance Document. The guidance document required all blood collection facilities to comply with the options available under the guidance document, which includes the INTERCEPT Blood System, for all platelet collections, no later than 18 months from the issuance date. However, in December 2020, the FDA updated the Final Guidance Document and extended the compliance grace period until October 1, 2021. 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 adopt INTERCEPT over other options or at what levels. In addition, if we are not successful in expanding the label claims for our platelet kits in the U.S., including permitting storage of INTERCEPT-treated platelet units for up to seven days and approval of our processing set for triple dose platelet collections, U.S. blood centers or their hospital customers may choose alternative products in order to comply with the guidance document. Significant product revenue from customers in the U.S. may not occur timely, if at all, until we have been able to successfully implement the platelet and plasma systems and demonstrate that they 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. If the COVID-19 crisis persists or continues to worsen, customers may not be able to implement new technologies such as INTERCEPT and may instead choose to utilize other allowable methods with which they have more familiarity. Moreover, if hospitals are not able or willing to allow our employees to gain access to their facility or personnel, our ability to market and commercialize PRCFC directly to hospitals may be impaired and our results of operations negatively impacted. 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.

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 FDA 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;
- 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 process 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, 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 suppliers for the particular product or component they manufacture, 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;
- 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;
- 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.

In addition to the above, our ability to successfully commercialize the INTERCEPT Blood System in the U.S. is dependent on our ability to operate without infringing on the intellectual property rights of others. For example, we are aware of an expired U.S. patent that had been held by a third-party that covered 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 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 and the risk of an infringement claim will remain until the statute of limitations to bring an infringement claim has expired. 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.

These and the other risks described below related to the commercialization of the INTERCEPT Blood System could have a material adverse effect on our ability to successfully commercialize the INTERCEPT Blood System for platelets and plasma in the U.S.

***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 alternative 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 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 or clinical regimens, prospective customers may not adopt our platelet system.

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. Customers that attempt to optimize collections from individual donors in order to increase the volume of transfusable units from those collections may experience a less optimized yield as a result of adopting INTERCEPT as compared to collecting conventional platelet products. 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, efficacy or other factors.

The INTERCEPT Blood System does not inactivate all known pathogens, and the inability of the INTERCEPT Blood System to inactivate certain pathogens 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, our inability to inactivate, or limit 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. In addition, our products do not inactivate prions since prions do not contain nucleic acid. While transmission of prions has not been a major problem in blood transfusions, and we are not aware of any competing products that inactivate prions, the inability to inactivate prions may limit market adoption of our products. While we have data supporting INTERCEPT's ability to inactivate SARS-CoV-1 and MERS-CoV, both coronaviruses, we have only limited data supporting INTERCEPT's efficacy in inactivating the SARS-CoV-2 virus (the virus that causes COVID-19). Although we have several other studies underway to study the pathogen inactivation efficacy of INTERCEPT against SARS-CoV-2, we cannot assure you that the results of these studies will be successful. 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 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. When an *in vitro* test was not generally available or not well-established, we conducted *in vivo* studies in mammalian models to predict human responses. Although we have no reason to believe that the *in vitro* and *in vivo* studies are not predictive of actual results in humans, 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. 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 convince a blood center to treat 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 use of our products. In addition, some hospitals may decide to purchase and transfuse both INTERCEPT-treated blood components and conventional blood components, including PRCFC 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 delay in market adoption. Further, in certain markets, potential customers may require us to develop, sell, and support data management application software for their operations before they would consider adopting INTERCEPT. Such software development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Developing, maintaining and supporting software can be time consuming, costly and may require resources and skill sets that we do not possess. Failure to do so may limit market adoption in geographies where we commercialize the INTERCEPT Blood System, including the U.S. 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 the 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 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 are consolidating, are laying off workers or are filing 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 INTERCEPT-treated platelets and plasma in the outpatient setting in 2015, but have not obtained HCPCS reimbursement codes for our products, PRCFC or the derivative, pathogen-reduced plasma, cryoprecipitate reduced, which were approved in November 2020. Our ability to successfully market and sell our PRCFC or the derivative, pathogen-reduced plasma, cryoprecipitate reduced may be dependent on our ability to obtain a separate reimbursement code and pricing for such products. 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, including under HCPCS codes, the costs and expenses related to use of 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. The current HCPCS codes utilized by U.S. hospitals describe only the transfusion of traditional plasma cryoprecipitate, which is produced under much less labor-intensive processing and manipulation by blood centers. There is no current HCPCS code that accurately identifies the transfusion of highly processed plasma cryoprecipitation for fibrinogen deficiency, such as our product, PRCFC. Though we have applied for a specific HCPCS code for transfusion of highly processed plasma cryoprecipitation for fibrinogen deficiency, we cannot guarantee that we will receive approval for such HCPCS codes or that reimbursement under an approved HCPCS codes will be in an amount sufficient to cover the cost of our products to our hospital customers. 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.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even where our products receive regulatory approval and reimbursement is available, 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. We cannot guarantee the long-term volume or timing of commercial purchases that the American Red Cross may make, if any, under our agreement. Our ability to gain 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 and broad-based utilization of INTERCEPT and distribution of INTERCEPT-treated products may be concentrated in a limited number of centers or may occur slowly, if at all. Conversely, given the large relative size of the American Red Cross, should they deploy the technology rapidly, 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 September 2019, the FDA issued a final guidance document, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion." The guidance document requires all blood collection facilities to comply with the options available under the guidance document, which includes the INTERCEPT Blood System, for all platelet collections, no later than October 1, 2021. Should the American Red Cross or a large number of blood centers wait until the end of the compliance period to produce INTERCEPT at sufficient volumes to comply with the guidance document, we may not have sufficient resources or product available to allow customers to timely and successfully implement INTERCEPT before the end of the compliance grace period. Should we be unable to manufacture INTERCEPT in sufficient quantities in a timely manner, or have adequate resources to assist customer 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 PRCFC. Also, if the COVID-19 crisis persists or continues to worsen, customers may not be able to implement new technologies such as INTERCEPT and may instead choose to utilize other allowable methods with which they have more familiarity. Similarly, if we are not successful in expanding the label claims for our platelet kits in the U.S., including permitting storage of INTERCEPT-treated platelet units for up to seven days and approval of our processing set for triple dose collections, U.S. blood centers or their hospital customers may choose alternative products in order to comply with the FDA guidance document. 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 territories 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 product. The review period for a new MAA can be up to 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 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 our results of operations and financial results. 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. Should German blood centers not adequately market and sell or assist their hospital customers 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 July 2017, we entered into new agreements with Établissement Français du Sang, or EFS, to supply illuminators and platelet and plasma disposable kits. The agreement for supply of illuminators and platelet disposable kits provided for a base term of two years, with two options for EFS to extend for one year each, both of which have been exercised by EFS. 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. 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 contract. 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. Our contracts with EFS do not contain purchase volume commitments and as such, we may see variability in purchase levels or an altogether cessation. 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. This in turn, may negatively impact our potential revenues from existing and prospective customers.

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. We also understand that the Japanese Red Cross had begun formal evaluation of a competing technology. Before the Japanese Red Cross considers 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 may be constrained due to a variety of factors, including 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 such disruptions or supply shortages, we may have to allocate available products to customers, which could negatively impact our business and reputation or cause those customers to look for alternatives to 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.***

Our ability to generate significant product revenue from our platelet and plasma systems depends in part on our ability to achieve market acceptance of, and to otherwise effectively market, our platelet, plasma, and cryoprecipitation systems in the U.S. Even if we

are able to achieve market acceptance in the U.S. or newly commercialized markets, we have provided and may provide adoption incentives in the future which may negatively impact our reported sales. We currently plan to sell PRCFC directly to hospitals. This is a new business model with which we have no experience. This new business model may contemplate the replacement of expired PRCFC with new units of PRCFC 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 also sell the disposable kits related to the INTERCEPT Blood System for Cryoprecipitation directly to blood centers for the manufacture of PRCFC for their own account. As a result, we may be directly competing with these blood centers for the sale of PRCFC. These blood centers have more experience and existing contracts with the hospitals, and may be able to offer synergies that we cannot, each of which may negatively impact our ability to compete successfully. 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 and plasma systems in the U.S. As a result of the COVID-19 crisis, we may continue to have difficulties recruiting, on-boarding and training new field-based personnel, or we may choose to defer recruiting for certain positions due to the ongoing pandemic. In addition, our field personnel, if available, may be unable to gain access to blood center or hospital accounts, which may limit our ability to effectively sell our products. 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. In addition, in November 2020, we obtained approval for PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced, both of which are created through the use of the INTERCEPT Blood System for Cryoprecipitation, or the cryoprecipitation system. The cryoprecipitation system also uses treated plasma components from the INTERCEPT Blood System for plasma. We may seek additional approval of unique biological products created by use of the INTERCEPT Blood System in the future and may choose to sell these treated end products directly to hospitals using our commercial organization. While we are working on implementing the infrastructure we believe will be necessary to market the PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced directly to hospitals, we have no experience selling biological end products directly to hospitals, which may cause a distraction for our commercial organization or require us to supplement our commercial organization with new personnel with experience in selling products directly to hospitals. We may fail to develop or maintain an effective and qualified commercial infrastructure to serve these customers. Further, 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. In addition, we may never achieve market acceptance and adoption of our newly approved PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced 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. In addition, the commercialization of our PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced will also expose us to risks inherent in the marketing and sale of 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 has been received. For example, in cases where we have obtained regulatory 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. 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. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that

the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. 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 or another governmental 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. Repeated product malfunctions or deficiencies may result in a voluntary or involuntary product recall. We are required to follow detailed recordkeeping requirements for all company-initiated corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the applicable reporting regulations. 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. 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 than we market our products, or receive regulatory approval before our products, our commercial opportunities could be reduced or 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 will depend 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 have not demonstrated a high level of inactivation. While studies have demonstrated that our products can effectively inactivate a broad spectrum of pathogens in blood components, market adoption of our products may be reduced if

customers determine that competitors' products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. 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.

In Europe, several companies are developing or selling commercial pathogen reduction systems or services. Octapharma AG, or Octapharma, has FDA approval to sell treated fresh frozen plasma for certain indications and is currently commercially available. In addition, we understand that Octapharma received approval to sell fresh frozen plasma in France. Octapharma's entry into the French market may pose a competitive threat to other pathogen reduced plasmas, including INTERCEPT and may in turn limit the potential market available to us in France. Should Octapharma enter into exclusive agreements with key customers, our plasma system may encounter market resistance and we will have a more limited market into which we can sell. 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.

MacoPharma SA, or Macopharma, has received CE Mark for a UVC-based product for pathogen reduced platelets. Macopharma has recently completed a Phase 3 clinical trial in Germany for expanded approvals. The data from this trial has not yet been made publicly available. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has been issued CE Marks for its system for both platelets and plasma and received Swissmedic approval for platelets. We further understand that Terumo BCT developed a pathogen reduction system for whole blood and received a Class II CE Mark. Each of these companies' products may offer competitive advantages over our INTERCEPT Blood System. In addition, these companies are multinational corporations with more mature products and relationships than we have. Our ability to commercialize our products in certain markets may be negatively affected by their larger resources and their pre-existing relationships with regulators and customers.

Grifols S.A., Kedrion Biopharma, and other companies have or are developing competing products and may also offer and sell other blood-banking products and services. New methods of testing whole blood for specific pathogens have been approved by the FDA and in Europe, as have tests for bacteria in platelets. Other companies are marketing rapid, point-of-care bacterial tests, and developing synthetic blood product substitutes and products to stimulate the growth of platelets. Development and commercialization of any of these or other related technologies could limit the potential market for our products as would a mandate of any competing technology other than INTERCEPT.

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 PRCFC has many advantages over competitors, traditional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Hospitals may not perceive the advantage of PRCFC 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. Further, competitors may have more experience marketing and selling products directly to hospitals. In addition, regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets.

***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 Platelet Additive Solutions, or PASs. 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.



There are several third-party manufacturers of pooling sets to allow for such combination. Our customers' ability to use our INTERCEPT products may be impaired should manufacturers of those products not provide access to their products allowing for the combination of multiple components or if such manufacturers experience a shortage of their products or encounter defects with their products. In addition, we do not yet know what impact, if any, the new European Medical Device Regulation, or MDR, may have on these suppliers or their products. Should manufacturers of collection devices, compatible assays and blood bags, pooling sets or platelet additive solutions fail to obtain or maintain regulatory approval, including the MDR, experience unexpected production disruption, or decide to cease distribution of those respective products to customers and prospective customers, our ability to sell the INTERCEPT Blood System may be impaired and acceptance in 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. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. 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. We have conducted and may conduct additional *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. 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. Our failure to obtain FDA and foreign regulatory approvals of any new configurations could significantly limit product revenue from sales of the platelet system. 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 and maintain an adequate concentration for a triple therapeutic dose. In any event, delays in receipt or failure to receive approval could reduce our sales and negatively impact our profitability potential and future growth prospects. 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, 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. The COVID-19 pandemic has delayed certain product configuration activities, including extended storage platelets for the U.S. market and data generation for a platelet set used to treat and provide three therapeutic doses from a single platelet donor in the U.S. While activities surrounding these product configuration activities have resumed, should the pandemic persist or continue to worsen or should other factors outside of our control limit our ability to generate the aforementioned data needed for licensure, beyond the end of the compliance grace period covered by the FDA guidance document for platelet safety, customers and prospective customers may choose to implement other acceptable alternatives in order to comply with the guidance document. 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. These development activities will increase our costs significantly and may not be successful. We may 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. Delays in obtaining any future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our product revenue and potential future profitability.

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

***Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. We will have to refile and obtain CE Mark approval under the MDR for all of our products and product candidates. If our preclinical and clinical data are not considered sufficient by a country's regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate product revenue in that country. Our investigational red blood cell system requires extensive additional testing and development.***

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. These regulations are wide-ranging and govern, among other things:

- development;
- testing;
- manufacturing;
- labeling;
- storage;
- clinical trials;
- environmental;
- product safety;
- pre-market clearance or approval;
- sales and distribution;
- use standards and documentation;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- post-launch surveillance and post-approval studies;
- quality;
- advertising and promotion;
- product import and export; and
- reimbursement.

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. In addition, our approved labels 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 FDA 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 and the manufacturers are generating data to support expansion of the approved claims for INTERCEPT-treated platelets collected on and used with additional storage solutions, we cannot assure you that the data generated will be acceptable to the FDA. Such discrepant collection methodologies and storage solutions and conditions also exist for red blood cells. 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, in order to generate data that would be satisfactory to the FDA, we need to test our products with different blood center production configurations producing otherwise saleable products for the blood center. As such, we will generally need to purchase blood components which are expensive and may be limited during periods of low availability. For example, we continue to experience such availability constraints for platelets, and expect even more constraints on availability during the COVID-19 pandemic. Any such inability to procure blood components at a reasonable price, or at all, to conduct studies in order to generate data sufficient for label claim expansions may negatively impact our business opportunities.

## *Clinical and Preclinical*

Clinical trials are particularly expensive and have a high risk of failure. Any of our trials may fail or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. 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 addition, during the current COVID-19 pandemic, several of the hospital clinical trial sites for our RedeS and ReCePI temporarily suspended the studies and several red blood cell production partners for the studies temporarily suspended production in order to conserve red blood cells to meet hospital demand during the pandemic. While certain enrollment sites and blood center production partners have resumed enrolling patients and producing INTERCEPT-treated red blood cells, many hospital sites have not yet resumed enrollment and those that have are proceeding at a reduced capacity. Further delays or a resurgence of COVID-19 at sites where we are conducting studies and trials may recur in the future should the COVID-19 pandemic persist or continue to worsen. We have restricted travel by our employees in states that are subject to mandatory stay-at-home orders and may again in the future need to restrict travel to certain clinical trial sites for monitoring site visits or to otherwise manage the trial. Significant delays in clinical testing could also materially impact our clinical trials. Some clinical sites for the RedeS study are located in areas that are also 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. We cannot be certain that further delays in the RedeS study or other clinical trials will not occur because of the pandemic or otherwise. 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. We do not yet know when our employees will have access to a vaccine or if such a vaccine will be effective.

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, ReCePI trial, and may impact other studies. Consequently, we may be unable to recruit suitable patients into clinical trials on a timely basis, if at all, which may lead to higher costs or the inability to complete the clinical trials. 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 trials. 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 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. Each of these studies and any additional studies that the FDA may require could involve significant expense and may require us to secure adequate funding to complete. 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 outside of the U.S. may also require post-marketing studies. 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. Under the Final Guidance Document our INTERCEPT Blood System for platelets is an approved option for blood centers to meet the guidance document requirements. However, we do not yet have approved label claims for all platelet processing standards or storage claims supporting transfusion of INTERCEPT-treated platelets out to seven days. Our inability to meet such operational or processing constraints may impair our potential results permanently or until we are able to obtain such claims, or customers may be forced to choose alternative options to comply with the guidance document by the end of the extended compliance grace period, October 1, 2021. Should that occur, we may be unable to subsequently convert blood centers to INTERCEPT Blood System for platelets which would limit our market potential. In addition, we do not know what effect, if any, the COVID-19 pandemic will have on blood centers abilities to comply with the guidance document. If the COVID-19 crisis persists or continues to worsen, customers may not be able to implement new technologies such as INTERCEPT and may instead choose to utilize other allowable methods with which they have more familiarity. Moreover, if hospitals are not able or willing to allow our employees to gain access to their facility or personnel, our ability to market and commercialize PRCFC directly to hospitals may be impaired and our results of operations negatively impacted. Outside 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. In Germany, blood centers need to obtain marketing authorizations before they can submit for reimbursement or sell to hospitals. 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.

### *Red Blood Cell System*

While we are in the process of submitting for CE Mark approval of our red blood cell system, it has not been approved 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 regulatory approvals for the product. Final development of the red blood cell system may never occur and failure can occur any time during the process. Any failure or delay in completing the development activities for the red blood cell system would prevent or delay its commercialization, which could 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. Many of the factors described above that can contribute to the failure or delay of a clinical trial could impact the trials we conduct for our red blood cell system. Even if we are successful in earlier clinical trials, the results of those early trials may not be predictive of results obtained in later and larger clinical trials of the red blood cell system or the results of routine use if we are able to commercialize the red blood cell system. In those cases, the FDA or foreign regulatory agencies may require us to conduct additional clinical trials or further studies or analysis which may be costly and time-consuming. Furthermore, regulators 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 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 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. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our failure or the failure of our product manufacturers to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process. We must be able to demonstrate stability of our active compounds manufactured under cGMP which meets release specifications. We have not been able to demonstrate that our product manufacturers or we are able to meet those requirements. 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 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. Over the past few years, qualified and prospective suppliers of one of the key reagents used in our red blood cell system have declared bankruptcy. We recently qualified a different manufacturer to produce the key reagent compound for our red blood cell system beyond our existing inventory levels, although production is in much smaller batch sizes which may prove more costly. We may pursue identification and qualification of another reagent supplier which may be costly, time consuming or unsuccessful. Other suppliers may become insolvent or file for bankruptcy, which would negatively impact our ability to produce our products or components to our products. Although we will try to identify and qualify alternate manufacturers, and negotiate new agreements on favorable terms, we may be unable to produce product or complete clinical studies on-time, if at all. We also understand that stricter regulations are being considered for certain raw materials used in our red blood cell processing sets, notably non-DEHP plastics. Should such regulations be enacted we may need to qualify alternate plastics which comply with the stricter regulations which may be costly and time consuming.

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. In a subsequent Phase 1 clinical trial that we initiated in the fourth quarter of 2008 to evaluate recovery and survival of treated red blood cells with the modified process, there were no adverse events reported. Based on the results from that trial, we obtained approval for and commenced two Phase 3 clinical trials in Europe using the modified process in patients with acute and chronic anemia, respectively. We successfully completed the European Phase 3 acute anemia clinical trial and the European Phase 3 chronic anemia clinical trial, with the INTERCEPT Blood System for red blood cells meeting its primary efficacy and safety endpoints in both trials. However, 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 the future. In addition, although our completed European Phase 3 clinical trials in acute anemia patients and chronic anemia patients using our modified process met their primary endpoints, we cannot assure you that the same or similar results will be observed in current and potential future clinical trials using our modified process. We 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. The COVID-19 pandemic has caused disruption in enrolling patients in clinical trials in the U.S. While those trials are currently enrolling patients, they may be disrupted again should the pandemic continue to worsen or recur in areas enrolling patients. Even prior to the pandemic, 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. 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, including the potential for additional Phase 3 clinical trials beyond what is currently contemplated with the RedeS and ReCePI 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 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 recently agreed to modify the criteria for a clinical pause in the RedeS study if we see three or more treatment emergent antibodies with amustaline specificity without evidence of hemolysis in patients receiving INTERCEPT-treated red blood cells in that 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. Should we see events where antibodies to amustaline (S-303) are formed without evidence of hemolysis, the Data and Safety Monitoring Board, or DSMB, and we will need to assess the underlying information and either agree to continue the study or either delay completion of the study or permanently halt the study until we can demonstrate that the antibodies were not clinically significant. To date, two S-303 antibody events without evidence of hemolysis have been detected in the RedeS study. We do not yet know if the S-303 antibody events were in the control or test arm, however the events are not clinically significant. These events have been reviewed by the DSMB who did not express concerns with respect to patient safety. 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 September 2020, we began the process to resubmit our application under the new MDR. Accordingly, we do not expect to receive any regulatory approvals of our red blood cell system prior to 2022, if ever. We do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to receive CE Mark approval or if we will be able to receive broad label claim approval for both acute and chronic anemia indications. 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, when we transition to that standard. If such data is deemed insufficient, we may need to generate additional safety data in clinical trials to satisfy the MDR standards. We may also need to generate additional safety data from commercial use 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. 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, un-treated red blood cells and the significantly lower lifespan for INTERCEPT-treated red blood cells compared to conventional, un-treated 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. In addition, if we are unable to secure the full amount of funding contemplated by the BARDA agreement for any reason, or if the costs to complete the activities are more than allowed for by our BARDA agreement, our ability to complete the development activities required for potential licensure in the U.S. may require additional capital beyond that which we currently have, 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, certain activities expected to be performed under our BARDA agreement have been significantly delayed as a result of the COVID-19 pandemic. Should BARDA disallow extensions of time to perform the contemplated activities, we would have to either fund the completion of the activities ourselves or discontinue pursuit. Further, while we believe that our available cash and cash equivalents and short-term investments, as well as cash to be 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. If alternative sources of funding are not available, we may be forced 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. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues 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 costs may 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.

### *Platelet and Plasma Systems*

In 2007, we obtained a CE Mark approval from E.U. regulators for our platelet system under the MDD and have subsequently received periodic extensions in accordance with the five-year renewal schedule. In March 2020, we received an extension of the CE Mark approval to 2024, under the MDD. While we currently received an extension of registration under the MDD, we cannot assure you that our products will timely meet the requirements of the new MDR prior to the expiration of the MDD extension. We or our customers have received approval for the sale and/or use of INTERCEPT-treated platelets within Europe in France, Switzerland,

Germany and Austria. 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 2006, we obtained a CE Mark approval from E.U. regulators for our plasma system under the MDD and have subsequently received periodic extensions in accordance with the five-year renewal schedule. In March 2020, we received an extension of the CE Mark approval to 2024, under the MDD. While we currently received an extension of registration under the MDD, we cannot assure you that our products will timely meet the requirements of the new MDR prior to the expiration of the MDD extension. We or our customers have received approval for the sale and/or use INTERCEPT-treated plasma within Europe in France, Switzerland, Germany and Austria. 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 growth prospects would be materially and adversely impacted.

The FDA has approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components collected and stored in InterSol and 100% plasma 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. Additionally, the FDA 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 conducted and are conducting additional *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. Failure to obtain any of these label expansion claims may negatively affect market adoption and our growth prospects would be materially and adversely affected.

As a condition to the initial FDA approval of the platelet system, we are required to submit data from a post-approval clinical study of the platelet system. Although we have recently completed this study, we are in the process of evaluating the data from the study. If the study reveals unacceptable safety risks, we could be required to perform additional studies, which may be costly, and even lose U.S. marketing approval of the platelet system. Further, we are 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. Successful enrollment and completion of this additional study will also 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. Previously these studies and other studies had been delayed as a result of the COVID-19 pandemic and may be delayed in the future if the COVID-19 pandemic persists or continues to worsen. If we are unable to complete the required studies in a timely manner or at all, or the results of the studies reveal unacceptable safety risks, we could be required to perform additional studies, which may be costly. 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 operating results, financial condition and stock price. In addition, there is a risk that these studies will 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.

#### *INTERCEPT Blood System for Cryoprecipitation to Produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex and Pathogen Reduced Plasma, Cryoprecipitate Reduced*

In November 2020, we obtained FDA approval of INTERCEPT Blood System for Cryoprecipitation to produce PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced. We are currently validating with our manufacturing partners the process to produce these new products in accordance with our specifications. Once the process at our manufacturing partners is validated, we will be eligible to sell and deliver these new products only to hospital customers in the state of manufacture until our manufacturing partners receive approval of their manufacturing site Biologics License Applications, or BLAs. We cannot provide any assurance that our manufacturing partners will receive BLA approval from the FDA on a timely basis or at all. In addition, in order to market and sell PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced to hospital customers throughout the U.S., we will need to identify and validate additional manufacturing partners. We cannot guarantee that we will be able to successfully negotiate additional agreements with manufacturing partners on terms that are acceptable to us. If we are unable to obtain additional manufacturing partners, our ability to market and sell our new products outside of the four states where we currently have manufacturing partners may be severely curtailed or limited. PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced are products 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 pathogen reduced cryoprecipitated fibrinogen complex and its derivative product, pathogen reduced plasma, cryoprecipitate reduced. 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.

### *Post-Marketing Approval*

We are also required to comply with applicable FDA and other regulatory requirements now that we have obtained approval for the INTERCEPT Blood System for platelets, plasma and cryoprecipitation. These requirements relate 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 cGMP and current QSR requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections. We understand that the manufacturing facility which produces our platelet and plasma systems will be audited by the FDA in the near term. We and our contract manufacturers will need to satisfactorily resolve and comply with adverse findings of the audit, if any. 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. We are required to report certain adverse events and production problems, if any, to the FDA and foreign regulatory authorities, when applicable, and must additionally 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. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. 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, 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 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. Any enforcement action brought by a federal, state or foreign authority could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, 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, and diminished profits and future earnings. In addition, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA 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. Product liability claims are expensive to defend, divert our management's attention, result in substantial damage awards against us and harm our reputation. Regulatory authorities may also challenge the classification of our approvals for our products.

Should a regulatory agency question a reported adverse event, we may not be able to rule out product failure as the cause, whether or not product failure is the cause of the reported adverse event. If a regulatory agency 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 agency 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, 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;
- refusal to grant export or import approval for our products;



- withdrawing 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. Any failure to comply with ongoing or changing regulatory requirements may significantly and adversely affect our ability to successfully commercialize and generate additional product revenues from our platelet and plasma systems or any future products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to continue to generate product revenues from the sale of our platelet and plasma systems, our potential for achieving operating profitability will be diminished and the need for additional capital to fund our operations will be increased.

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, we may be required to develop a registry of patients receiving INTERCEPT-treated red blood cells for future data collection and evaluation. Should we become subject to such a requirement post-approval, we may incur significant costs to develop, create and implement such a registry. 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 instance, we understand that we will have to re-register our CE Marked products under the new MDR, (as required by all manufacturers who sell in Europe under a CE Mark), while we anticipate this will be a formality, there is always a possibility of new requirements. 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 agency's 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 or plasma 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 agencies 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. We understand that the manufacturing facility which produces our platelet and plasma systems will be audited by the FDA in the near term. 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 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 and operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing approval in the U.S. or elsewhere, our suppliers will have to pass an audit by the FDA or other regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits. Such audits and any audit remediation may be costly. Failure to pass such audits by any of our suppliers would affect our ability to obtain licensure in the U.S. or elsewhere.

***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 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 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, due to the obsolescence of certain parts, we have redesigned 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 in the U.S. or under CE Mark. We understand that a solvent used to make the plastic beads in our plasma compound adsorption devices is 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. In addition, in order to address the entire market in the U.S., we will need to obtain approval for additional configurations of the platelet system, including triple dose collections and random donor platelets. Our approved labels 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. Such discrepant collection methodologies and storage solutions and conditions also exist for red blood cells. 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. We have conducted and may conduct additional *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations could significantly limit product revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales and negatively impact our profitability potential and future growth prospects. 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 have no experience selling 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.***

Our ability to successfully commercialize our INTERCEPT Blood System for Cryoprecipitation in the U.S. will depend on our ability to do the following, among other things:

- 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 manufacturers of the pathogen reduced-cryoprecipitated fibrinogen complex and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced;
- support blood center manufacturing partners in obtaining biologic license applications (BLAs) for interstate commerce;
- create market demand through our education, marketing and sales activities, including the ability to demonstrate to the transfusion community and other health care constituencies that pathogen reduction, including pathogen reduced-cryoprecipitated fibrinogen complex for the treatment and control of bleeding, and the INTERCEPT Blood System is safe, effective and cost effective;
- hire, train, deploy, support and maintain a qualified U.S.-based commercial organization and field sales force;
- comply with requirements established by the FDA, including post-marketing requirements and label restrictions; and
- comply with other U.S. healthcare regulatory requirements.

Our ability to commercialize pathogen reduced-cryoprecipitated fibrinogen complex and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced in the U.S. will initially be limited to the four states of California, Texas, Louisiana and Wisconsin. Our ability to sell this product in other states is dependent on the approval of manufacturing site BLAs by the FDA and we cannot be sure that the sites will receive such authorizations in a timely manner, if at all.

While we are working on implementing the infrastructure we believe will be necessary to market pathogen reduced-cryoprecipitated fibrinogen complex and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced directly to hospitals, we have no experience selling to hospitals nor do we have experience or expertise complying with regulations governing finished biologics. If we are unable to successfully market this product to hospitals or comply with such unique regulations, our ability to monetize and deliver such product will be negatively impacted.

If the COVID-19 crisis persists or continues to worsen, customers may not be able to implement new technologies such as INTERCEPT and may instead choose to utilize other allowable methods with which they have more familiarity. Moreover, if hospitals are not able or willing to allow our employees to gain access to their facility or personnel, our ability to market and commercialize PRCFC directly to hospitals may be impaired and our results of operations negatively impacted.

***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 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 have a wholly-owned subsidiary, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in Europe, the CIS and the Middle East. Our commercial activities for the U.S., Latin and South America and Asia are based out of our headquarters in Concord, California with certain support from our European headquarters in the Netherlands, with certain individuals servicing Latin and South America and Asia, domiciled outside of the U.S. Given the relatively concentrated customer base in the U.S., coupled with the FDA guidance document on platelet safety requiring all blood centers to comply by March 2021 by using a relatively small number of options, including INTERCEPT Blood System for platelets, should blood centers deploy INTERCEPT Blood System for platelets rapidly, our resources may be inadequate to fulfill the demands, which could result in a loss of product revenues or customer contracts, or both. 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. Additionally, such business models may be viewed as a threat to existing customers. We cannot assure you that we will pursue such business models or if we do, that we will be successful or that our existing customers will not feel threatened.

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 have and how such withdrawal will affect us.

***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 limiting the kinds of financial arrangements we may have with hospitals, physicians, 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 member states. There are a variety of organizations and entities within E.U. 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 E.U. 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, 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, physicians, 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 recent trend of increased U.S. federal, state and local regulation of payments and transfers of value provided to healthcare professionals or entities. Section 6002 of the ACA, known as 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 the Centers for Medicare & Medicaid Services, or CMS, for payments and other transfers of value provided by them, directly or indirectly, to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Beginning in 2022, applicable manufacturers will also be required to report information related to payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in significant civil monetary penalties. Due to the difficulty in complying with the Physician Payments Sunshine Act, we cannot assure that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. 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 detailed information 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 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.

In the E.U., the GDPR, which is wide-ranging in scope, imposes several requirements relating to the control over personal data by individuals to whom the personal data relates, the information provided 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. One of the mechanisms for transfers of personal data from Europe to

the U.S., the EU-U.S. Privacy Shield Framework, was invalidated by the Court of Justice of the European Union in a July 2020 decision. The decision also called into question whether companies can lawfully use the European Commission's Standard Contractual Clauses as a compliance mechanism for transfers of personal information from Europe to the United States or most other countries.

The CCPA, GDPR and other 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, 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.

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 regulation, 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 or distributors 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 or distributors 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.

Further, the U.S. Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, among other things, amends the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with healthcare providers and entities, including, but not limited to, hospitals, physicians, healthcare providers and our distributors, and certain sales and marketing practices, including the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws.

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 has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Most of these laws apply to not only the actions taken by us, but also actions taken by our distributors or other third-party agents. 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.

In addition, the scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. U.S. federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any U.S. federal or state or foreign regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive. Compliance with these and other changing regulations will increase our costs and may require increasing management attention.

***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 remain judicial and Congressional challenges to numerous provisions of the ACA, as well as efforts that were taken by the U.S. government to repeal or replace certain aspects of the ACA. For example, President Trump signed several 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 considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, or the Tax Act, includes 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". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the ACA or 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 and financial condition.

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, including the Bipartisan Budget Act of 2018, will stay in effect through 2030, unless additional congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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.

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 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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of President Trump's importation executive order, which directed HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and make other changes allowing for personal importation of drugs from Canada. The FDA final rule provides guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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, particularly as a result of the recent presidential election. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

### **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 from our agreement, this could 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 anticipate that a significant portion of the funding for the development of the red blood cell system 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 \$213.9 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 \$116.9 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 cost more than is covered by the BARDA contract and 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. 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. For instance, our RedeS and ReCePI studies, which are being funded as part of our agreement with BARDA, have been temporarily suspended at some of our hospital clinical sites and blood centers producing INTERCEPT-treated red blood cells as a result of the COVID-19 pandemic. In addition, the studies are being conducted in areas that are also subject to disruption due to severe weather such as flooding or hurricane. 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. 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. 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, 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 recommence and complete studies if and when the COVID-19 crisis subsides and we are able to restart many suspended or delayed activities.

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 BARDA agreement, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these 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 impact our financial results. 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. Should we sell illuminators to distributors or other customers without follow-on purchases of disposable kits, our revenue potential will be impaired. 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. In addition, although our agreements with our distributors generally require compliance with local anti-corruption laws, the U.S. Foreign Corrupt Practices Act, and other local and international regulations, we have limited ability to control the actions of our distributors to ensure they are in compliance. Noncompliance by a distributor could expose us to civil or criminal liability, fines and/or prohibitions on selling our products in certain countries.

Currently, a fairly concentrated number of distributors make up 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. Furthermore, there may be local or regional restrictions on travel due to the COVID-19 crisis, which could impact our distributors or our ability to service customers in the field should issues arise. 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 revenue would be negatively impacted.

***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. 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. Until we either expand the number of manufacturing partners producing PRCFC for us, or our manufacturing partners for PRCFC receive approval of their BLAs, we are reliant on the manufacturing partners in the four states in which they are located to maintain their licenses to manufacture PRCFC, manufacture such products in accordance with the applicable specifications and deliver products timely to our hospital customers. In addition, our blood center manufacturing partners for PRCFC may not be able to produce a sufficient quantity of PRCFC to meet customer demand. Accordingly, we may choose to sell INTERCEPT for cryoprecipitation disposable kits to blood centers that are not manufacturing PRCFC for us. Additionally, because PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced 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 PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced.

In October 2015, we amended and restated our manufacturing and supply agreement with Fresenius. In December 2020, we further amended the agreement to set the pricing for 2021, among other items. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase finished disposable kits for the platelet, plasma and red blood cell kits from Fresenius with certain exceptions permitted. The initial term of the amended agreement extends through July 1, 2025, and is automatically renewed thereafter for additional two-year renewal terms, 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. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products, although we are currently working with Fresenius to identify and qualify additional sites for the production of components and of finished disposable kits. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business. Disruptions to our supply chain as a result of any potential ensuing protests, strikes or other work-

stoppages would be detrimental to our business and operating results. In the event Fresenius refuses or is unable to continue operating under the agreement, 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 also have contracts with other third-party suppliers, including Ash Stevens for the manufacture of amotosalen, our proprietary compound for reducing pathogens that is used in our platelet and plasma systems; Purolite, and separately, Porex, for the manufacture of components of the compound adsorption devices used in our platelet and plasma systems; and Nova for the manufacture of illuminators and certain components of the INTERCEPT Blood System. These independent suppliers are currently our sole qualified suppliers for such components and products.

Our manufacturing and supply agreement with Ash Stevens continues until December 31, 2021, and will continue to automatically renew thereafter for periods of two years each, but may be terminated by Ash Stevens provided that Ash Stevens notifies us in writing at least two years in advance. We have not been notified by Ash Stevens of their intention to terminate the agreement.

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 12 months' prior written notice, if annual production falls below a mutually agreed threshold. The amended and restated Porex agreement was renewed as of January 1, 2020, for an additional two years. In December 2020, we reached agreement with Porex regarding pricing for 2021, consistent with the process set forth in the original agreement. In addition, we entered into an amended and restated supply agreement with Brotech Corporation d/b/a Purolite Company, or Purolite, for the supply of raw materials used to make the compound adsorption devices. The amended supply agreement expires in February 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. 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. Our agreement with Nova, which manufactures our illuminators, currently extends through September 2021 and is automatically renewable for one year terms, but may be terminated by Nova on at least 12 months' prior written notice. We have not been notified by Nova of their intention to terminate the agreement.

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, given our recent rapid growth and potential for continued or even accelerated growth, we may need to identify, validate and qualify additional manufacturing capacity with existing or new suppliers. Further, customer demand for our platelet kits may 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 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. In addition, while our suppliers have initiated business continuity plans with minimal disruption to our supply, we cannot be certain that any prolonged, intensified, worsened, or recurring effect from the COVID-19 pandemic would not impact our supply chain. Although we are actively evaluating alternate suppliers and additional sites within our existing supplier's networks for certain components, 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. For example, we understand that a compound adsorbent housing component is no longer available and an alternate housing will need to be qualified by Fresenius. 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.

Currently Nova is manufacturing illuminators to meet customer demand and maintain our own inventory levels. 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. We are currently redesigning the illuminator which is expected to take several years. We will need to obtain regulatory approval for the redesigned illuminator before it can be commercialized in the U.S. or under CE Mark. Our failure to obtain regulatory approvals of a new illuminator could constrain our ability to penetrate our markets and may otherwise significantly limit product revenue from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive these approvals could reduce our sales and negatively impact our profitability potential and future 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. Software development is inherently risky and may be time consuming and costly.

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.

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. For example, in September 2020, we learned that certain components which we source from PuroLite and Porex did not pass quality standards despite testing. The quality failure in manufacturing by the suppliers resulted 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. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations could be harmed and we would incur unforeseen losses.

In the event of a failure by Fresenius or other manufacturers to perform their obligations to supply kits, illuminators or components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Many of our supply agreements contain limitations on incidental and consequential damages that we may recover. A supplier's potential liability in the event of non-performance may not be sufficient to compel the supplier to continue to act in conformity with our agreements. Our product supply chain requires us to purchase certain components in minimum quantities 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 production cycles which could lead to inefficient use of cash or may impair our ability to supply customers with product.

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. 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 FDA platelet safety guidance document, 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, some of which 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 operation to INTERCEPT. Should we or our suppliers encounter any manufacturing issues, we may not be able to satisfy all of the global demand or may have to allocate available product to certain customers which may negatively impact our customers operations and consequently, our 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. Additionally, should we conclude that existing suppliers are not able to produce sufficient quantities to meet the demand for our products, we may choose to invest in manufacturing capacity at existing or new facilities with existing or new suppliers, which could be costly and disruptive to our management.

We currently have no experience with customer expectations regarding turnover or inventory levels of PRCFC held at either our blood center manufacturing partners or at the hospitals themselves. Our PRCFC 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 to no cost to the hospital, we may need to keep additional inventory or manufacture PRCFC above levels generating an economic return.

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 no experience manufacturing or working with manufacturers outside of our current manufacturing footprint.

***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 supplied plastics, saline and reagents for processing, storing and manufacturing blood components. If the blood product industry experiences shortages 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 a raw material for our plasma compound adsorption device may no longer be 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. In any event, the amount of material is finite and we and our contract manufacturer may need to qualify an alternate solvent used in the manufacture of the raw material or build sufficient levels of inventory until we can redesign our products. 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. 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 be able to successfully 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.***

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. The platelet and plasma systems have been approved in the U.S. only since December 2014 and are not approved in many countries around the world. Similarly, our PMA supplement for the INTERCEPT Blood System for Cryoprecipitation to produce PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced was approved in November 2020 in the U.S. and is not approved anywhere else in the world. We plan to begin selling PRCFC to hospital customers in a limited launch in the U.S. beginning in 2021. The red blood cell system is in the development stage and may never emerge from the development stage as a marketed product. 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. At our present and expected 2021 sales levels of the platelet and plasma systems, and of PRCFC, our costs to manufacture, distribute, market, sell, support the systems and develop new products are and are expected to continue to be in excess of our product revenue. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur. To prepare for commercial launch of PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduce, we have begun to hire employees and are looking to retain additional contract resources to sell PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced directly to hospitals and may choose to sell INTERCEPT Blood System for Cryoprecipitation disposable kits to blood centers that are not contracted with us as manufacturing partners. 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 we are required to conduct in connection with the FDA approval 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. Presently, we anticipate that the stress of COVID-19 on healthcare systems around the globe may negatively impact our ability to conduct clinical trials in the near term due primarily to the lack of resources at clinical trial sites and the resulting challenge to enroll patients in these trials. 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. The timing of other planned clinical trials has also been delayed due to the pandemic. Many hospital sites have not yet resumed enrollment and those that have are proceeding at a reduced capacity. 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.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Healthcare reform in the U.S. has also placed downward pressure on the pricing of medical products that could have a negative impact on our profit margins.

### ***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.***

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercialization of our platelet and plasma systems and the anticipated launch of PRCFC and its derivative product, pathogen-reduced plasma, cryoprecipitate reduced, 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 may be required to



conduct to satisfy regulators or achieve broader market acceptance, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our products, 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 BARDA agreement, 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 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.

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, 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.

While we expect to receive significant funding under our agreement with BARDA, our ability to obtain the funding we expect to receive under the agreement is subject to various risks and uncertainties, including with respect to BARDA's ability to terminate the agreement for convenience at any time and our ability to achieve the required milestones under the agreement, including with respect to the conduct of the RedeS and ReCePI studies, enrollment for which have been suspended at many of the hospital sites due to the COVID-19 pandemic. Many hospital sites where enrollment was suspended have not yet resumed enrollment and those that have are proceeding at a reduced capacity. Accordingly, many of the activities expected by BARDA have been delayed and will require an extension of time under the contract to complete. Should BARDA disallow any extension, we will need to pay for the costs to complete the activities or stop pursuing them altogether. 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. This in turn would impair our ability to recommence and complete studies if and when the COVID-19 crisis subsides and we are able to restart many suspended or delayed activities. 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. 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, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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. 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 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 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.***

As of December 31, 2020, our total indebtedness under our Term Loan Credit Agreement and Revolving Loan Credit Agreement was approximately \$48.1 million. All of our current and future assets, except for intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., 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. In addition, receipt of a qualified audit opinion (other than as to going concern or a qualification resulting solely from the scheduled maturity of term loans occurring within one year from the date such opinion is delivered) would be a violation of an affirmative covenant under the Term Loan Credit Agreement. While we believe that our available cash and cash equivalents and short-term investments, as well as cash to be received from product sales and under our agreement with BARDA, 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 BARDA agreement or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. 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.

***If the London Inter-Bank Offered Rate, or LIBOR, is discontinued, interest payments under our Term Loan Credit Agreement or Revolving Loan Credit Agreement may be calculated using another reference rate.***

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 by the end of 2021. 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. U.S. dollar LIBOR is used as a benchmark rate in our Term Loan Credit Agreement and Revolving Loan Credit Agreement. 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 known. 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, 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 would adversely affect the operations of our business.

### **Risks Related to Managing Our Growth and Other Risks**

***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. 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. We do not yet know when our employees will have access to a vaccine or if such a vaccine will be effective.

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. 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.

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.

***As our international operations grow, we may be subject to adverse fluctuations in exchange rates between the U.S. dollar and foreign currencies, as well as to tariffs and other trade restrictions.***

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 affected by changes in these or other factors.

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. Foreign exchange rate fluctuations are recorded as a component of other income, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. dollar may materially affect our results of operations. For example, the announcement of Brexit caused severe volatility in global currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we transact business. Should this foreign exchange volatility continue or increase, it could cause volatility in 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 grow.

Additionally, the U.S. government has called for substantial changes to foreign trade policy and has recently imposed tariffs on certain U.S. imports. Canada, the E.U., China and other countries have responded with retaliatory tariffs on certain U.S. exports. We also rely on various U.S. corporate tax provisions related to international commerce. If we are subject to new regulations, including those under the Tax Act, or if restrictions and tariffs increase our operating costs in the future, and we are not able to recapture those costs from our customers, or if such initiatives, regulations, restrictions or tariffs make it more difficult for us to compete in overseas markets, our business, financial condition and results of operations could be adversely impacted.

***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 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 and attempts to gain unauthorized access to computer systems and networks have increased in frequency and sophistication. Our and our supplier's information technology, systems and networks are potentially vulnerable to breakdown, 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 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 requirements that obligate us to use industry-standard or reasonable measures to safeguard personal information. We also may be subject to laws that require 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 breaches may adversely affect our business. 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 breaches occur in the future, production may be impacted, information infiltrated 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 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.

***We currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.***

Our shares of common stock are currently quoted on the Nasdaq Global Market under the symbol "CERS." The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered, which may limit our ability to effectively raise money. In addition, due to the limitations

of our market and the volatility in the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to sell. As a result of this lack of trading activity, the quoted price for our common stock is not necessarily a reliable indicator of its fair market value.

***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 the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, 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 the Tax Act or the CARES Act. In general, under Sections 382 and 383 of the Code, 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. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. 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 2021 and 2037. 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 2021 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, including in connection with our

planned commercialization of the platelet and plasma systems in the U.S. 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 India, jurisdictions where we are currently expanding our commercialization efforts through distributors. In certain countries, 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. Additionally, if we identify one or more material weaknesses in our internal control over financial reporting, we will not be able 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.

***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. In addition, newly contracted or prospective customers may be unable to on-board, train staff and implement new technologies such as INTERCEPT due to the COVID-19 pandemic which would limit our ability to grow our business.

The sales of our products in Europe and the Commonwealth of Independent States, or CIS, countries are denominated in Euros and other non-U.S. currencies. As a result, we are exposed to foreign exchange risk, and our results of operations have been and will continue to be impacted by fluctuations in the exchange rate between the U.S. dollar and other currencies, in particular the Euro. In addition, there have been concerns for the overall stability and suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of, or the announcement of the withdrawal of, one or more member countries from the European Union, or E.U., following the United Kingdom's, or U.K.'s, withdrawal from the E.U., or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect our product revenue. In certain territories that we currently sell into, a devaluation of local currency against the U.S. Dollar is occurring and is making purchase of our products more expensive for customers. Should this persist or worsen, customers may not be able to afford purchasing our Euro or U.S. Dollar priced products, or we may choose to lower prices to those customers which would negatively impact our results of operations.

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 prices and the ongoing civil, political and economic disturbances in Russia, Turkey and Ukraine, 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. In particular, the unprecedented 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, and our business in Russia and other CIS countries may be negatively impacted further or never recover to historical levels.

Moreover, the U.S. administration has imposed tariffs on certain imports into the U.S., and the E.U., China and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating trade tensions. However, these tariffs and other trade restrictions could increase our operating costs, reduce our gross margins or otherwise negatively impact our financial results.

In addition, terrorist attacks and civil unrests in some of the countries where we do business, and the resulting need for enhanced security measures may impact our ability to deliver services, threaten the safety of our employees, and increase our costs of operations.

***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. In addition, Section 203 of the Delaware General Corporation Law, unless its application has been waived, provides certain default anti-takeover protections in connection with transactions between us and an "interested stockholder". Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent 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 a 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 10, 2021, we had 133 holders of record of our common stock.

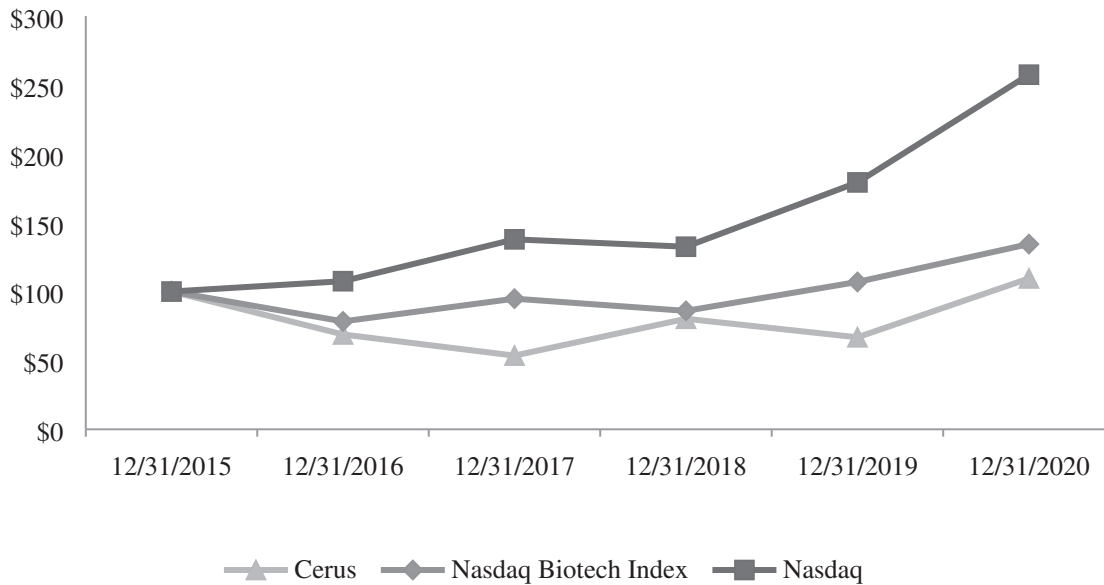
**Dividends**

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 <sup>(1)</sup>**

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, 2015, and tracked the performance through December 31, 2020, for (i) our common stock, (ii) the Nasdaq Biotechnology 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.

**Comparison of 5-year Cumulative Total Return on Investment**



	December 31,					
	2015	2016	2017	2018	2019	2020
Cerus Corporation .....	\$ 100.00	\$ 68.83	\$ 53.48	\$ 80.22	\$ 66.77	\$ 109.49
Nasdaq Biotech Index .....	100.00	78.32	94.81	85.97	106.95	134.42
Nasdaq.....	100.00	107.50	137.86	132.51	179.19	257.38

<sup>(1)</sup> 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.**     *Selected Financial Data*

The Company has elected to comply with Item 301 of Regulation S-K, as amended February 10, 2021 and is omitting this disclosure in reliance thereon.

## 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, 2020. Operating results for the year ended December 31, 2020 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 Pathogen Reduced Cryoprecipitated Fibrinogen Complex, or PRCFC, 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 CE Marks and U.S. Food and Drug Administration, or FDA, approval and are being marketed and sold in a number of countries around the world. Additionally, in November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce PRCFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. We currently sell both the platelet and plasma systems using our direct sales force and through distributors and plan to sell PRCFC 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 kits to blood centers that are not manufacturing partners for PRCFC.

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 being discussed with FDA. 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 September 2020, we began the process to resubmit our application under the new MDR. Accordingly, we do not expect an approval decision until 2022, if ever. We do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to receive CE Mark approval or if approved, that the data will be considered sufficient to receive broad usage indications for both chronic and acute anemia or more limited. In 2017, we initiated a Phase 3 clinical, double-blind study, known as the RedeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional, un-treated, 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. In September 2020, we began the process of resubmitting for CE Mark approval under the MDR for the red blood cell system with two of four modules submitted. We must demonstrate 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. The requirements apply to all suppliers providing raw materials, active ingredients, intermediates and final product. We understand that while the data generated from our European Phase 3 clinical trials may be sufficient to receive CE Mark approval we may not receive broad usage indications for both chronic and acute anemia usage and, we may need to generate additional safety data from commercial use in order to achieve broad 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, un-treated red blood cells and the significantly lower lifespan for INTERCEPT-treated red blood cells compared to conventional, un-treated 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 the Biomedical Advanced Research and Development Authority, or 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 April 2020, 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 2021. 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. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce PRCFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. We currently have agreements with certain blood center manufacturing partners and are actively working to identify additional partners to manufacture the extended-storage cryoprecipitate. We are also working on implementing the infrastructure we believe will be necessary to market extended-storage cryoprecipitate product directly to hospitals. Until our blood center manufacturing partners receive BLAs from the FDA, we will be limited to selling in those states where we have manufacturing partners located. In addition, we may, in the future, sell the INTERCEPT Blood System for Cryoprecipitation kits to blood centers that are not our manufacturing partners for PRCFC. Accordingly, this dynamic may in turn create pricing pressures, distrust with our contracted blood center manufacturing partners and competition for hospital business.

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, 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. 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., we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. In September 2019, the FDA issued a final guidance document, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion." At the time it was issued, the guidance

document required all blood collection facilities to comply with the options available under the guidance document, which includes the INTERCEPT Blood System, for all platelet collections, no later than October 1, 2021. Blood centers may wait until later in the compliance grace period before beginning to take steps to implement INTERCEPT. Should a large number of blood centers wait, we may not have sufficient resources or product available to allow customers to timely and successfully implement INTERCEPT before the end of the compliance grace period. Should we be unable to manufacture INTERCEPT in sufficient quantities in a timely manner, or have adequate resources to assist customer 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 PRCFC. 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. In July 2017, we entered into agreements with Établissement Français du Sang, or EFS to supply illuminators and platelet and plasma disposable kits. The agreement for supply of illuminators and platelet disposable kits provided for a base term of two years, with two options for EFS to extend for one year each, both of which have been exercised by EFS. 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. We cannot assure that EFS will use the INTERCEPT Blood System for plasma at historical levels or at all. We understand that EFS has adopted the platelet system across France but cannot provide any assurance that national usage is sustainable, since no purchase volume commitments have been made by EFS in our current contract or otherwise. In addition, significant product revenue from the French market may decline or not consistently occur quarter-over-quarter. We also cannot provide any assurance 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 contract.

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 PRCFC, 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 United States to respond to the COVID-19 pandemic, Fresenius has recently reconfigured production workflow to ensure employee safety and to comply with local requirements for social distancing. 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 13, *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, 2020, 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 \$116.9 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 \$213.9 million through December 31, 2021. 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. We are currently responsible for co-investment of approximately \$5.0 million, and would be responsible for an additional \$9.6 million, if certain additional Option Periods are exercised by BARDA. See Note 13, *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 13, *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 10, *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<sup>SM</sup> 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 8, *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. We do not yet know when our employees will have access to a vaccine or if such a vaccine will be effective. 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 2020 and 2019 items and year-to-year comparisons between 2020 and 2019. Discussions of 2018 items and year-to-year comparisons between 2019 and 2018 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 21, 2020.

### ***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 and storage solutions, and maintenance services of illuminators. We sell the platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. 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. 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 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 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, 2020, 2019 and 2018*

#### *Revenue*

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2020	2019	2018	2020 to 2019	2019 to 2018
Product revenue .....	\$ 91,920	\$ 74,649	\$ 60,908	23%	23%
Government contract revenue .....	22,329	19,125	15,143	17%	26%
Total revenue .....	<u>\$ 114,249</u>	<u>\$ 93,774</u>	<u>\$ 76,051</u>	22%	23%

Product revenue increased by \$17.3 million during the year ended December 31, 2020, compared to the year ended December 31, 2019, primarily due to year-over-year sales volume growth in disposable platelet system kit sales in the U.S., and in Europe, in addition to increased plasma system kit sales in Europe and Middle East regions during the year ended December 31, 2020, compared to the year ended December 31, 2019.

We anticipate product revenue for INTERCEPT disposable kits will increase in future periods driven by the expected continued expansion of U.S. sales as 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 plan to begin selling PRCFC to hospital customers in a limited launch beginning in 2021. 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 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.

We recognized \$22.3 million and \$19.1 million of revenue from our government contracts during the years ended December 31, 2020 and 2019, respectively, as a result of the direct and indirect contract costs incurred under those agreements. We are uncertain if or how long the COVID-19 pandemic may disrupt our operations or activities supported by BARDA, but it is possible that reported government contract revenue may decrease as a result of the COVID-19 pandemic.

### ***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, and certain order fulfillment costs, to the extent applicable. Inventory is accounted for on a first-in, first-out basis.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2020	2019	2018	2020 to 2019	2019 to 2018
Cost of product revenue .....	\$ 41,157	\$ 33,419	\$ 31,634	23%	6%

Cost of product revenue increased by \$7.7 million during the year ended December 31, 2020, compared to the year ended December 31, 2019. The increase was primarily due to increased sales, and to a lesser extent the write-off of certain inventory components that did not meet our quality standards, partially offset by volume tier discounts from a contract manufacturer and the impact of favorable foreign exchange rates.

Our gross margin on product sales was 55% during the year ended December 31, 2020, compared to 55% during the year ended December 31, 2019. 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 agreement with Fresenius, 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. 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. 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 of both work-in-process and finished goods in quantities sufficient to meet forecasted demand. While our suppliers have initiated business continuity plans with minimal disruption to our supply, we cannot be certain that any prolonged, intensified or worsened effect from the COVID-19 pandemic would not impact our supply chain.

### ***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.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2020	2019	2018	2020 to 2019	2019 to 2018
Research and development.....	\$ 64,410	\$ 60,376	\$ 42,564	7%	42%

Research and development expenses increased \$4.0 million during the year ended December 31, 2020, compared to the year ended December 31, 2019, primarily due to costs for our red blood cell program, inclusive of activities related to the BARDA agreement, increased costs associated with product enhancements and initiatives for expanded platelet label claims, and preliminary design efforts on our illuminator.

We expect to incur additional research and development costs associated with planning, publishing data from our required post-approval studies for 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., 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, 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 global pandemics and natural disasters, including the current 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.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2020	2019	2018	2020 to 2019	2019 to 2018
Selling, general and administrative .....	\$ 67,015	\$ 66,205	\$ 56,841	1%	16%

Selling, general, and administrative expenses increased \$0.8 million, driven by stock-based compensation during the year ended December 31, 2020, compared to the year ended December 31, 2019.

We anticipate our selling, general, and administrative spending to increase over the coming year relative to our 2020 selling, general, and administrative expenses.

### ***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.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2020	2019	2018	2020 to 2019	2019 to 2018
Foreign exchange gain (loss) .....	\$ 793	\$ (86)	\$ (87)	(1,022%)	(1%)
Interest expense .....	(3,746)	(6,065)	(4,008)	(38%)	51%
Other income, net.....	1,713	1,396	1,748	23%	(20%)
Total non-operating expense, net .....	\$ (1,240)	\$ (4,755)	\$ (2,347)	(74%)	103%

### ***Foreign Exchange Gain (Loss)***

We experienced foreign exchange gains during the year ended December 31, 2020, compared to foreign exchange losses during the year ended December 31, 2019, which was primarily due to a higher foreign exchange rate for Euro to U.S. dollar.

### ***Interest Expense***

Interest expense decreased during the year ended December 31, 2020, compared to the year ended December 31, 2019, primarily due to primarily due to the loss of \$2.1 million on the extinguishment of a previous loan and security agreement during the year ended December 31, 2019. See *Note 8, Debt*, in Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K for more information.

### ***Other Income, Net***

Other income, net increased by \$0.3 million during the year ended December 31, 2020, compared to the year ended December 31, 2019, primarily due to the gain related to the unrealized gains associated with the revaluation of certain investments.

## Provision for Income Taxes

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2020	2019	2018	2020 to 2019	2019 to 2018
Provision for income taxes.....	\$ 284	\$ 263	\$ 229	8%	15%

For each of the years ended December 31, 2020 and 2019, we recorded a tax expense of \$0.3 million, which was 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, 2020 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, 2020. As of December 31, 2020, there have been no material changes to our total amount of unrecognized tax benefits.

## 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, 2020 and December 31, 2019, we had the following cash and cash equivalents, short-term investments and restricted cash (in thousands):

	December 31, 2020	December 31, 2019
Cash and cash equivalents .....	\$ 36,594	\$ 34,986
Short-term investments .....	97,000	50,732
Restricted cash .....	2,309	2,435
Total .....	<u>\$ 135,903</u>	<u>\$ 88,153</u>

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, 2020 and December 31, 2019, we had the following indebtedness (in thousands):

	December 31, 2020	December 31, 2019
Debt – current .....	\$ 8,516	\$ 5,017
Debt – non-current .....	39,588	39,414
Total .....	<u>\$ 48,104</u>	<u>\$ 44,431</u>

## Operating Activities

Net cash used in operating activities was \$40.7 million during the year ended December 31, 2020, compared to \$65.8 million net cash used in operating activities during the year ended December 31, 2019. The decrease in net cash used in operating activities was primarily related to increased product sales and revenue from our BARDA agreement, partially offset by the timing of payments during the year ended December 31, 2020, compared to the same period in 2019. In addition, during the year ended December 31, 2019, we made a one-time payment of \$6.2 million to Fresenius in August 2019.

## Investing Activities

Net cash used in investing activities was \$49.6 million during the year ended December 31, 2020, compared to \$28.2 million net cash provided by investing activities during the year ended December 31, 2019. The change period over period was primarily the result of higher purchases of investments during the year ended December 31, 2020, resulting from the proceeds from our January 2020 public offering of common stock.

### *Financing Activities*

Net cash provided by financing activities was \$91.8 million during the year ended December 31, 2020, compared to \$43.5 million net cash provided by financing activities during the year ended December 31, 2019. The increase in net cash provided by financing activities was primarily due to the proceeds of approximately \$62.7 million, net of the underwriting discounts and other issuance costs, received from our January 2020 public offering of common stock.

### *Working Capital*

Working capital increased to \$123.5 million at December 31, 2020, from \$77.8 million at December 31, 2019, primarily due to the cash received from our January 2020 public offering of common stock, and proceeds from the issuance of common stock associated with equity awards, offset by the increased cash used to support ongoing operations.

### *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 and plasma systems and the commercial launch of the INTERCEPT Blood System for Cryoprecipitation, 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 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 not sold any shares of our common stock under the Sales Agreement.

While we expect to receive significant funding under our agreement with BARDA, our ability to obtain the funding we expect to receive under the 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 the agreement, including with respect to the conduct of the RedeS and ReCePI studies, enrollment for which has been suspended 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, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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 10, 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 and Off-Balance Sheet Arrangements**

See *Note 8, 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 9, 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 the operating leases.

We did not have any off-balance sheet arrangements as of December 31, 2020.

#### **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, 2020, 2019 and 2018. 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, 2020, we held cash, cash equivalents, short-term investments and investments in marketable equity securities of \$133.6 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, 2020, were 1.64%.

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 \$39.6 million and Revolving Loan Credit Agreement of \$8.5 million as of December 31, 2020, 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 2020 by approximately \$0.5 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, 2020, would have negatively impacted our annual financial results by \$1.0 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 Rules 13a-15(e) under the Exchange Act), 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, 2020, 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, 2020, 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, 2020, 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, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Cerus Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, 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, 2020, and the related notes and our report dated February 25, 2021 expressed an unqualified opinion thereon.

### Basis for Opinion

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

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

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

### Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Ernst & Young LLP

Redwood City, California  
February 25, 2021

**Item 9B. Other Information**

None.



## **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 2021 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***

Information required by this item regarding executive officers, directors and nominees for directors, including information with respect to our audit committee and audit committee financial expert, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, 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](http://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 incorporated herein by reference to our Proxy Statement.

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

The information required by this item is incorporated herein by reference to our Proxy Statement.

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

The information required by this item is incorporated herein by reference to our Proxy Statement.

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

The information required by this item is incorporated herein by reference to our Proxy Statement.

## 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) *Financial Statements.*

	<u>Page</u>
Report of Ernst & Young LLP, Independent Registered Public Accounting Firm .....	86
Consolidated Balance Sheets .....	88
Consolidated Statements of Operations .....	89
Consolidated Statements of Comprehensive Loss .....	90
Consolidated Statements of Stockholders' Equity .....	91
Consolidated Statements of Cash Flows .....	92
Notes to Consolidated Financial Statements.....	93

Other information is omitted because it is either presented elsewhere, is inapplicable or is immaterial as defined in the instructions.

(b) *Exhibits.*

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
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(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.
<b><i>Supply and/or Manufacturing Agreements</i></b>	
10.1(17)†	Amended and Restated Supply Agreement, dated April 21, 2014, by and between Cerus Corporation and Purolite Corporation.
10.2	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(19)†	Amended and Restated Manufacturing and Supply Agreement, dated October 19, 2015, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.6(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.
10.7(30) ††	Side Letter to Supply Agreement, dated January 14, 2020, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.8††	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.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.9(3)†	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.10(20)†	Amendment #1 to the Manufacturing and Supply Agreement, dated March 15, 2016, by and between NOVA Biomedical Corporation and Cerus Corporation.
10.11(10)†	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.12(14)†	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
<b><i>Loan and Security Agreements</i></b>	
10.13(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.
10.14	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.
10.15(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.
10.16 ††	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.
<b><i>Real Estate Lease Agreements</i></b>	
10.17(24) †	Lease, dated February 16, 2018, between Cerus Corporation and 1200 Concord LLC.
10.18(25)	First Amendment to Lease, dated May 11, 2018, between Cerus Corporation and 1200 Concord LLC.
10.19(26)	Second Amendment to Lease, dated August 10, 2018, between Cerus Corporation and 1200 Concord LLC.
10.20(27)	Third Amendment to Lease, dated October 5, 2018, between Cerus Corporation and 1200 Concord LLC.
10.21(27)	Fourth Amendment to Lease, dated November 30, 2018, between Cerus Corporation and 1200 Concord LLC.
<b><i>Employment Agreements or Offer Letters</i></b>	
10.22(9)*	Employment Letter, by and between Cerus Corporation and William M. Greenman, dated May 12, 2011.
10.23(13)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.24(25)*	Amendment to Employment Letter, by and between Cerus Corporation and William M. Greenman, dated April 17, 2018.
10.25(15)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.26(8)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.27(6)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.28(25)*	Amendment to Employment Letter, by and between Cerus Corporation and Kevin Green, dated April 17, 2018.
10.29(13)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.30(15)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
10.31(18)*	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPath, dated May 12, 2015.
10.32(22)*	Employment Letter, by and between Cerus Corporation and Vivek Jayaraman, dated May 31, 2016.
<b><i>Stock Plans and Related Forms</i></b>	
10.33(31)*	Amended and Restated 1996 Employee Stock Purchase Plan, effective June 3, 2020.
10.34(31)*	Amended and Restated 2008 Equity Incentive Plan, effective June 3, 2020.
10.35(11)*	Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.
10.36(11)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.
10.37(11)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
10.38(21)*	Cerus Corporation Inducement Plan.
10.39(21)*	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Cerus Corporation Inducement Plan.
10.40(21)*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Cerus Corporation Inducement Plan.
10.41(25)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan, amended as of April 17, 2018.
10.42(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.
<b><i>Other Compensatory Plans or Agreements</i></b>	
10.43(13)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.44(25)*	Cerus Corporation Change of Control Severance Benefit Plan, amended as of April 17, 2018.
10.45(5)*	Form of Severance Benefits Agreement.
10.46(30)*	Amended and Restated Non-Employee Director Compensation Policy, effective March 27, 2020.
10.47(28)*	2018 and 2019 Executive Officer Compensation Arrangements.
10.48(30)*	2019 and 2020 Executive Officer Compensation Arrangements.
10.49(31)*	Nonqualified Plan Service and Expense Agreement, by and between Cerus Corporation and Principal Life Insurance Company, dated May 21, 2020.
10.50(31)*	The Executive Nonqualified Excess Plan Adoption Agreement, dated May 21, 2020.

### ***Other Material Agreements***

- 10.51(1) Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
- 10.52(4) Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
- 10.53(32) Controlled Equity Offering<sup>SM</sup> Sales Agreement, dated December 11, 2020, by and among Cerus Corporation, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated.
- 10.54(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(33) 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) 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 25, 2021 expressed an unqualified opinion thereon.

### **Basis for Opinion**

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

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

### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the 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, 2020, the Company recognized \$91.9 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 25, 2021

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

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 36,594	\$ 34,986
Short-term investments .....	97,000	50,732
Accounts receivable .....	21,166	16,882
Inventories, net .....	23,254	19,490
Prepaid and other current assets .....	<u>5,417</u>	<u>6,018</u>
Total current assets .....	183,431	128,108
Non-current assets:		
Property and equipment, net .....	13,867	14,898
Goodwill .....	1,316	1,316
Operating lease right-of-use assets .....	13,122	14,122
Intangible assets, net .....	-	132
Restricted cash .....	2,309	2,435
Other assets .....	<u>7,370</u>	<u>4,524</u>
Total assets .....	<u>\$ 221,415</u>	<u>\$ 165,535</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 24,213	\$ 22,185
Accrued liabilities .....	24,753	20,951
Debt – current .....	8,516	5,017
Operating lease liabilities – current .....	1,915	1,613
Deferred product revenue .....	<u>577</u>	<u>570</u>
Total current liabilities .....	59,974	50,336
Non-current liabilities:		
Debt – non-current .....	39,588	39,414
Operating lease liabilities – non-current .....	16,873	18,406
Other non-current liabilities .....	<u>1,174</u>	<u>327</u>
Total liabilities .....	<u>117,609</u>	<u>108,483</u>
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, 2020 and 2019, respectively		
Common stock, \$0.001 par value; 225,000 shares authorized; 168,170 and 144,291 shares issued and outstanding at December 31, 2020 and 2019, respectively .....	168	144
Additional paid-in capital .....	1,012,932	906,905
Accumulated other comprehensive income .....	674	114
Accumulated deficit .....	<u>(909,968)</u>	<u>(850,111)</u>
Total stockholders' equity .....	<u>103,806</u>	<u>57,052</u>
Total liabilities and stockholders' equity .....	<u>\$ 221,415</u>	<u>\$ 165,535</u>

See accompanying Notes to Consolidated Financial Statements.

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

	<b>Year Ended December 31,</b>		
	<b>2020</b>	<b>2019</b>	<b>2018</b>
Product revenue.....	\$ 91,920	\$ 74,649	\$ 60,908
Cost of product revenue .....	41,157	33,419	31,634
Gross profit on product revenue .....	50,763	41,230	29,274
Government contract revenue .....	22,329	19,125	15,143
Operating expenses:			
Research and development .....	64,410	60,376	42,564
Selling, general and administrative.....	67,015	66,205	56,841
Total operating expenses .....	131,425	126,581	99,405
Loss from operations .....	(58,333)	(66,226)	(54,988)
Non-operating expense, net:			
Foreign exchange gain (loss) .....	793	(86)	(87)
Interest expense.....	(3,746)	(6,065)	(4,008)
Other income, net.....	1,713	1,396	1,748
Total non-operating expense, net .....	(1,240)	(4,755)	(2,347)
Loss before income taxes .....	(59,573)	(70,981)	(57,335)
Provision for income taxes .....	284	263	229
Net loss .....	<u>\$ (59,857)</u>	<u>\$ (71,244)</u>	<u>\$ (57,564)</u>
Net loss per share:			
Basic and diluted.....	\$ (0.37)	\$ (0.51)	\$ (0.44)
Weighted average shares used for calculating net loss per share:			
Basic and diluted.....	163,949	139,831	131,663

See accompanying Notes to Consolidated Financial Statements.

**CERUS CORPORATION**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(in thousands)

	Year Ended December 31,		
	2020	2019	2018
Net loss .....	\$ (59,857)	\$ (71,244)	\$ (57,564)
Other comprehensive income (loss)			
Unrealized gains (losses) on available-for-sale investments, net of taxes .....	560	395	(184)
Comprehensive loss .....	\$ (59,297)	\$ (70,849)	\$ (57,748)

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	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017 .....	115,555	\$ 115	\$ 760,225	\$ (97)	\$ (721,303)	\$ 38,940
Issuance of common stock from public offering, net of offering costs.....	18,202	18	85,067	—	—	85,085
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases .....	3,096	3	7,845	—	—	7,848
Stock-based compensation .....	—	—	10,394	—	—	10,394
Other comprehensive loss .....	—	—	—	(184)	—	(184)
Net loss.....	—	—	—	—	(57,564)	(57,564)
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 offerings, 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 .....	<u>168,170</u>	<u>\$ 168</u>	<u>\$ 1,012,932</u>	<u>\$ 674</u>	<u>\$ (909,968)</u>	<u>\$ 103,806</u>

See accompanying Notes to Consolidated Financial Statements.

**CERUS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2020	2019	2018
<b>Operating activities</b>			
Net loss .....	\$ (59,857)	\$ (71,244)	\$ (57,564)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	3,109	2,403	1,445
Stock-based compensation .....	18,029	13,312	10,394
Non-cash operating lease cost .....	1,346	1,580	—
Changes in valuation of warrant investment .....	(422)	—	—
Net loss on sale of available-for-sale securities .....	234	—	1,248
Loss on disposal of property and equipment .....	—	15	5
Impairment of long-lived assets .....	274	—	—
Non-cash interest expense .....	478	386	—
Changes in operating assets and liabilities:			
Accounts receivable .....	(4,284)	(8,130)	3,663
Inventories .....	(4,030)	(6,043)	806
Other assets .....	(623)	1,787	(2,744)
Accounts payable .....	2,236	5,017	5,683
Accrued liabilities and other non-current liabilities .....	2,760	1,295	6,046
Manufacturing and development obligations .....	—	(6,288)	(266)
Deferred product revenue .....	7	72	38
Net cash used in operating activities .....	<u>(40,743)</u>	<u>(65,838)</u>	<u>(31,246)</u>
<b>Investing activities</b>			
Capital expenditures .....	(1,615)	(8,935)	(1,144)
Purchases of investments .....	(98,793)	(43,907)	(80,701)
Proceeds from maturities and sale of investments .....	50,850	81,027	37,997
Net cash (used in) provided by investing activities .....	<u>(49,558)</u>	<u>28,185</u>	<u>(43,848)</u>
<b>Financing activities</b>			
Net proceeds from equity incentives .....	11,750	3,210	7,848
Net proceeds from public offerings .....	76,534	26,931	85,036
Net proceeds from revolving line of credit .....	3,499	5,017	—
Proceeds from loans .....	—	39,433	—
Repayment of debt .....	—	(31,104)	(133)
Net cash provided by financing activities .....	<u>91,783</u>	<u>43,487</u>	<u>92,751</u>
Net decrease in cash, cash equivalents and restricted cash .....	1,482	5,834	17,657
Cash, cash equivalents and restricted cash, beginning of period .....	37,421	31,587	13,930
Cash, cash equivalents and restricted cash, end of period .....	<u>\$ 38,903</u>	<u>\$ 37,421</u>	<u>\$ 31,587</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest .....	\$ 3,269	\$ 3,077	\$ 2,728
Cash paid for income taxes .....	265	229	254
Non-cash investing activities:			
Non-cash leasehold improvements .....	—	2,949	2,222

See accompanying Notes to Consolidated Financial Statements.

**CERUS CORPORATION**  
**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 and red blood cells.

The Company sells its INTERCEPT platelet and plasma systems in the United States of America (“U.S.”), Europe, the Commonwealth of Independent States (“CIS”) countries, the Middle East and selected countries in other regions around the world. 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 and its subsidiary, Cerus Europe B.V. (together with Cerus Corporation, hereinafter “Cerus” or the “Company”) after elimination of all intercompany accounts and transactions. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”) and pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”).

**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”), 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 uses a binding purchase order or signed sales contract as evidence of a contract and satisfaction of its policy. Generally, the Company’s contracts 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, 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. See “Note 13. Development and License Agreements—Government contracts”. 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. These audits could result in an adjustment to government contract revenue previously reported, which adjustments potentially could be significant. 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. 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, 2020, 2019 and 2018, were as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Product revenue:			
Europe, Middle East and Africa.....	\$ 57,427	\$ 52,499	\$ 46,974
North America.....	32,380	20,936	12,696
Other.....	2,113	1,214	1,238
Total product revenue.....	<u>\$ 91,920</u>	<u>\$ 74,649</u>	<u>\$ 60,908</u>

### ***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 estimated to be unconditional. The Company had no contract assets at December 31, 2020 and December 31, 2019.

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 increase in the deferred product revenue balance as of December 31, 2020 is primarily driven by performance obligations not satisfied but invoiced as of December 31, 2020, offset by \$0.6 million of product revenue recognized that were included in the deferred product revenue balance as of December 31, 2019.

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 and under its U.S. government contract. Actual results may differ from those estimates under different assumptions or conditions.

### **Cash Equivalents**

The Company considers all highly liquid investments with original 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, 2020 and December 31, 2019, \$0.2 million and zero, respectively, were included in other assets, net, which represents the cash surrender value of the associated life insurance policies, and \$0.2 million and zero, respectively, were included in other long-term liabilities, 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, and corresponding changes in their deferred compensation liability are included in operating expenses.

### **Restricted Cash**

As of December 31, 2020 and December 31, 2019, the Company's "Restricted cash" consisted primarily of a letter of credit relating to an office building lease. As of December 31, 2020 and December 31, 2019, 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, 2020, 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 trade receivables 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 three customers that accounted for more than 10% of the Company's outstanding trade receivables at both December 31, 2020 and December 31, 2019, respectively. These customers cumulatively represented approximately 51% and 56% of the Company's outstanding trade receivables at December 31, 2020 and December 31, 2019, respectively. To date, the Company has not experienced collection difficulties from these customers.

### **Inventories**

At December 31, 2020 and December 31, 2019, inventory consisted of work-in-process and finished goods only. 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 months shelf lives from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. 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. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production within the next 12-month period and evaluates its finished units in order to sell to existing and prospective customers within the next 12-month period. It is not customary for the Company's production cycle for inventory to exceed 12 months, however, in certain circumstances the Company may decide purchase 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 work-in-process and finished units to meet the Company's forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At December 31, 2020 and December 31, 2019, the Company classified its work-in-process inventory as a component of inventory on its consolidated balance sheets based on its evaluation that the work-in-process inventory would be sold to Fresenius for finished disposable kit production within each respective subsequent 12-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or net realizable value. The Company uses significant 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 in "Cost of product revenue" on the Company's consolidated statements of operations. At December 31, 2020 and December 31, 2019, the Company had less than \$0.1 million and \$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, 2020 and 2019, the Company had non-cash purchases of capital expenditures of \$0.5 million and \$3.1 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.

As a matter of policy, the Company performs an impairment test on its intangible assets, should they exist, if certain events or changes in circumstances occur which indicate that the carrying amounts of its intangible assets may not be recoverable. If the intangible assets are not recoverable, an impairment loss would be recognized by the Company based on the excess amount of the carrying value of the intangible assets over its fair value. During the year ended December 31, 2020, 2019 and 2018, there were no impairment charges recognized related to the acquired intangible assets.

### **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 in "Foreign exchange gain (loss)" 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.

For stock-based awards issued to non-employees, the Company recognizes stock-based compensation expense for the grant date fair value of the vested portion of the awards in its consolidated statements of operations.

See Note 11 for further information regarding the Company's stock-based compensation assumptions and expenses.

### **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 2000 through 2019, California tax returns for years through 2019, and Netherlands tax returns for years 2016 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

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share 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, 2020, 2019 and 2018, 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, 2020, 2019 and 2018 (in thousands, except per share amounts):

	Year Ended December 31,		
	2020	2019	2018
Numerator for Basic and Diluted:			
Net loss used for basic calculation .....	<u>\$ (59,857)</u>	<u>\$ (71,244)</u>	<u>\$ (57,564)</u>
Denominator:			
Basic weighted average number of shares outstanding .....	163,949	139,831	131,663
Effect of dilutive potential shares .....	<u>—</u>	<u>—</u>	<u>—</u>
Diluted weighted average number of shares outstanding .....	<u>163,949</u>	<u>139,831</u>	<u>131,663</u>
Net loss per share:			
Basic and diluted .....	\$ (0.37)	\$ (0.51)	\$ (0.44)

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, 2020, 2019 and 2018 (shares in thousands):

	Year Ended December 31,		
	2020	2019	2018
Weighted average number of anti-dilutive potential shares:			
Stock options .....	17,692	17,401	18,031
Restricted stock units .....	5,485	3,361	1,902
Employee stock purchase plan rights .....	<u>32</u>	<u>72</u>	<u>20</u>
Total .....	<u>23,209</u>	<u>20,834</u>	<u>19,953</u>

## 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, 2020 and December 31, 2019, 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 indemnification 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, 2020 and December 31, 2019.

### 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.

### New Accounting Pronouncements

#### *Recently adopted accounting pronouncements*

In June 2016, the Financial Accounting Standard Board issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held. The standard is effective for annual periods beginning after December 15, 2019, and interim periods thereafter, with early application permitted. The Company adopted the new accounting standard on January 1, 2020, using the modified retrospective transition method. The adoption of this ASU had no material impact on the Company's consolidated financial statements.

### 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, 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 .....	<u>\$ 102,529</u>	<u>\$ 677</u>	<u>\$ (3)</u>	<u>\$ —</u>	<u>\$ 103,203</u>

The following is a summary of available-for-sale securities at December 31, 2019 (in thousands):

	December 31, 2019				
	<u>Amortized Cost</u>	Gross		<u>Allowance for Credit Loss</u>	<u>Fair Value</u>
		<u>Unrealized Gain</u>	<u>Unrealized Loss</u>		
Money market funds .....	\$ 8,860	\$ —	\$ —	\$ —	\$ 8,860
United States government agency securities.....	15,545	16	—	—	15,561
Corporate debt securities.....	35,073	98	—	—	35,171
Total available-for-sale securities .....	<u>\$ 59,478</u>	<u>\$ 114</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 59,592</u>

Available-for-sale securities at December 31, 2020 and December 31, 2019, consisted of the following by contractual maturity (in thousands):

	December 31, 2020		December 31, 2019	
	<u>Amortized Cost</u>	<u>Fair Value</u>	<u>Amortized Cost</u>	<u>Fair Value</u>
	One year or less .....	\$ 64,857	\$ 65,117	\$ 43,822
Greater than one year and less than five years .....	37,672	38,086	15,656	15,685
Total available-for-sale securities .....	<u>\$ 102,529</u>	<u>\$ 103,203</u>	<u>\$ 59,478</u>	<u>\$ 59,592</u>

The following table shows 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, 2020					
	Less than 12 Months		12 Months or Greater		Total	
	<u>Fair Value</u>	<u>Unrealized Loss</u>	<u>Fair Value</u>	<u>Unrealized Loss</u>	<u>Fair Value</u>	<u>Unrealized Loss</u>
Corporate debt securities.....	\$ 5,105	\$ (3)	\$ —	\$ —	\$ 5,105	\$ (3)

As of December 31, 2019, the Company did not have any available-for-sale securities in an unrealized net loss position.

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, 2020, 2019 and 2018, 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 gross realized gains of less than \$0.1 million and gross realized losses of \$0.3 million from the sale or maturity of available-for-sale investments during the year ended December 31, 2020. The Company did not record any gross realized gains or losses from the sale or maturity of available-for-sale investments during the year ended December 31, 2019 and 2018.

#### *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, 2020, 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, 2020, 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, 2020 (in thousands):

	<b>Balance sheet classification</b>	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Money market funds .....	Cash and cash equivalents	\$ 6,203	\$ 6,203	\$ —	\$ —
United States government agency securities .....	Short-term investments	30,683	—	30,683	—
Corporate debt securities .....	Short-term investments	66,317	—	66,317	—
Total short-term investments .....		103,203	6,203	97,000	—
Warrants.....	Other assets	422	—	—	422
Total financial assets .....		<u>\$ 103,625</u>	<u>\$ 6,203</u>	<u>\$ 97,000</u>	<u>\$ 422</u>

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2019 (in thousands):

	<b>Balance sheet classification</b>	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Money market funds .....	Cash and cash equivalents	\$ 8,860	\$ 8,860	\$ —	\$ —
United States government agency securities .....	Short-term investments	15,561	—	15,561	—
Corporate debt securities .....	Short-term investments	35,171	—	35,171	—
Total financial assets .....		<u>\$ 59,592</u>	<u>\$ 8,860</u>	<u>\$ 50,732</u>	<u>\$ —</u>

The Company did not have any transfers among fair value measurement levels during the years ended December 31, 2020 and December 31, 2019.

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,		
	2020	2019	2018
Gain from changes in the fair value of level 3 investments.....	\$ 422	\$ —	\$ —

#### Note 4. Inventories, net

Inventories, net at December 31, 2020 and December 31, 2019, consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Work-in-process .....	\$ 5,097	\$ 5,160
Finished goods.....	18,157	14,330
Total inventories .....	<u>\$ 23,254</u>	<u>\$ 19,490</u>

#### Note 5. Property and Equipment, net

Property and equipment, net at December 31, 2020 and December 31, 2019, consisted of the following (in thousands):

	December 31,	
	2020	2019
Construction-in-progress .....	\$ 292	\$ 74
Machinery and equipment.....	3,446	2,833
Computer equipment and software .....	3,425	3,306
Furniture and fixtures .....	2,065	2,061
Leasehold improvements.....	12,802	12,881
Consigned equipment.....	1,416	1,373
Total property and equipment, gross .....	23,446	22,528
Accumulated depreciation and amortization.....	(9,579)	(7,630)
Total property and equipment, net.....	<u>\$ 13,867</u>	<u>\$ 14,898</u>

Depreciation and amortization expense related to property and equipment, net was \$2.2 million, \$2.2 million and \$1.1 million for the years ended December 31, 2020, 2019 and 2018, 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, 2019 and 2018.

#### Note 6. Goodwill and Intangible Assets, net

##### *Goodwill*

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

##### *Intangible Assets, net*

Intangible assets, net, which include a license for the right to commercialize the INTERCEPT Blood System in Asia, were subject to ratable amortization over the original estimated useful life of ten years. Intangible assets were fully amortized as of December 31, 2020. Accumulated amortization of intangible assets as of December 31, 2020, and December 31, 2019, was \$2.0 million and \$1.9 million, respectively.



## Note 7. Accrued Liabilities

Accrued liabilities at December 31, 2020 and December 31, 2019, consisted of the following (in thousands):

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Accrued compensation and related costs .....	\$ 15,999	\$ 12,703
Accrued professional services .....	3,020	3,489
Other accrued expenses .....	5,734	4,759
Total accrued liabilities .....	<u>\$ 24,753</u>	<u>\$ 20,951</u>

## Note 8. Debt

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

	<u>December 31, 2020</u>		
	<u>Principal</u>	<u>Unamortized Discount</u>	<u>Total</u>
Term Loan Credit Agreement .....	\$ 40,000	\$ (412)	\$ 39,588
Less: current portion of term loan .....	—	—	—
Non-current portion of term loan .....	<u>\$ 40,000</u>	<u>\$ (412)</u>	<u>\$ 39,588</u>

Debt consisted of the following (in thousands):

	<u>December 31, 2019</u>		
	<u>Principal</u>	<u>Unamortized Discount</u>	<u>Net Carrying Value</u>
Term Loan Agreement .....	\$ 40,000	\$ (586)	\$ 39,414
Less: current portion of term loan .....	—	—	—
Non-current portion of term loan .....	<u>\$ 40,000</u>	<u>\$ (586)</u>	<u>\$ 39,414</u>

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

<u>Year ended December 31,</u>	<u>Principal</u>	<u>Interest and Fees</u>	<u>Total</u>
2021 .....	\$ —	\$ 3,041	\$ 3,041
2022 .....	15,000	2,660	17,660
2023 .....	20,000	1,203	21,203
2024 .....	5,000	1,264	6,264
Total .....	<u>\$ 40,000</u>	<u>\$ 8,168</u>	<u>\$ 48,168</u>

### Loan Agreements

On March 29, 2019 (the “Closing Date”), 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 Company repaid principal and interest in an aggregate amount equal to approximately \$31.2 million and prepayment fees in an aggregate amount equal to approximately \$0.6 million, and terminated all obligations under prior loan agreement. As a result, the Company recorded a loss of \$2.1 million on the extinguishment of the prior loan agreement within “Interest expense” on the Company's consolidated statements of operations during the year ended December 31, 2019. The second advance of \$15.0 million (“Tranche 2”) is to be available to be drawn by the Company through March 31, 2021, and the third advance of \$15.0 million (“Tranche 3”) will be available to the Company starting March 31, 2021, through September 30, 2021, subject to the Company's satisfaction of certain other conditions described in the Term Loan Credit Agreement. The borrowings under the 2019 Term Loan bears interest at the sum of a fixed percentage spread and the greater of (i) 1.8% or (ii) one month LIBOR. The effective interest rate on the Term Loan, was approximately 7.50%. All three tranches require interest only payments through March 1, 2022, followed by 24 months of payments with interest and equal payment of principal. The interest only payment period can be extended for 12 months

upon achievement of a specified trailing twelve month net revenue target. 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 also entered into a Credit, Security and Guaranty Agreement (Revolving Loan) (the “Revolving Loan Credit Agreement”) with MidCap on March 29, 2019, to initially borrow up to \$5.0 million. The borrowing limit was expanded to \$10.0 million in December 2020. The amount borrowed under the Revolving Loan Credit Agreement can be increased, upon request by the Company by up to an additional \$10.0 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, 2020 and December 31, 2019, the Company had borrowed \$8.5 million and \$5.0 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, 2020. Additionally, both agreements are secured by substantially all of the Company’s assets, with some exclusions.

## Note 9. 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):

	<u>Year Ended</u> <u>December 31, 2020</u>
Cash payments for operating leases .....	\$ 3,400
Right-of-use assets obtained in exchange for operating lease obligations.....	344
	<u>December 31, 2020</u>
Weighted-average remaining lease term .....	8.5 years
Weighted-average discount rate .....	9.0%

Future minimum non-cancelable payments under operating leases as of December 31, 2020, were as follows (in thousands):

	<u>Operating Leases</u>
2021.....	\$ 3,535
2022.....	3,008
2023.....	2,840
2024.....	2,735
2025.....	2,716
Thereafter .....	<u>13,337</u>
Total future lease payments .....	28,171
Less imputed interest .....	<u>9,383</u>
Present value of lease liabilities.....	<u>\$ 18,788</u>

During the years ended December 31, 2020, 2019 and 2018, the Company recorded operating lease expenses of \$3.3 million, \$3.4 million and \$1.6 million, respectively. As of December 31, 2020, 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, 2020, the Company had \$28.9 million of short-term purchase commitments and \$4.0 million of long-term purchase commitments, which are not recorded in the Company's consolidated balance sheets.

### **Note 10. Stockholders' Equity**

#### *Public Offering of Common Stock*

In January 2020, the Company issued and sold 16,866,667 shares of common stock, par value \$0.001 per share, at \$3.75 per share in an underwritten public offering. The total proceeds from this offering were approximately \$62.7 million, net of the underwriting discount and other issuance costs.

#### *Sales Agreements*

On August 4, 2017, the Company entered into Amendment No. 3 to the Controlled Equity Offering <sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co. (as amended on August 4, 2017, the "Amended Cantor Agreement"). Under the Amended Cantor Agreement, Cantor also acted as the Company's sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by the Company pursuant to the Amended Cantor 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, 2020, 2.5 million shares of the Company's common stock were sold under the Amended Cantor Agreement for net proceeds of \$13.9 million, after which time the Amended Cantor Agreement was fully utilized and automatically terminated.

On December 11, 2020, the Company entered into the Controlled Equity Offering <sup>SM</sup> Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated (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 its 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, 2020, no shares of the Company's common stock were sold under the Sales Agreement.

### **Note 11. 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, 2020, the Company had 1.8 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. Option

awards under the Amended 2008 Plan generally have a maximum term of 10 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 or cash awards granted under the Amended 2008 Plan are limited to either 500,000 shares of common stock or \$1.0 million per recipient per calendar year. At December 31, 2020, 20,000 performance-based stock awards were outstanding.

At December 31, 2020, the Company had an aggregate of approximately 30.5 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 16.3 million shares and 5.7 million shares were subject to outstanding options and unvested RSUs, respectively, and approximately 8.4 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, 2019 .....	16,830	\$	4.53
Granted.....	2,237		5.22
Exercised.....	(2,658)		4.01
Forfeited/canceled.....	(103)		5.27
Balances at December 31, 2020 .....	<u>16,306</u>		<u>4.71</u>

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, 2019 .....	4,098	\$	5.24
Granted <sup>(1)</sup> .....	3,433		5.17
Vested <sup>(1)</sup> .....	(1,631)		5.05
Forfeited <sup>(1)</sup> .....	(161)		5.73
Balances at December 31, 2020 .....	<u>5,739</u>		<u>5.24</u>

(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, 2020, 2019 and 2018, were \$6.8 million, \$5.6 million and \$2.8 million, respectively.

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2020, 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, 2020						
Stock options outstanding.....	16,306	\$	4.71	5.26	\$	36,180
Stock options vested and expected to vest.....	16,151		4.70	5.22		35,905
Stock options exercisable .....	12,735		4.61	4.36		29,535

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, 2020, 2019 and 2018, was \$7.9 million, \$1.6 million and \$7.1 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, 2020, 2019 and 2018, was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development.....	\$ 3,739	\$ 2,472	\$ 1,669
Selling, general and administrative .....	14,290	10,840	8,725
Total stock-based compensation expense .....	<u>\$ 18,029</u>	<u>\$ 13,312</u>	<u>\$ 10,394</u>

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, 2020, 2019 and 2018. The Company has also not recorded any stock-based compensation associated with performance-based stock options during the years ended.

As of December 31, 2020, the Company expects to recognize the remaining unamortized stock-based compensation expense of \$7.0 million and \$18.2 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 1.8 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, 2020, 2019 and 2018, was as follows:

	Year Ended December 31,		
	2020	2019	2018
<b>Stock Options:</b>			
Expected term (in years) .....	6.89	5.59	6.07
Estimated volatility .....	52%	50%	50%
Risk-free interest rate .....	0.94%	2.32%	2.72%
Expected dividend yield.....	0%	0%	0%
<b>Employee Stock Purchase Plan Rights:</b>			
Expected term (in years) .....	0.72	0.80	0.74
Estimated volatility .....	53%	46%	47%
Risk-free interest rate .....	0.86%	2.04%	2.34%
Expected dividend yield.....	0%	0%	0%

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2020, 2019 and 2018, was \$2.71 per share, \$2.73 per share and \$2.41 per share, respectively. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2020, 2019 and 2018, was \$1.71 per share, \$1.84 per share and \$2.29 per share, respectively.

## Note 12. 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 13. 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 are initially fixed and decline 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 the Company purchases finished disposable kits using those components. The Supply Agreement also required the Company to make certain payments totaling 8.6 million (“Manufacturing and Development Payments”) to Fresenius. In 2016, the Company paid \$3.4 million ( 3.1 million) to Fresenius. In August 2019, the Company paid the remaining \$6.2 million ( 5.5 million) to Fresenius.

The Supply Agreement also required the Company to make payments to support certain projects Fresenius has and will perform on behalf of the Company related to certain R&D activities and manufacturing efficiency activities for which certain assets have been established in the Company’s consolidated balance sheets. The manufacturing efficiency asset is expensed on a straight-line basis over the life of the Supply Agreement. The prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company is expensed over the period which such activities occur. The following table summarizes the amounts of prepaid R&D asset and manufacturing efficiency asset at December 31, 2020 and December 31, 2019 (in thousands).

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Prepaid R&D asset – current <sup>(1)</sup> .....	\$ —	\$ 54
Prepaid R&D asset – non-current <sup>(2)</sup> .....	2,088	2,094
Manufacturing efficiency asset <sup>(2)</sup> .....	1,104	1,349

(1) Included in “Prepaid and other current assets” in the Company’s consolidated balance sheets.

(2) Included in “Other assets” in the Company’s consolidated balance sheets.

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.

The Company made payments to Fresenius of \$31.3 million, \$29.5 million and \$21.3 million relating to the manufacturing of the Company’s products during the years ended December 31, 2020, 2019 and 2018, respectively. The following table summarizes the amounts of the Company’s payables to and receivables from Fresenius at December 31, 2020 and December 31, 2019 (in thousands).

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Payables to Fresenius <sup>(1)</sup> .....	\$ 13,838	\$ 8,470
Receivables from Fresenius <sup>(2)</sup> .....	2,380	1,796

(1) Included in “Accounts Payable” and “Accrued Liabilities” in the Company’s consolidated balance sheets.

(2) Included in “Prepaid and other current assets” in the Company’s consolidated balance sheets.

## 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 options (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 April 2020, BARDA committed an additional \$13.8 million raising the committed funding to up to \$116.9 million as of December 31, 2020, 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 \$213.9 million through December 31, 2021. 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 is responsible for co-investment of \$5.0 million and would be responsible for an additional \$9.6 million, if certain Option Periods are exercised. Through December 31, 2020, the Company has incurred approximately \$2.2 million related to the co-investment. 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, 2020 and December 31, 2019, \$4.6 million and \$4.2 million, respectively, of billed and 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, 2020, less than \$0.1 million of billed and unbilled amounts were included in accounts receivable on the company’s consolidated balance sheets related to FDA.

## Note 14. Income Taxes

U.S and foreign components of consolidated loss before income taxes for the years ended December 31, 2020, 2019 and 2018, was as follows (in thousands):

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Loss before income taxes:			
U.S. ....	\$ (61,246)	\$ (71,946)	\$ (58,048)
Foreign.....	1,673	965	713
Loss before income taxes.....	<u>\$ (59,573)</u>	<u>\$ (70,981)</u>	<u>\$ (57,335)</u>

The provision for income taxes for the years ended December 31, 2020, 2019 and 2018, was as follows (in thousands):

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Provision for income taxes:			
Current:			
Foreign.....	\$ 274	\$ 255	\$ 225
Federal.....	—	—	—
State.....	—	2	—
Total current.....	<u>274</u>	<u>257</u>	<u>225</u>
Deferred:			
Foreign.....	—	—	—
Federal.....	6	4	3
State.....	4	2	1
Total deferred.....	<u>10</u>	<u>6</u>	<u>4</u>
Provision for income taxes.....	<u>\$ 284</u>	<u>\$ 263</u>	<u>\$ 229</u>

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, 2020, 2019 and 2018, was as follows (in thousands):

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Federal statutory tax .....	\$ (12,510)	\$ (14,906)	\$ (12,040)
Federal research credits.....	(1,630)	(1,857)	(1,390)
State research credits.....	(749)	(821)	(655)
Expiration of federal carryovers .....	9,200	5,472	4,154
Expiration of state carryovers .....	—	—	1,344
Change in valuation allowance .....	6,738	13,059	9,913
Compensation related items .....	978	158	(361)
State taxes .....	(1,921)	(1,111)	(1,141)
Other .....	178	269	405
Provision for income taxes.....	<u>\$ 284</u>	<u>\$ 263</u>	<u>\$ 229</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. The significant components of the Company's deferred tax assets and liabilities at December 31, 2020, 2019 and 2018, were as follows (in thousands):

	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 141,176	\$ 135,536
Research and development credit carryforwards .....	28,892	28,291
Capitalized research and development.....	10,756	12,832
Compensation related items .....	10,957	9,843
Operating leases .....	4,214	4,374
Other.....	6,051	4,547
Total deferred tax assets .....	202,046	195,423
Valuation allowance .....	(199,042)	(192,304)
Net deferred tax assets.....	<u>\$ 3,004</u>	<u>\$ 3,119</u>
Deferred tax liabilities:		
Right-of-use assets .....	\$ 2,892	\$ 3,017
Amortization of goodwill.....	163	143
Total deferred tax liabilities.....	<u>\$ 3,055</u>	<u>\$ 3,160</u>

The valuation allowance increased by \$6.7 million for the year ended December 31, 2020, compared to the increase of \$13.1 million and \$9.9 million for the years ended December 31, 2019 and 2018, 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, 2020, 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 2021-2023	Expires 2024-2030	Expires 2031-2040	No Expiration
Federal losses carryovers .....	\$ 638,103	\$ 55,587	\$ 190,581	\$ 209,368	\$ 182,567
California loss carryovers .....	75,407	—	28,779	46,628	—
Federal research credits .....	19,249	7,786	2,248	9,215	—
California research credits .....	12,207	—	—	—	12,207
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, 2020	December 31, 2019
Unrecognized tax benefits at beginning of period .....	\$ 10,842	\$ 11,063
Decreases related to expired carryforwards .....	(1,171)	(729)
Increases related to current year tax positions .....	439	508
Unrecognized tax benefits at end of period .....	\$ 10,110	\$ 10,842

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 15. 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, 2020, 2019 and 2018 (in percentages):

	Year Ended December 31,		
	2020	2019	2018
Établissement Français du Sang .....	21%	27%	38%
American Red Cross .....	20%	14%	*

\* Represents an amount less than 10% of product revenue.

Revenues by geographical location were based on the location of the customer during the years ended December 31, 2020, 2019 and 2018, and was as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Product revenue:			
United States.....	\$ 31,517	\$ 20,611	\$ 12,563
France .....	19,404	20,075	23,043
Belgium .....	6,921	7,272	6,788
Other countries .....	34,078	26,691	18,514
Total product revenue .....	91,920	74,649	60,908
Government contract revenue:			
United States.....	22,329	19,125	15,143
Total government contract revenue .....	22,329	19,125	15,143
Total revenue .....	<u>\$ 114,249</u>	<u>\$ 93,774</u>	<u>\$ 76,051</u>

Long-lived assets by geographical location at December 31, 2020 and December 31, 2019, were as follows (in thousands):

	December 31,	
	2020	2019
U.S. and territories .....	\$ 13,559	\$ 14,619
Europe & other .....	308	411
Total long-lived assets .....	<u>\$ 13,867</u>	<u>\$ 15,030</u>

#### Note 16. Subsequent Event

In February 2021, the Company entered into a joint venture (“JV”) agreement with a company in China with the intent to develop, obtain regulatory approval for, manufacture and commercialize the INTERCEPT Blood System for platelets and red blood cells in China. Cerus and the Chinese company are the sole equity holders in the JV, with Cerus owning a majority (51%) of the entity. Cerus will contribute an exclusive license to commercialize the INTERCEPT Blood System for platelets and red blood cells for the JV to market in China.

## 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 25th day of February, 2021.

### 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ WILLIAM M. GREENMAN          </u> <b>William M. Greenman</b>	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 25, 2021
<u>          /s/ KEVIN D. GREEN          </u> <b>Kevin D. Green</b>	Vice President, Finance and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 25, 2021
<u>          /s/ DANIEL N. SWISHER, JR.          </u> <b>Daniel N. Swisher, Jr.</b>	Director and Chair of the Board of Directors	February 25, 2021
<u>          /s/ TIMOTHY B. ANDERSON          </u> <b>Timothy B. Anderson</b>	Director	February 25, 2021
<u>          /s/ ERIC H. BJERKHOLT          </u> <b>Eric H. Bjerkholt</b>	Director	February 25, 2021
<u>          /s/ TIMOTHY L. MOORE          </u> <b>Timothy L. Moore</b>	Director	February 25, 2021
<u>          /s/ JAMI NACHTSHEIM          </u> <b>Jami Nachtsheim</b>	Director	February 25, 2021
<u>          /s/ GAIL SCHULZE          </u> <b>Gail Schulze</b>	Director	February 25, 2021
<u>          /s/ FRANK WITNEY, PH.D.          </u> <b>Frank Witney, Ph.D.</b>	Director	February 25, 2021

## 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 25, 2021

/s/ WILLIAM M. GREENMAN

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

## 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 25, 2021

/s/ KEVIN D. GREEN

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

**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, 2020, 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 25th day of February, 2021.

/s/ WILLIAM M. GREENMAN

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

/s/ KEVIN D. GREEN

Kevin D. Green  
Chief Financial 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.



