Risk Factors Comparison 2024-03-05 to 2023-03-01 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading " Item 1A — Risk Factors " in Part I of this Annual Report on Form 10- K. • ~~The evolving effects of the COVID- 19 pandemic have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which these effects will impact our future results of operations and overall financial performance remains uncertain. •~~ We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets, plasma and cryoprecipitation in the U. S., and our inability to successfully commercialize the INTERCEPT Blood System in the U. S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects. • The INTERCEPT Blood System may not achieve **or be able to sustain** broad market adoption. • We are exposed to risks associated with the highly concentrated market for the INTERCEPT Blood System. • We may be unable to develop and maintain an effective and qualified U. S. based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our products in the U. S. • We have very limited experience selling directly to hospitals or expertise complying with regulations governing finished biologics, and our inability to successfully commercialize the INTERCEPT Blood System for cryoprecipitation in the U. S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects. • If our competitors develop products superior to ours, market their products more effectively, or receive regulatory approval or certification before our products, our commercial opportunities could be reduced or be eliminated. **Competitors have and may continue to file claims in order to impede the marketability of our products, regardless of the merit of such claims.** • Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals or certification for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects. • The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity. • ~~We expect to continue to generate losses. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur. •~~ Our company, our products, and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic and foreign authorities. • If we or our third- party suppliers fail to comply with the U. S. Food and Drug Administration' s, or FDA' s, or other regulatory authorities' good manufacturing practice regulations, it could impair our ability to market our products in a cost- effective and timely manner. • If we modify our FDA- approved or CE Marked products, we may need to seek additional approvals or certification, which, if not granted, would prevent us from selling our modified products. • We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business. • A significant portion of the funding for the development of the red blood cell system **has come and** is expected **to continue** to come from our BARDA agreement, and if BARDA were to eliminate, reduce or delay, or object to extensions for funding of our agreement, it would have a significant, negative impact on our government contract revenues and cash flows, and we may be forced to suspend or terminate our U. S. red blood cell development program or obtain alternative sources of funding **. Our ability to be repaid and compensated by the DoD is predicated on our ability to achieve the stated milestones in the agreement and for the DoD to agree with the successful completion of each** . • We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries. • Our manufacturing supply chain exposes us to significant risks. • We expect to continue to generate losses and we may never achieve a profitable level of operations. • If we fail to obtain the capital necessary to fund our future operations or if we are unable to generate positive cash flows from our operations, we will need to curtail planned development or sales and commercialization activities. • We operate a complex global commercial organization, with limited experience in many countries. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies. We may be distracted by expansion into new geographies where we do not have experience and we may be unsuccessful in monetizing such opportunities for the benefit of our organization at large. • **Adverse market and economic conditions, including those resulting from the effects of macroeconomic conditions such as pandemics or other health crises, civil or political unrest or military conflicts around the world, such as the military conflict between Ukraine and Russia and the state of war between Israel and Hamas and the risk of a larger regional conflict, inflation, rising interest rates and / or the prospects of a recession, may exacerbate certain risks affecting our business. •** Risks associated with our operations outside of the United States could adversely affect our business. • We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others **. • Our stock price is volatile** . Item 1. Business Overview We are a biomedical products company focused on developing and commercializing the INTERCEPT Blood System to enhance blood safety. The INTERCEPT Blood System, which is based on our proprietary technology for controlling biological replication, is designed to reduce blood- borne pathogens in donated blood components intended for transfusion. Our INTERCEPT Blood System is intended for use with blood components and certain of their derivatives: platelets, plasma, red blood cells and to produce INTERCEPT Fibrinogen Complex, or IFC, and pathogen reduced plasma, cryoprecipitate reduced. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT

Blood System for plasma, or plasma system, have received a broad range of regulatory approvals and certification, including but not limited to FDA approval in the U. S., CE Certificates of Conformity delivered in accordance with the Medical Devices Directive 93 / 42 / EEC, or MDD, ~~permitting us to affix the CE Mark to our products~~ and ~~place them on the market in the European Union in accordance with the transitional provisions of~~ the Medical Devices Regulation 2017 / 745, or MDR, **permitting us to affix the CE Mark to our products and place them on the market in the European Union** and other jurisdictions that recognize the CE Mark, and are being marketed and sold in a number of countries around the world, including the U. S., certain countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East, and Latin America and selected countries in other regions of the world. Additionally, we have received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. In addition, the INTERCEPT Blood System for Cryoprecipitation is used to produce pathogen reduced plasma, cryoprecipitate reduced. We currently sell the platelet and plasma systems using our direct sales force and through distributors and sell IFC or disposable kits to manufacture IFC in the U. S. using our direct sales force. If we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including in the U. S., we will have difficulties achieving profitability. The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development. In the U. S., we are currently conducting two Phase 3 clinical trials- the RedeS study, to assess the safety and efficacy of INTERCEPT- treated red blood cells when compared to conventional, un- treated, red blood cells and the ReCePI study to evaluate the efficacy and safety of INTERCEPT- treated red blood cells in patients requiring transfusion for acute blood loss during surgery. In the European Union, or EU, we completed the resubmission of our application for a CE Certificate of Conformity under the new Medical Device Regulation 2017 / 745, or MDR, in June 2021 ~~; however,~~ **. While at this time** we ~~do not~~ expect **a** ~~an approval~~ decision ~~will occur for at least another 12 months~~ **concerning certification in the second half of 2024, we cannot predict with certainty when** , if ever **, a decision concerning certification will actually occur. See also the risk factor entitled " The red blood system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity " under " Item 1A — Risk Factors " of this Annual Report on Form 10- K for additional information with respect to timing of the ultimate decision on our CE Certificate of Conformity application** . Contribution margins from our sales is expected to be less than the cost of our operating expenses. In order to successfully commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products and product candidates, which, together with anticipated increased selling, general and administrative expenses, are expected to result in substantial operating losses. Accordingly, we may never achieve a profitable level of operations in the future. We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Our wholly- owned subsidiary, Cerus Europe B. V., was formed in the Netherlands in 2006. Information regarding our revenues, net losses, and total assets for the last three fiscal years can be found in the consolidated financial statements and related notes found elsewhere in this Annual Report on Form 10- K. Product Development Background The INTERCEPT Blood System is designed to broadly target and inactivate blood- borne pathogens, such as viruses (for example, HIV, West Nile, SARS, hepatitis B and C), bacteria and parasites, as well as potentially harmful white blood cells, while preserving the therapeutic properties of platelet, plasma, red blood cell and IFC transfusion products. The INTERCEPT Blood System has been shown to inactivate a broad array of pathogens and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective, is not available or is not performed. We believe that the INTERCEPT Blood System also has the potential to inactivate most new pathogens before they are identified and before tests are developed and adopted commercially to detect their presence in donated blood. Products, Product Candidates and Development Activities The following table identifies our products, product candidates and product development activities and their current status: Product or Product Candidate Under Development Product or Development Status INTERCEPT Blood System — Platelets • Commercialized in the U. S., Canada and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world • **Received** ~~Refiled for~~ CE Certificate of Conformity under MDR ~~; pending review~~ **in December 2023** • Post- marketing recovery and survival study underway INTERCEPT Blood System — Plasma • Commercialized in the U. S. and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world • **Received** ~~Refiled for~~ CE Certificate of Conformity under MDR ~~; pending review~~ **in December 2023** • Received FDA approval of the premarket approval supplement, or PMA, to produce IFC in 2020 INTERCEPT Blood System — Red Blood Cells • U. S. Phase 3 clinical trial, known as the RedeS study, enrolling patients • U. S. Phase 3 acute anemia clinical trial, known as the ReCePI study, ~~enrolling patients~~ **completed enrollment; expect to report top- line data later in the first quarter of 2024** • Additional U. S. studies also planned • European Phase 3 acute anemia clinical trial completed in 2014; European Phase 3 chronic anemia clinical trial completed in 2017 • Application for CE Certificate of Conformity under MDR ~~submitted~~ **resubmitted** in 2021 **; decision concerning certification expected in the second half of 2024** INTERCEPT Blood System — Cryoprecipitation • FDA approval in November 2020 • U. S. agreement with certain blood center manufacturing partners • Limited commercialization in the U. S. INTERCEPT Blood System for Platelets, Plasma and Cryoprecipitation The platelet system and plasma system are designed to inactivate blood- borne pathogens in platelets and plasma donated for transfusion. Both systems received a CE Certificate of Conformity permitting us to affix the CE Mark in the European Economic Area, or EEA, 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., countries in 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 the European Union recognize 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. ~~We~~ **In December 2023, we** received CE Certificates of Conformity **to affix the CE Mark** in accordance with the ~~MDD~~ **MDR** for our INTERCEPT platelet and plasma systems ~~,~~ which **allows us** ~~currently will expire in May 2024. European Union regulators have enacted legislation that requires all medical devices~~ to ~~comply with the requirements of the new MDR, including the related transitional provisions. To~~ continue to place our platelet and plasma systems on the European Union market **under the** ~~, we will need to obtain~~ new ~~CE Certificates~~ **regulatory requirements** of ~~Conformity under~~ the ~~new~~ MDR ~~. We have submitted our application and technical documentation for CE Certificates of Conformity under the MDR for both our INTERCEPT platelet and plasma systems which are currently under review by our Notified Body~~ . The FDA has approved the platelet system for ex vivo preparation of pathogen- reduced apheresis platelet components collected and stored in 100 % plasma or InterSol in order to reduce the risk of transfusion- transmitted infection, or TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion- associated graft versus host disease. **We have** ~~In 2021, we~~ completed ~~one of~~ the two post- approval studies that FDA required as part of its approval of the platelet system- a haemovigilance study evaluating the incidence of acute lung injury following transfusion of INTERCEPT- treated platelets **and** ~~. The second required post- approval study -~~ a recovery study of platelets treated with the platelet system **,** ~~- is~~ currently ~~in progress~~ **under review by the FDA** . The FDA has also approved the plasma system for ex vivo preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion. We have also received FDA approval for the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce pathogen reduced plasma, cryoprecipitate reduced. We expect our commercial efforts in ~~2023~~ **2024** will continue to largely be focused on enabling blood centers that are using INTERCEPT to increase the number of platelet and plasma units produced and made available to patients. In addition we plan to sell the INTERCEPT Blood System for Cryoprecipitation to certain blood center customers and to sell IFC to hospital customers. In addition, we will continue to develop awareness of INTERCEPT' s product profile relative to other platelet and plasma products, including conventional, un- treated components. To enable broader patient access to IFC in the U. S., U. S.- based blood centers need to complete process validations and obtain site- specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, before IFC can be made available to hospital customers outside of the state of IFC production. We have contracted with several blood centers to produce IFC for us which we ~~plan to~~ sell directly to hospitals. **Of** ~~All of~~ the blood centers that we have contracted with to produce IFC for us **, three** have **received** ~~submitted for~~ their interstate licenses, or BLAs. Until BLAs are more broadly obtained, we expect that our direct sales of IFC will be limited. Further, the hospital customers of blood centers may need to complete changes to their administrative processes of generating internal tracking codes to integrate INTERCEPT- treated products into their inventories prior to receiving INTERCEPT- treated components. In addition, we estimate that the majority of platelets used in the U. S. are collected by apheresis, which is part of our FDA- approved label for the platelet system, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. While available in Europe and other regions around the world, in order to gain FDA approval for a pathogen reduction system compatible with triple dose collections and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials, and will need to obtain FDA approval of a PMA supplement. We do not currently have plans to pursue these configurations. In addition, we may pursue development projects for other plasma derived biological products, which may require the submission and approval of additional PMA supplements for the plasma system. These development activities will be costly and may not be successful should we choose to pursue them. Our failure to seek and obtain FDA and foreign regulatory approvals or certification of new configurations could limit revenues from sales of our products. INTERCEPT Blood System for Red Blood Cells The red blood cell system is designed to inactivate blood- borne pathogens in red blood cells intended for transfusion. We completed a series of in vitro and in vivo tests with the red blood cell system, including successfully completing recovery and survival studies measuring red cell recovery twenty- four hours after transfusion. Previously, we terminated Phase 3 clinical trials for acute and chronic anemia using a prior generation of the red blood cell system due to the detection of antibody reactivity to INTERCEPT- treated red blood cells, or RBCs, in two patients in the trial for chronic anemia. The antibody eventually cleared and the subjects had no adverse health consequences. After unblinding the data from the original Phase 3 clinical trials, we found that we had met the primary endpoint in the clinical trial for acute anemia. We evaluated the antibodies detected and developed process changes to diminish the likelihood of antibody reactivity in RBCs treated with our modified process. We have since successfully completed **European** Phase 3 clinical trials of the red blood cell system for subjects with acute and chronic anemia patients to support an application for a CE Certificate of Conformity. We filed our application for a CE Certificate of Conformity for the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the application for a CE Certificate of Conformity under the new MDR. We have been notified that all four modules of our submission have been reviewed by our notified body, TÜV SÜD **and** ~~. Furthermore,~~ the Dutch Medical Evaluation Board (CBG), the competent authority for our red blood cell product **. We** ~~, has reviewed the relevant sections of our submission and~~ have **responded and** ~~asked numerous questions. We~~ will need to **continue to** satisfactorily respond to ~~those~~ **any** questions **posed by TÜV or CBG** timely ~~and~~ **in connection** with ~~satisfactory~~ **our application. We are still in the process of submitting additional** data **to TÜV that is required** before our products will be considered for certification. We cannot predict when, if ever, **a decision concerning certification. In addition, CBG has asked TÜV SÜD to assess the need for consultation of additional substances contained within the INTERCEPT RBC Processing Set (Processing Solution and SAG- M Storage Solution). We cannot predict when, if ever,** we will be able to ~~answer~~ **resolve** ~~those~~ -- **the** ~~questions and supply~~ **requirement for consultation, or complete** the **consultation, if** required ~~data or~~ **, and therefore** whether a decision

concerning **the** certification will occur. See also the risk factor entitled " The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificate of Conformity " under " Item 1A — Risk Factors " of this Annual Report on Form 10- K for additional information with respect timing of the ultimate decision on our application for a CE Certificate of Conformity. We previously completed a European Phase 3 clinical trial of RBCs treated with the INTERCEPT Blood System for acute anemia in cardiovascular surgery subjects announced that the trial met its primary endpoint, with preliminary analysis demonstrating that the mean hemoglobin content (53. 1g) of INTERCEPT- treated RBCs, on day 35 of storage met the protocol- defined criteria for equivalence based on the inferiority margin of 5g compared to conventional RBCs (55. 8g). The randomized, double- blind, controlled, multi- center Phase 3 clinical trial of the red blood cell system evaluated the efficacy of the red blood cell system to process RBCs with quality and mean hemoglobin content (> 40 g) suitable to support transfusion according to the European Directorate for the Quality of Medicines. The blood components were transfused to 51 cardiovascular surgery subjects at two German clinical trial sites to evaluate transfusion efficacy and overall safety. There were no clinically relevant trends in severe or serious treatment related adverse events by system organ class. The observed adverse events were within the expected spectrum of co- morbidity and mortality for subjects of similar age and with advanced cardiovascular diseases undergoing cardiovascular surgery requiring red cell transfusion. No subjects exhibited an immune response to INTERCEPT- treated RBCs. Additionally, we previously announced that the European Phase 3 clinical trial of chronic anemia evaluating INTERCEPT- treated RBCs in thalassemia subjects met its primary efficacy and safety endpoints. Regardless of the potential sufficiency of clinical data required to receive a CE Certificate of Conformity, we understand that we will need to generate additional safety data from commercial use in order to achieve broad market acceptance, if ever certified. In the U. S., we successfully completed a Phase 2 recovery and lifespan study. Subsequently, we initiated a double- blind Phase 3 clinical study, known as the RedeS study, to assess the safety and efficacy of INTERCEPT- treated RBCs when compared to conventional RBCs in regions impacted by the Zika virus epidemic. The RedeS study was expanded to other areas at risk for transfusion- transmitted infections. The FDA has agreed to modify the criteria for a clinical pause if we see three or more treatment emergent antibodies with amustaline specificity without evidence of hemolysis in patients receiving INTERCEPT- treated RBCs in our RedeS study. We will now be allowed to continue study enrollment for the RedeS study while we investigate the clinical significance of the antibodies. If we determine that there is no clinical significance and no impact on patients, then there will be no impact on study enrollment. If treatment emergent antibody reactions associated with hemolysis are observed in any of our Phase 3 trials, the FDA will require us to place a clinical hold and we will need to investigate the underlying cause. Such investigations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product' s reputation and may force us to suspend or terminate development activities related to the red blood cell system in the U. S., which would have a material adverse effect on our business and business prospects. The trial has been further expanded to include a 6- month chronic phase for subjects requiring simple repeat transfusions and also to include up to thirty patients with Sickle Cell Disease requiring red cell exchange. Subjects that would qualify for inclusion into the chronic phase would be those with conditions such as Sickle Cell Disease, Thalassemia or Myelodysplasia. This expansion of study population requires the inclusion of additional sites beyond the nine currently engaged in the trial up to fifteen. RedeS is a double- blind, controlled, parallel group study where up to 800 subjects will be randomized to receive either 28 days, or 28 days plus 6 months of transfusion support with INTERCEPT- treated RBCs or conventional RBCs, with a primary endpoint of hemoglobin increment following transfusion. These data from the expanded RedeS study ~~will~~ **are expected to** support our chronic use assessment in our submission for approval to the FDA. We also received investigational device exemption, or IDE, approval from the FDA to initiate a Phase 3 clinical trial, known as the ReCePI study, that is designed to evaluate the efficacy and safety of INTERCEPT- treated RBCs in patients requiring transfusion for acute blood loss during surgery. Up to 600 subjects are expected to be transfused in up to 19 participating sites in the U. S. Subjects will be randomized on a 1: 1 basis either to the treatment arm transfused with RBCs treated with or to the control arm transfused with conventional RBCs. The primary efficacy endpoint is the proportion of subjects experiencing acute kidney injury as an assessment of RBC efficacy in providing tissue oxygenation, measured as an increase in serum creatinine compared to pre- surgery, baseline levels within 48 hours after the surgery. Enrollment in the ReCePI study is **complete, though** ~~currently underway at 15 sites. Enrollment in~~ the ~~ReCePI~~ **database is still locked and therefore, we are still blinded to the data. We expect to report top- line data from the** study ~~began~~ **later** in ~~2019. Both RedeS and ReCePI trials have seen significant delays in subject recruitment due to COVID- 19. Several participating institutions implemented policies that limited clinical research activities and some eligible subjects have rejected participation because of~~ the **first quarter of 2024** ~~need for follow- up. Furthermore, some study sites have withdrawn from study participation. Additionally, delays in progressing new site commitments to participate in the trials were seen due to hospital clinical research staff reductions and institutional commitments to COVID- 19 related activities~~ . The RedeS and ReCePI studies are being funded as part of our agreement with BARDA. In addition to successfully conducting and completing the RedeS and ReCePI studies, we also understand that one or more additional in vitro studies will be required to be successfully completed and submitted to the FDA before the FDA will consider our red blood cell product for approval ~~. Should the COVID- 19 pandemic resurge in areas where we are enrolling patients, our ability to complete the clinical trials timely, or at all, may be jeopardized~~ . Additional information regarding our interactions with the FDA, our application for a CE Certificate of Conformity in the European Union for the red blood cell system, and potential future clinical development of the INTERCEPT Blood System in Europe and in the U. S. can be found under " Item 1A — Risk Factors " of this Annual Report on Form 10- K, under the risk factors titled " Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals or certification for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects " and " The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates

of Conformity, ” as well as generally under the heading “ Risks Related to Regulatory Approval, CE Certificates of Conformity and Oversight, and Other Legal Compliance Matters. ” INTERCEPT Blood System Technology Both our platelet system and plasma system employ the same technology. Platelet or plasma components collected from blood donors are transferred into plastic INTERCEPT disposable kits and are mixed with our proprietary compound, amotosalen, a small molecule compound that has an affinity for nucleic acid. The disposable kits are then placed in an illumination device, or illuminator, where the mixture is exposed to ultra- violet A, or UVA, light. If pathogens such as viruses, bacteria or parasites, as well as leukocytes, or white cells, are present in the platelet or plasma components, the energy from the UVA light causes the amotosalen to bond with the nucleic acid. Since platelets and plasma do not rely on nucleic acid for therapeutic efficacy, the INTERCEPT Blood System is designed to preserve the therapeutic function of the platelet and plasma components and IFC when used in human transfusions. The ability of amotosalen to form both cross- links between strands of nucleic acid and links to single nucleic acid strands results in a strong chemical bond between the amotosalen and the nucleic acid of the pathogens. The presence of these bonds is designed to prevent replication of the nucleic acid within pathogens, effectively inactivating the pathogens. A high level of inactivation has been demonstrated in a broad range of pathogens studied by us and others in laboratory testing. For instance, INTERCEPT has demonstrated inactivation of a number of single stranded nucleic acid- based viruses such as HIV, hepatitis B, hepatitis C (using a model virus), West Nile, chikungunya and certain influenza viruses. Following the inactivation process, residual amotosalen and by- products are reduced by more than 99 % through use of a compound adsorption device, which is an integrated component of the disposable kit. We have performed extensive toxicology testing on the residual amotosalen and its by- products and good safety margins have been demonstrated. Any remaining amotosalen which may be transfused, should any exist, is rapidly excreted by humans. Leukocytes, also known as white blood cells, are typically present in platelet and plasma components collected for transfusion and can cause adverse transfusion reactions as well as an often fatal disease called graft- versus host disease. Leukocytes, like pathogens, rely on nucleic acid for replication and cellular function. The INTERCEPT Blood System, with its combination of the amotosalen and UVA light, is designed to inactivate leukocytes in the same manner it inactivates pathogens. Like the platelet and plasma systems, the red blood cell system is designed to prevent pathogen replication by using a small molecule additive compound to form bonds with nucleic acid in pathogens that may be present in donated red blood cell collections. The red blood cell system is designed to preserve the therapeutic qualities of the red blood cells, which, like platelets and plasma, do not rely on nucleic acid for their therapeutic efficacy. The red blood cell system uses another of our proprietary compounds, amustaline. Unlike the platelet and plasma systems, the chemical bonds from amustaline are not triggered by UVA light, but instead, by the pH level of the red blood cell components. After mixture with the red blood cell components in plastic disposable kits and resulting nucleic- acid bonding, amustaline is designed to rapidly break down into a form that is no longer chemically reactive with nucleic acid. As with the platelet and plasma systems, a high level of inactivation in a broad range of pathogens has been demonstrated with the red blood cell system in the clinical setting. We plan on conducting additional pathogen- inactivation studies of the red blood cell system, broadening our understanding of the pathogens the system may be able to inactivate. By treating blood components with INTERCEPT within a day of collection, the inactivation of bacteria prevents bacterial growth that could create increased risk of inflammatory response or dangerous levels of endotoxins. Extensive clinical testing has been done on platelet and plasma products treated with the INTERCEPT Blood System, as well as post- marketing haemovigilance studies of the treated blood products in routine use. We believe that, due to their mechanisms of action, the platelet system, plasma system, and red blood cell system will potentially inactivate blood- borne pathogens that have not yet been tested with our systems, including emerging and future threats to the blood supply. We do not claim, however, that our INTERCEPT Blood System will inactivate all pathogens, including prions **or spores** , and our inactivation claims are limited to those contained in our product specifications. There can also be no assurance that INTERCEPT will inactivate even those pathogens where claims exist, in every instance or under every processing condition. Manufacturing and Supply We have used, and intend to continue to use, third parties to manufacture and supply the illuminators, components, disposable kits and inactivation compounds that make up the INTERCEPT Blood System for use in clinical trials and for commercialization. With the exception of certain components, we rely solely on Fresenius Kabi AG, or Fresenius, for the manufacture of disposable kits for the platelet and plasma systems. We rely on other contract manufacturers for the production of our reagents, inactivation compounds, compound adsorption components of the disposable kits, illuminators and other disposable kits or disposable accessories used in the INTERCEPT Blood System. We currently do not have alternate manufacturers for many of the components in our products or product candidates beyond those that we rely on, but we are in the process of identifying potential alternate manufacturers for several components, reagents and compounds. On May 2, 2022, we entered into the Second Amended and Restated Supply and Manufacturing Agreement, or the 2022 Agreement, with Fresenius Kabi AG, Fenwal France SAS, Fenwal International, Inc. and Fresenius Kabi Deutschland GmbH, or collectively, Fresenius, for the manufacture and production of disposable sets for the INTERCEPT Blood System until December 31, 2031. Under the terms of the 2022 Agreement, Fresenius is obligated to manufacture, and we are obligated to purchase, finished disposable kits for the platelet and plasma systems. The 2022 Agreement permits us to purchase sets for the platelet and plasma 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. Fresenius will expand manufacturing of the disposable sets to three production facilities, following qualification and licensure of such additional facilities. The term of the 2022 Agreement will automatically renew for successive two- year periods unless terminated by either party upon two years' prior written notice, in the case of the initial term, or one year prior written notice, in the case of any successive renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach. Pricing under the 2022 Agreement for the initial term is based on volume purchases by us and subject to an annual adjustment based on variation in a price index. Components of the compound adsorption devices used in our platelet and plasma disposable kits are manufactured by **many third- parties, including,** Porex Corporation, or Porex. **We and Porex have** ~~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 **currently** our sole supplier for ~~certain components of and manufacturing of the~~ compound adsorption devices. Under the amended and restated Porex agreement, we are no longer subject to a minimum annual purchase requirement; however, Porex has the right to terminate the agreement, upon twelve months' prior written notice, if annual production falls below a mutually agreed threshold. The amended and restated Porex agreement ~~was renewed in December 2021 and~~ will continue until December 31, 2024. Commercially viable alternatives, if ever available, are likely several years away. We also have an amended and restated supply agreement with Purolite LLC, formerly Purolite Corporation, or Purolite, for the supply of raw materials used to make the compound adsorption devices. The amended supply agreement expires in April ~~2024~~ **2025** , 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. **We have completed the** ~~Pursuant to a contract that we and Nova Biomedical Corporation, or Nova, entered into in September 2008, Nova had been~~ manufacturing **for** the current model of ~~illuminators for us. In February 2022, Nova completed a last time build of our current model~~ illuminator **and maintain an inventory** ~~, which is being phased out~~ of **those final devices** ~~manufacture due to obsolescence of certain components~~ . Although still in development, we have completed the redesign of the new illuminator, which is expected to take more than twelve months to obtain regulatory approval. Until such time as we obtain approval for the redesigned illuminator, if ever, the demand for illuminators may be higher than the remaining number of illuminators in inventory, resulting in possible customer allocations or loss of sales. ~~Our Nova~~ **We have contracts for certain critical components and for the manufacture of our new illuminator. However, we do not know if those** ~~agreement~~ **agreements** ~~expired in September 2022~~ **will be active when our new illuminator is approved, if ever** . We operate with an amended manufacturing and supply agreement with Piramal, formerly, Ash Stevens, Inc., 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. The term of the amended manufacturing and supply agreement with Piramal ~~will expire on~~ **automatically renewed for two years until** December 31, ~~2023~~ **2025** 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 Piramal. Neither party has delivered notice of its intent to terminate the agreement. We and our contract manufacturers purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound adsorption devices and UVA illuminators from a limited number of suppliers. Some of those raw material suppliers require minimum annual purchase amounts. While we believe that there are alternative sources of supply for such materials, parts and devices, we have not validated or qualified any alternate manufacturers. As such, establishing additional or replacement suppliers for any of the raw materials, parts and devices, if required, will likely not be accomplished quickly and could involve significant additional costs and potential regulatory reviews that could limit our ability to supply customer demand. Certain regions that we sell into or may sell into in the future may give priority to those products that are manufactured locally in their jurisdiction. Our failure to meet these local manufacturing conditions may prevent us from successfully commercializing our product in those geographies. In addition, should we choose to manufacture locally in those jurisdictions, we would likely incur additional costs, may be unable to meet our quality system requirements or successfully manufacture products, and such activities will be a distraction from our current focus and operations. We have limited experience managing local manufacturing or working with local manufacturers in geographies or jurisdictions outside of our existing manufacturing operations. Marketing, Sales and Distribution The market for the INTERCEPT Blood System, including the U. S. market, is dominated by a relatively small number of blood collection organizations. Accordingly, there may be an extended period during which some potential U. S.- based customers may first choose to validate our technology or run experience studies themselves before deciding to adopt the system for commercial use, which may never occur. On October 1, 2021, all U. S. blood centers had to be compliant with the FDA guidance document, " Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, " or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U. S. blood centers for compliance under the Final Guidance Document, we cannot predict if U. S. customers will continue to adopt INTERCEPT over other options or at what levels. The American Red Cross represents the largest single portion of the blood collection market in the U. S. and is one of our key customers. While we believe adoption of the INTERCEPT Blood System will afford the American Red Cross with many benefits, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make. 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 a CE Certificate of Conformity ~~permitting~~ **permits** us to affix the CE Mark and sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute, or PEI, a German governmental regulatory body overseeing the marketing authorization of certain medical products, before being allowed to sell platelet and plasma components treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, several blood centers in Germany have received such requisite approvals and authorizations for the platelet system. Given the competitive nature of the German blood banking market, pricing for blood components is relatively low compared to other markets. INTERCEPT- treated platelets received national reimbursement in Germany in 2018 at a premium to untreated platelets. While this dynamic has the potential to generate economic value for blood centers in Germany, we cannot ensure that blood centers will understand or act on the potential economic and logistical benefits of using

INTERCEPT compared to conventional blood components as well as the potential safety benefits of INTERCEPT- treated blood components. Following the inclusion of pathogen- inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using the INTERCEPT Blood System. The review period for a new MAA can be twelve months or longer following submission and we cannot predict which German customers or potential customers will obtain an MAA. Without broad approvals of MAA applications obtained by potential German customers, our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect the potential for growth in that region. In addition, the reimbursement awarded to INTERCEPT in Germany may not be considered by German blood centers as attractive enough to implement pathogen reduction or cover the entirety of their blood center platelet collections which may in turn limit the market acceptance in Germany. We do not yet know if or how German blood centers plan to market and sell to their hospital customers nor do we have the ability to influence and control implementation in hospitals in Germany to administer pathogen- reduced platelets. Should German blood centers be ineffective in marketing and selling INTERCEPT- treated platelets or if hospitals object, or are slow implementing the steps needed to procure and administer pathogen reduced platelets, our market in Germany may be limited or be slow to realize acceptance. In France, broad product adoption is dependent on a central decision by the Établissement Français du Sang, or EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France. In October 2021, we entered into a new agreement with EFS to supply platelet disposable kits. The agreement for supply of platelet disposable kits provides for a base term of two years, with two options for EFS to extend for one year each. **EFS exercised the first option in June 2023.** In January 2020, we entered into a new agreement with EFS to supply plasma disposable kits and maintenance services for illuminators for a base term of two years, with two options for EFS to extend for one year each. EFS exercised the second option in ~~September~~ **August** 2022 **. EFS exercised the first supplementary extension of six months in January 2024** . While EFS has standardized production of its platelets using the INTERCEPT Blood System, we cannot provide any assurance that the national deployment of INTERCEPT to treat platelets in France will be sustainable, or that we will be able to secure any subsequent contracts with EFS or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contracts. If we are unable to continue to successfully support EFS' national adoption of the INTERCEPT Blood System for platelets, EFS' use of the INTERCEPT Blood System for Plasma or the final commercial terms of any subsequent contract for platelet or plasma disposable kits are less favorable than the terms under our existing contracts, our financial results may be adversely impacted. In England, decisions on product adoption are centralized in the National Blood Service, or NHSBT, which collects, tests, processes and supplies blood products to hospitals in England and North Wales. The National Blood Service has implemented bacterial detection for platelets for several years. We do not know when, if ever, the NHBST will consider adoption of a product for pathogen reduction, including INTERCEPT. In Japan, the Japanese Red Cross controls a significant majority of blood centers and exerts a high degree of influence on the adoption and use of blood safety measures. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. Before the Japanese Red Cross considers our products, we understand that we may need to complete certain product configuration changes, which may not be economically or technologically feasible for us to complete. The FDA has granted Breakthrough Device Designation and has since approved the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce the derivative product, pathogen reduced plasma, cryoprecipitate reduced. We have entered into manufacturing agreements with certain blood centers to produce IFC for us. In addition, we have entered into agreements with certain blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation. In order to successfully commercialize IFC, we will need to generate commercial use data in order to influence the market and sell directly to hospital users and blood center producers of cryoprecipitate ~~. We are adding to and reorganizing our existing commercial teams to commercialize IFC~~ . We do not know if IFC will be perceived as clinically, operationally, or economically attractive to hospital customers or at what price, if any, or if the investment needed to sell IFC will be sustainable. Should our sale of kits to produce IFC alienate our contracted manufacturing partners, it may put pressure on the pricing for IFC in the marketplace or limit commercialization of IFC in the U. S. Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of coverage and adequate reimbursement from governments, managed care payors, such as insurance companies, and / or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept **, may not have resources to adopt new technologies,** or may not have the budget to purchase INTERCEPT- treated blood products ~~. We understand that due to the COVID- 19 pandemic, many hospitals have consolidated, laid off workers or have filed for bankruptcy protection, and other hospitals may have such significant budget shortages that they are unable to afford pathogen- reduced blood components. In addition, some hospitals are seeing such a high influx of COVID- 19 cases, that, regardless of whether they have sufficient staff to handle the high case load, they may be unable or unwilling to allocate sufficient resources to implement a new technology such as INTERCEPT~~ . Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the federal and, in some cases, state levels, regulators, healthcare facilities and third- party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, commercial use of our products may not

be covered by governmental or commercial third- party payors for health care services and may never be covered. Even if we received national reimbursement for our products, we may not be able to ~~convince~~ **educate adequate numbers of** blood center customers ~~to change~~ **on the benefits of changing** their operating practices and produce INTERCEPT- treated platelets and plasma. In the U. S., we obtained HCPCS reimbursement codes for hospital outpatient billing and payment of INTERCEPT-treated platelets and plasma in 2015, and for IFC and the derivative, pathogen- reduced plasma, cryoprecipitate reduced in 2021. We cannot guarantee that the HCPCS codes for our products will be assigned payment rates in amounts sufficient to cover the cost of our products to hospital customers. The costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third- party payors, the costs and expenses specific to the INTERCEPT Blood System may not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and / or products at the site of patient care. Governmental or third- party payors may change reimbursement rates, year over year, or in reaction to submitted claims for reimbursement of costs and expenses related to blood components treated with INTERCEPT. If the costs to the hospital for INTERCEPT processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, or if reimbursement rates are insufficient or decreased in any given year for blood components treated with INTERCEPT, hospital billing and / or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products. We maintain a wholly- owned subsidiary, Cerus Europe B. V., headquartered in the Netherlands, which focuses its efforts on marketing and selling the INTERCEPT Blood System in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world. We have a small scientific affairs group in the U. S. and the Netherlands that supports our commercialization efforts as well as hospital affairs professionals, to help educate hospitals and physicians on our products, clinical trial history and publications. We have a small group of individuals to which we may add to in the future to market and sell IFC in the U. S. We have a small number of employees focused on servicing the markets in Asia-Pacific and Latin American regions and rely primarily on distributors to market and sell our products in those regions. In February 2021, we entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd., or ZBK, to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD., which we refer to as the JV, for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood transfusion for platelets and red blood cells in the People' s Republic of China. We own 51 % of equity in the JV. The JV will need to obtain regulatory approval for the INTERCEPT Blood System for platelets and red blood cells before it can begin commercializing in China. In order to obtain that regulatory approval, the JV may need to run additional clinical studies in China. We cannot assure you the JV will be successful in meeting the endpoint, once defined, or that it will ever receive regulatory approval. We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our products directly. In certain of these jurisdictions, we rely on these distributors to obtain any necessary in- country regulatory approvals, in addition to marketing and selling the INTERCEPT Blood System, providing customer and technical product support, maintaining inventories, and adhering to our quality system in all material respects, among other activities. Selected areas where we have entered into geographically exclusive distribution agreements include but are not limited to certain countries in the CIS, the Middle East, Latin America, and Southeast Asia. Our success in these regions is dependent on our ability to support our distributors and our distributors' ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements meaningfully contribute to our revenues. As such, declining performance or the outright termination or loss of certain distributor relationships could harm our existing business, may impact our growth potential, and could result in higher operating costs for us. As our distributors play a critical role in our commercialization efforts, we evaluate their performance on an ongoing basis. As we continue to evaluate our distributors, we may take further actions in the future which may have an impact on our operating results. In the past, we have transitioned certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors as well as transitioned some of these territories to a Cerus direct option ~~for EFS to extend for one year each sales effort~~ , which we believed would provide us with better visibility into and control of sales execution. We may undertake similar changes in the future. As a result, we may experience a decrease in the volume of INTERCEPT disposable kit sales for the impacted territories as outgoing distribution partners sell through their disposable kit inventory. In addition, any new distributors or our own direct sales force may require some time to develop the market with the same proficiency as previous distributors. We cannot provide assurance that any such changes will achieve the same level of operations or proficiency as previous distributors. Government Contracts We operate directly under three contracts with U. S. Federal Agencies, one with BARDA, one with the FDA, and another with the ~~Department of Defense, or~~ DoD. Revenue from the cost reimbursement provisions under our BARDA and the FDA 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. Our ability to recognize revenue under our contract with DoD for the development of pathogen reduced, lyophilized cryoprecipitate is based on the application of the cost- to- cost input method, which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs. Revenue is recorded as a percentage of the transaction price based on the extent of progress towards completion. 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, the FDA, and the DoD, 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 — **Exhibits and** Financial Statement Schedules — Financial Statements " of this Annual Report on Form 10- K for information on significant accounting policies related to our government contract revenue and other financial information for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~

. 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 **has come and** is expected **to continue** to come from our BARDA agreement, and if BARDA were to eliminate, reduce, delay, or object to extension for funding of our agreement, it would have a significant, negative impact on our government contract revenues and cash flows, and we may be forced to suspend or terminate our U. S. red blood cell development program or obtain alternative sources of funding " and " Unfavorable provisions in government contracts, including in our contracts with BARDA, FDA and DoD, 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 reduction 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 regulatory approval or certification 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 plasma derived fibrinogen concentrates. While we believe that IFC has many advantages over competitors, conventional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Hospitals may not perceive the advantage of IFC over the competing products, we may be ineffective in selling blood components directly to hospitals or be unable to ~~convince~~ **demonstrate to** hospitals ~~of~~ the economic or patient advantages relative to the competitors. In Europe, several companies, including Grifols, Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has received a Class II CE Certificate of Conformity and affixed the CE Mark for such system for both platelets and plasma and received Swissmedic approval for platelets treated with their system. MacoPharma has received a CE Certificate of Conformity for a UVC- based pathogen reduction product for platelets. MacoPharma completed a Phase 3 clinical trial in Germany to generate additional data for possible expanded approvals. We understand that Terumo BCT also developed a pathogen reduction system for whole blood receiving a Class II CE Certificate of Conformity. 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. 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 **. We are currently the only approved pathogen reduction product in the U. S. and therefore subject to Department of Justice, or DOJ, anti- trust oversight** . 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, our products would likely directly compete against its products 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~~ **educate** 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 or certifications for our products, and our ability to continue supplying quality and effective products to our customers and prospective customers. Patents, Licenses and Proprietary Rights Our commercial success will depend in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U. S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, ~~2022~~ **2023** , we owned ~~10~~ **11** issued or allowed U. S. patents and approximately ~~70~~ **112** issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2025 and 2040. 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~~ **that**

expire **later** ~~at various dates~~ in ~~2023 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 and certification for shelf lives ranging from 6 to 24 months. Our INTERCEPT Blood System for Cryoprecipitation has received regulatory approval and certification for a shelf life of 12 months. Although we have regulatory approval and certification for our products in most regions for up to a 24 month shelf life, the FDA has limited our platelet product to a six month shelf life and has asked for additional stability and aging data on newly manufactured lots ~~which~~ **. While we have generated stability data beyond six months, we** will ~~require us~~ **need to continue** to manage our U. S. supply chain closely until we ~~generate the requested data and~~ receive approval for longer shelf lives from the FDA. Illuminators and replacement parts do not have regulated expiration dates. We own raw materials, work- in- process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these finished goods and separately, components, held as work- in- process on our consolidated balance sheets, may potentially take over one year to sell or complete production before being utilized in finished disposable kits or illuminators. We maintain inventory based on our current and future 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** ~~Except for our active pharmaceutical ingredients, illuminators and certain raw materials used in the production of certain components, it~~ is not customary for our production cycle for inventory to exceed twelve months. Instead, we use our best judgment to factor in lead times for the production of our finished units to meet our current demands. Occasionally, we make last- time- buys of certain components or raw materials when such components or raw materials are considered at risk of being discontinued which allows us to ensure continuity of production and sufficient time to develop or identify, qualify and secure alternate raw materials or components. Inventory is recorded at the lower of cost, determined on a first in, first out basis, or market value. We use judgment to analyze and determine if the composition of our inventory is obsolete, slow- moving, or unsalable and frequently review such determinations. We rely on our direct sales team and distributors to provide accurate forecasts of sales in their territory. If our forecasts or those of our distributors are inaccurate, we could face backlog situations or conversely, may produce and carry an abundance of inventory that would consume cash faster than we have currently planned. Generally, we write- down specifically identified unusable **, expired** , 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~~ **forecasted demands** . Any write- down of our inventory to net realizable value establishes a new cost basis ~~and~~ **that** will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent **fiscal** 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 have also entered into agreements with certain blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation for their production of IFC and sale to their hospital customers. We may encounter pricing challenges and competition between the direct to hospital sales model and kit sale to blood center model. Research and Development Expenses A significant portion of our operating expenses is related to research and development, and we intend to maintain a balanced yet strong commitment to our research and development efforts. As we look ahead, we anticipate that ~~the~~ **maintaining compliance with** regulatory **requirements and obtaining** ~~submission processes related to~~ potential PMA supplements for the platelet and plasma systems or post market approval requirements will require substantial continued investment in research and development activities, as will our ongoing clinical, development and chemistry manufacturing and control, or CMC, work for our red blood cell system in Europe as well as our whole- blood initiative in collaboration with the FDA **and lyophilized IFC development initiative in collaboration with the DoD** . In the U. S., we expect to incur research and development expenses associated with pursuing licensure of the red blood cell system including the RedeS study, the ReCePI study and an additional Phase 3 clinical trial for chronic anemia, 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. Our ability to receive funding under our contract with DoD for the development of pathogen reduced, lyophilized cryoprecipitate is based on achievement of milestones which cannot be guaranteed. If we are unable to achieve any of those milestones, funding may be limited **, delayed** , less than expected, or non- existent for that particular milestone, which in all cases would negatively impact our cash flows and financial results. 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, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ . Government Regulation We and our products are comprehensively regulated in the U. S. by the FDA and by comparable governmental authorities in other jurisdictions. **We initially received a CE Certificate of Conformity in accordance with** ~~Our European Union investigational plan has been based on the INTERCEPT Blood System being categorized as Class III drug / device combination under~~ the MDD **for our platelet system** ~~. Medical devices, including INTERCEPT will need to be re- registered~~ and ~~approved under~~ **separately for our plasma system in 2002 and 2006. We CE Marked our products accordingly, and have regularly filed and obtained required extensions to continue to market** ~~the those new~~ **products in the EU and other countries that recognize the CE Mark. On May 26, 2021, the** MDR ~~which~~ entered into application ~~on May 26~~ , **repealing and replacing the MDD. In December** ~~2021~~ **2023 , we** ~~. We initially~~ received ~~a~~ CE ~~Certificate~~ **Certificates** of Conformity ~~for our platelet system and separately for our plasma system~~ in **accordance with the MDR to affix** ~~2002 and 2006, respectively. In March 2020, we received an extension of~~ the CE **Mark** ~~Certificate of Conformity~~ to ~~2024, under the MDD. While~~ our ~~current extension of registration is based on the MDD for the~~ platelet and plasma systems ~~, we cannot assure you that these products will timely meet the requirements of the MDR prior to the expiration of the CE Certificate of Conformity granted on the basis of the MDD~~ . ~~A~~ **We must receive a** separate CE Certificate of Conformity in accordance with the MDR ~~must be received~~ for the red blood cell system **and affix the related CE Mark to permit the product** to be sold in the European Union and in other countries recognizing the CE Mark. We filed our application for a CE Certificate of Conformity of the red blood cell system ~~in December 2018~~ under the **MDR** ~~MDD, and~~ in June 2021 ~~, we completed the process to resubmit our application under the new MDR~~ . **We have been notified** ~~However, we do not expect~~ that **all four modules of our submission have been reviewed by our notified body, TÜV SÜD. Furthermore, the Dutch Medical Evaluation Board, or CBG, the competent authority for our red blood cell product, has reviewed the relevant sections of our submission and have asked numerous questions. We will need to satisfactorily respond to those questions timely and with satisfactory data before our products will be considered for certification. We cannot predict when, if ever, our answers to those questions and the required data will support** a decision ~~under~~ **concerning certification. In addition, CBG has asked TÜV SÜD to assess** the ~~MDR~~ **need for consultation of additional substances contained within the INTERCEPT RBC Processing Set (Processing Solution and SAG- M Storage Solution). We cannot predict, when, if ever, we will be able to resolve the requirement for consultation, or complete the consultation, if required, and therefore whether a decision concerning the certification** will occur ~~for at least another 12 months, if ever~~ . In addition, France, Switzerland, Germany, and Austria require separate approvals for INTERCEPT- treated blood products. The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern, among other things, the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and pre- market clearance or approval of products subject to regulation. The steps required before a medical device may be approved for marketing in the U. S. pursuant to a PMA include: • preclinical laboratory and animal tests; • submission to the FDA of an investigational device exemption for human clinical testing, which must become effective before human clinical trials may begin; • appropriate tests to show the product' s safety; • adequate and well- controlled human clinical trials to establish the product' s safety and efficacy for its intended indications; • submission to the FDA of a PMA; and • FDA review of the PMA in order to determine, among other things, whether the product is safe and effective for its intended uses. The FDA has approved the platelet system for ex vivo preparation of pathogen- reduced apheresis platelet components in order to reduce the risk of TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion- associated graft versus host disease, or TA- GVHD. The FDA has also approved the plasma system for ex vivo preparation of pathogen- reduced, whole blood derived or apheresis plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion and as an alternative to gamma irradiation for prevention of TA- GVHD. We have also ~~recently~~ received FDA approval for the INTERCEPT Blood System for Cryoprecipitation, which uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency and to produce pathogen reduced plasma, cryoprecipitate reduced. We plan to conduct development activities, clinical studies and in vitro studies for our platelet system to expand our label claims in the U. S. As a condition to the FDA approval of the platelet system, we were required to conduct two post- approval studies of the platelet system studies- a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT- treated platelets; and a recovery study of platelets treated with the platelet system. The haemovigilance study has completed, met its end point, and results have been published in a peer- reviewed journal. **We have also** ~~However, we will need to successfully complete~~ **completed** the recovery and survival study of the platelet system **and have submitted the data to the FDA** . Should ~~we be unsuccessful in meeting~~ the ~~criteria~~ **FDA disagree with our conclusions** ~~for~~ **or require additional data** ~~the recovery and survival study~~ , use of the platelet system may be limited, require label and use restrictions or have a revocation or suspension of approval. In addition to these studies, the FDA has also required us to perform many studies to support changes to our products and to commit to perform other lengthy post- marketing studies, for which we will have to expend significant additional resources. In addition, there is a risk that post- approval studies will show results inconsistent with our previous

studies. Any modifications to the platelet and plasma systems that could significantly affect their safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in their intended use, manufacture, design, components, or technology requires FDA approval of a new PMA or PMA supplement. However, certain changes to a PMA- approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier' s decision. The FDA may not agree with our decisions regarding whether new submissions or approvals are necessary. Our products could be subject to recall if the FDA or other regulators determine, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. We will need to obtain regulatory approval of any future redesign of the illuminator before it can be commercialized. ~~In addition, certain solvents we used to make the plastic beads in the plasma kit compound adsorption devices are no longer available. We will need to qualify plastic beads produced with a new solvent prior to consuming available inventory levels.~~ Furthermore, in order to address the entire market in the U. S., we will need to develop and test additional configurations of the platelet system, including making the platelet system compatible with random donor platelets. Our failure to obtain FDA or foreign regulatory approvals of new platelet and plasma product configurations could significantly limit product revenues from sales of the platelet and plasma systems. With FDA approval of our platelet and plasma systems and the INTERCEPT Blood System for Cryoprecipitation, we are required to continue to comply with applicable FDA and other regulatory requirements related to, among other things, labeling, packaging, storage, advertising, promotion, record- keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory ~~agency~~ **authority** requirements, including, in the U. S., ensuring that quality control and manufacturing procedures conform to FDA- mandated current Good Manufacturing Practice, or cGMP, and Quality System Regulation, or QSR, requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections. The manufacturing facility which produces our platelet and plasma systems was recently audited by the FDA. While there were not objectionable conditions observed during the audit, the FDA or other regulatory ~~agencies~~ **authorities and Notified Bodies** may inspect and audit facilities manufacturing or products or components at any time. Complying with and resolving any audit findings may result in additional costs, changes to our manufacturers quality management systems or both. Failure to timely resolve and comply to audit findings, if any, may result in enforcement actions and may result in a disruption to the supply of our products. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. **Similar requirements and considerations apply in the EU for our platelet and plasma systems that have been CE Marked in accordance with the MDR.** The changes to the regulatory system implemented in the EU by the MDR ~~include~~ **have** stricter requirements for clinical evidence and pre- market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. ~~We are also required to provide clinical data in the form of a clinical evaluation report.~~ Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfill these obligations ~~or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations~~ to merit **the continued use of** a CE Certificate of Conformity under the MDR. We are also required to report certain adverse events and production problems, if any, to the FDA, competent authorities of the EU Member States and Notified Bodies, and foreign regulatory authorities, when applicable, and FDA, competent authorities of the EU Member States, or other foreign regulatory authorities may require us to recall products as a result of adverse events or production problems. Additionally, we are required to comply with requirements concerning advertising and promotion for our products. For example, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off- label, uses. If the FDA, competent authorities of the EU Member States, or other foreign regulatory authorities determine that our promotional materials or training constitute promotion of an off- label use, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state, competent authorities of the EU Member States, or foreign authorities might take action if they consider our promotional or training materials to constitute promotion of an off- label use, or a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. Although our policy is to refrain from statements that could be considered off- label promotion of our products, the FDA, competent authorities of the EU Member States, or another regulatory agency could disagree and conclude that we have engaged in off- label promotion. In addition, the off- label use of our products may increase the risk of product liability claims. We are also subject to other broadly applicable fraud and abuse and other healthcare laws and regulations, including anti- kickback, health care professional payment transparency, and health information privacy and security laws, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute our products. Any enforcement action brought by a federal, state or foreign authority could result in significant civil, criminal and / or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private " qui tam " actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, administrative burdens, diminished profits and future earnings, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement. In addition, our reputation could be damaged and adoption of the products could be impaired. Further discussion of the health care laws and regulations that may affect our can be found in " Item 1A — Risk Factors " of this Annual Report on Form 10- K, under the risk factor titled: " We are subject to

federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business. ” CBER is the center within the FDA principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our blood safety products, CBER also regulates the blood collection centers and would regulate any blood products that they prepare using the INTERCEPT Blood System. Many U. S.- based blood centers have completed and obtained site- specific licenses from CBER that allows them to make INTERCEPT- treated blood products available to their interstate hospital customers. Any significant product change that we make may require amendments or supplements to those site- specific licenses that could limit availability of INTERCEPT- treated blood products until the amendment or supplement is approved. Additionally, hospital customers of ours or of any of our blood center customers may need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT- treated products into their inventories or may need to amend or adjust those codes in connection with a significant product change that we make, which may adversely impact our ability to sell products in the U. S. Increasingly, the competent authorities of other countries are also developing equivalent rules and obligations. We supply the INTERCEPT Blood System for Cryoprecipitation to select blood centers that manufacture IFC for us. We plan to sell the finished IFC made by our manufacturing blood center partners directly to hospitals. Similar to our platelet and plasma products, any blood center manufacturing IFC will need to complete their process validations and obtain site- specific licenses from CBER before we or they can sell finished IFC to hospital customers outside of the states producing IFC. While ~~one~~ **three** of our manufacturing partners **have** received ~~its~~ **a** BLA from CBER ~~in 2021~~, we plan to continue working with our other U. S.- based blood centers manufacturing partners to support these activities and any delay in obtaining these licenses would adversely impact the nationwide availability of our finished IFC in the U. S **. In late 2023, we learned that Octapharma filed a complaint against the FDA regarding BLAs received by our manufacturing partners. While we understand that the complaint has been settled, it has and may continue slowing the licensure of additional BLAs. Until additional BLAs are issued to our manufacturing partners, we may not have enough production capacity to supply demand, especially in states outside of the home states of our manufacturing partners** . In addition, we have entered into certain agreements with blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation kits which will allow those blood centers and blood center affiliate organizations to produce finished IFC for their own sales efforts to hospitals. The preclinical and clinical studies of the INTERCEPT Blood System for red blood cells have been conducted using prototype system disposables and devices. In addition to the clinical trials, a number of manufacturing and validation activities must be completed before we could sell the red blood cell product. We believe that in deciding whether the INTERCEPT Blood System is safe and effective regulatory authorities have taken, and are expected to take, into account whether it adversely affects the therapeutic efficacy of blood components as compared to the therapeutic efficacy of blood components not treated with INTERCEPT. Data from human clinical studies must demonstrate the safety of treated blood components and their therapeutic comparability to untreated blood components. In addition, regulatory authorities will weigh INTERCEPT’ s safety, including potential toxicities of the inactivation compounds, and other risks against the benefits of using the system in a blood supply that has become safer. We have conducted many toxicology studies designed to demonstrate the INTERCEPT Blood System’ s safety. There can be no assurance that regulatory authorities will not require further toxicology or other studies of our products. **As an example, CBG has asked TÜV SÜD to assess the need for consultation of additional substances contained within the INTERCEPT RBC Processing Set (Processing Solution and SAG- M Storage Solution). We cannot predict when, if ever, we will be able to resolve the requirement for consultation, or complete the consultation, if required, and therefore whether a decision concerning the certification will occur. Should we be required to generate data for these ancillary solutions, an approval decision may be delayed or not be received at all.** Based on discussions with the FDA and European Union 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 or commercial use data supporting our IFC product. Accordingly, prospective blood center manufacturing partners, hospitals or physicians may require additional commercially derived data before choosing to use IFC. Such studies may be costly 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, in the European Economic Area, or EEA, the EU General Data Protection Regulation, or GDPR (Regulation 2016 / 679) and the related national rules of the individual EEA countries, and in the United Kingdom, or UK, the UK GDPR. 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,~~ **Foreign data privacy and security laws (including but not limited to** the EU GDPR **and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example** , **the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring** a ~~broad~~ **legal basis for personal data processing; requiring the appointment of a** data protection ~~framework that expanded~~ **officer in certain circumstances; limiting** the ~~scope~~ **collection and retention** of **personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority (ies) and affected individuals; and mandating the appointment of**

representatives in the UK and / or the EU ~~data protection laws to entities that process the personal information of EU subjects, including employee data and clinical trial data that may be processed outside the EU entered into application. The EU GDPR introduced more stringent operational requirements than its predecessor legislation. Further, the Court of Justice of the European Union ruled~~ in **certain circumstances** ~~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 did not provide an adequate level of protection for data transfers from Switzerland to the United States. Alternative transfer mechanisms may be used, including the standard contractual clauses, or SCCs, while the authorities interpret the decisions and scope of the invalidated Privacy Shield, but the SCCs have also been called into question in the same ruling that invalidated Privacy Shield~~ . Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CCPA and became effective in 2023. Also, in June 2018, the State of California enacted the CCPA, which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA requires covered companies to provide new disclosures to California consumers (as that word is broadly defined in the CCPA), provide such consumers new ways to opt- out of certain sales of personal information, and allow for a new cause of action for data breaches. Further, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020, election. Effective starting on January 1, 2023, the CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. Further discussion of our regulatory and clinical trial status can be found in " Item 1A — Risk Factors " of this Annual Report on Form 10- K, under the risk factors titled " Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals or certification for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects " and " The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity, " as well as generally under the heading " Risks Related to Regulatory Approval, CE Certificates of Conformity and Oversight, and Other Legal Compliance Matters. " U. S. Health Care Reimbursement and Reform Our ability to commercialize our products successfully in the U. S. will depend in part on the extent to which coverage and appropriate reimbursement levels for the cost of the products and related treatment are obtained. The INTERCEPT Blood System is currently sold to U. S. based blood collection entities. Because our INTERCEPT processing kits 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 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~~ **For example** ~~otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently~~ , **on** ~~Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties as of January 1, 2019, for not complying with the ACA' s individual mandate to carry health insurance and delaying the implementation of certain ACA- mandated fees. On~~ June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued that the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the health care reform measures of the Biden administration will impact the ACA. In addition, there has been heightened governmental scrutiny to control the rising cost of healthcare. For example, such scrutiny has resulted in several recent congressional inquiries, presidential executive orders, and federal and state legislative activity designed to, among other things, bring more transparency to pricing and reform government program reimbursement methodologies for pharmaceutical products. Further discussion of the impact of health care reform and laws governing our business practices on our business can be found in " Item 1A — Risk Factors " of this Annual Report on Form 10- K, under the risk factors titled " Legislative, regulatory, or other healthcare reforms may make it more difficult and costly for us to obtain regulatory approval or CE Certificates of Conformity of our products and to produce, market and distribute our

products after approval or certification 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, ~~2022~~ **2023** , we had ~~309~~ **288** employees representing at least ~~39~~ **33** nationalities which includes ~~6~~ **8** dedicated commercial consultants. Approximately ~~61~~ **60** % of our global employees are women. In addition, of our U. S. employees, approximately ~~47~~ **49** % identify as non- white. Below is additional demographic information about our current employee base as of December 31, ~~2022~~ **2023** . Cerus Employees Salaried workforce ~~289~~ **274** Managers and above ~~73~~ **71** Part- time employees 12 Average age 45 **. 7** years Average length of service in years 5. ~~2~~ **9** years Employee turnover rate **December 31, 2022 to 2023** (voluntary) ~~14~~ **4** . ~~6~~ **8** % 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. In ~~2022~~ **2023** we **created** ~~began creating~~ an Employee Value Proposition, or EVP **,** ~~. This effort was led by an~~ **and updated** ~~employee taskforce identified as leaders within~~ our ~~organization. The EVP~~ **external website to include that** proposition ~~will be presented to stakeholders in early 2023~~ . Environmental, Social and Governance **(ESG)** As our business continues to grow and develop, we recognize the importance of making responsible business decisions for the benefit of all of our stakeholders, including our stockholders, customers, employees, partners, the communities in which we work and live, as well as the planet. To that end, ~~we are~~ in **2022** ~~the process of implementing a corporate Environmental~~ , **we finalized** ~~Social and Governance, or~~ **our first** ~~ESG, program and have engaged an outside consultant to help us conduct a~~ materiality assessment **with the aim to identify** and ~~develop a~~ **prioritize issues that are most critical for inclusion in our ESG** strategy ~~, including short, intermediate and long- term objectives~~ . ~~We have begun~~ **In 2023, we continued** implementing our ESG strategy and expect to begin reporting on our progress to our various stakeholders annually ~~commencing~~ **later** in ~~2023~~ **2024** . Diversity, Equity and Inclusion **(DE & I)** 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. **In 2023, we developed a new page on our website highlighting the diversity within our workforce. We are proud of the diverse workforce we have at all levels of our organization and now reflect that on our updated website. In addition, we enhanced our training for DE & I awareness by adding a five- module training program to our annual curriculum.** Compensation and Benefits We strive to provide pay, benefits, and services that are competitive ~~to~~ **with local** ~~market~~ **markets** and create incentives to attract and retain employees ~~globally~~ **across the globe** . Our compensation package includes market- competitive pay, broad- based stock grants and bonuses, health care and retirement benefits, paid time off, paid **parental** ~~maternity, paternity, and family~~ leave **, tuition reimbursement** , 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. **Cerus encourages employees to become involved in their community by volunteering for activities that enhance and serve the communities in which they live and work. In 2023, we added a Volunteer Paid Time Off Program allowing employees to get paid for volunteering at a charity of their choice. We also partnered with LinkedIn to provide unlimited access to LinkedIn Learning, a robust online training platform providing employees with continuous learning opportunities.** Hybrid Workforce **Beyond providing offices and infrastructure for our employees** ~~Following the disruption resulting from the COVID- 19 pandemic, we made the decision~~ to ~~become~~ **work, we also allow for remote work and have adopted** a hybrid ~~employer~~ **workplace policy** . We provide 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 hybrid employees to ensure that our employees are maintaining their physical, mental and emotional wellbeing ~~. In addition, we require all of our U. S. workforce to be vaccinated for COVID- 19~~ . Communication and Engagement We strongly believe that Cerus' success depends on employees understanding how their work contributes to our overall strategy. To this end, we utilize a variety of channels to facilitate open and direct communication, including: (i) periodic CEO update emails; (ii) open forums or All Hands Meetings with executives and other leaders; and (iii) regular ongoing update communications. Health, Wellness and Safety We are committed to the safety of our employees and communities, from laboratory operations to product development to supplier partnerships. Our goal is to achieve zero serious injuries through continued investment in and focus on our core safety programs and injury- reduction initiatives. We provide access to a variety of innovative, flexible, and convenient health and wellness tools, including annual flu shots **, an onsite gym for our Concord based employees and gym membership reimbursement** for all **of our global** employees. Available Information We maintain a website at www. cerus. com. We make available free of charge on or through our website our annual report on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K and amendments to those reports filed or furnished pursuant to Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission. Information contained on or accessible through our websites is not incorporated into, and does not form a part of, this Annual Report **on Form 10- K** or any other report or document we file with the SEC, and any

references to our websites are intended to be inactive textual references only. Financial Information Our financial information including our consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of stockholders' equity, consolidated statements of cash flows, and the related footnotes thereto, can be found under " Financial Statement Schedules " in Part IV of this Annual Report on Form 10- K. Item 1A. Risk Factors Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this annual report on Form 10- K. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business. Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations. Risks Related to Our Business and Industry ~~As global economic conditions recover from the COVID- 19 pandemic, business activity may not recover as quickly as anticipated, and it is not possible at this time to estimate the long- term impact that the COVID- 19 pandemic could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Continued remote work policies, quarantines, shelter- in- place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the effects of the COVID- 19 pandemic has materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses. Our sales efforts have historically involved significant in- person interaction with potential customers and distributors. With respect to our commercial activities, many of our hospital and blood bank customers have been hesitant to hold in- person meetings and continue to predominantly default to video conferencing. We have attempted to shift our sales activities to video conferencing and other similar customer interaction models and we have found these alternative approaches to have varying degrees of effectiveness in comparison to in- person sales efforts. In addition, many of our blood center and hospital customers and study sites have experienced staffing shortages. As a result, our sales and marketing efforts may be slower than expected or may require compliance with new credentialing certifications by our personnel. To the extent that our employees' ability to gain access to hospitals and their personnel remains limited, our commercial and sales interactions with those hospitals and our ability to introduce the INTERCEPT Blood System, including IFC, may continue to be impaired. In addition, many new customers and prospective customers have been impacted by the COVID- 19 pandemic and the following staffing shortages and their ability to on- board, train staff and implement new technologies, including INTERCEPT, has and may continue to be negatively impacted, which may lead such customers to instead choose to utilize other allowable methods with which they have more familiarity. Blood products are currently in extremely short supply which is impacting our customers. Customers whose operations have been impacted may have difficulty paying timely, may ask for price reductions or may delay or cancel public tenders. In addition, we understand that use of blood components may at times be negatively impacted which in turn, may negatively impact our potential product revenues from existing and prospective customers. Conversely, either due to the pandemic or ongoing concern about pandemic preparedness, certain existing, new and prospective customers have and may continue to ask for increased utilization of our products beyond what was forecast, and we may not be able to timely satisfy this increase in demand. In addition, while our suppliers have initiated business continuity plans with minimal expected disruption to our supply, we cannot be certain that any prolonged, intensified or worsened effect from the pandemic including the impact of emerging variant strains of the SARS- CoV- 2 virus would not negatively impact our supply chain. For example, Fresenius, our primary manufacturing partner for our disposable kits, had to reconfigure production workflow to safely produce INTERCEPT disposable kits and in the future, restrictions and other limitations on Fresenius' ability to conduct business in the ordinary course could negatively impact production of INTERCEPT disposable kits. All of the aforementioned could adversely affect our sales, operating results and overall financial performance. The COVID- 19 pandemic has also negatively impacted our ability to perform many clinical trials, studies and activities, including those covered by our agreement with BARDA. Our ongoing and anticipated clinical trials, the post- approval platelet studies, as well as studies to support label expansion for the platelet system in the U. S. have been delayed because of the COVID- 19 pandemic. For example, for a brief time, several of the hospital clinical trial sites for our RedeS and ReCePI studies suspended enrollment and several red blood cell production partners for the studies suspended production in order to conserve red blood cells to meet hospital demand during the pandemic. Many hospital sites are proceeding at a reduced capacity and many are experiencing staffing shortages. Accordingly, many of the activities expected by BARDA have been delayed and will require an extension of time and / or additional funds under the contract to complete. In addition, should the clinical studies and other activities supported by our BARDA contract get further delayed as a result of the COVID- 19 pandemic or otherwise, we will need to continue to rely on modifications and extensions to the BARDA agreement to fund the completion of those activities. Should BARDA disallow any modification or extension, we will need to pay for the costs to complete the activities or stop pursuing them altogether. Further delays may recur in the future if patient enrollment sites need to pause participation in our clinical trials and studies and we cannot be certain that further disruption due to the COVID- 19 pandemic can be avoided. Should the COVID- 19 pandemic persist, continue to worsen, or resurface at locations where we conduct studies or clinical trials, our ability to commence and complete any contemplated studies may be negatively impacted. Furthermore, should we be unable to deploy personnel, derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed under our contract with BARDA, our cash flows would be negatively impacted and / or we may have to initiate furloughs and layoffs, which would prove disruptive to our management and operations. This in turn would impair our ability to complete ongoing studies or commence new studies. The duration and extent of the impact from the COVID- 19 pandemic depends on future developments that cannot be accurately predicted at this time, such as the severity and transmission rate of the virus, including any variants, and the extent and effectiveness of containment actions. Despite the increased availability of vaccines, due to the continuing and evolving nature of the COVID- 19 pandemic and the potential for periods of increases in case numbers and emergence and spread of virus variants in markets and communities in which we and our customers operate, it is not possible for~~

~~us to accurately predict the duration or magnitude of the adverse impacts of the pandemic and its effects on our business, results of operations, or financial condition. In addition, while the potential economic impact brought by the COVID- 19 pandemic may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. As a result of stimulus programs put in place over the past two years, the U. S. and many countries are currently experiencing an inflationary environment. This has led to the U. S. Federal Reserve taking action to raise interest rates which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, our labor and vendor costs may rise in an inflationary environment, costs to transport our products may increase, and availability and timeliness of shipping may be negatively impacted. 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.~~ Our business is dependent on our ability to grow and sustain commercialization of the INTERCEPT Blood System in the U. S. Significant product revenue from customers in the U. S. may not occur consistently, if at all, if we are unable to demonstrate that our products are economical, safe and efficacious for potential customers. Similar to our experience in foreign jurisdictions, some potential customers in the U. S. have chosen to first validate our technology or conduct other pre- adoption activities prior to purchasing or deciding whether to adopt the INTERCEPT Blood System for commercial use, which may never occur. Further, new hospital customers of any of our blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT- treated products into their inventories, which may further delay customer adoption in the U. S. These administrative processes necessary for implementation of INTERCEPT are further strained due to the staffing shortages seen globally. On October 1, 2021, all U. S. blood centers were required to be compliant with the FDA guidance document, " Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, " or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U. S. blood centers for compliance with the Final Guidance Document, we cannot predict if U. S. customers will continue to adopt INTERCEPT over other options or at what levels. If we are unable to successfully support the commercialization of our platelet system to U. S. customers that have elected to use the INTERCEPT Blood System, then those customers may be required to adopt competing products in order to comply with the Final Guidance Document. Further, U. S. blood centers will be required to change their historical operating practices to conform to our product specifications, or they or their hospital customers may be required to elect more than one option under the Final Guidance Document in order to comply, or they or their hospital customers may choose competing products to comply with the Final Guidance Document. We may be unable to subsequently convert blood centers that chose competing products to the platelet system, which would limit our market potential. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the U. S., we may never generate substantial product revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected. In any event, our ability to successfully commercialize the INTERCEPT Blood System for platelets, plasma, and ~~cryoprecipitation~~ **IFC** in the U. S. will depend on our ability to: • adequately respond to the potential increased U. S. customer demand resulting from the implementation of the Final Guidance Document; • achieve market acceptance and generate product sales through execution of sales agreements on commercially reasonable terms; • enter into and maintain sufficient manufacturing arrangements for the U. S. market with our third- party suppliers; • support blood center manufacturing partners in obtaining Biologics License Application, or BLAs, for interstate commerce; • effectively create market demand for the INTERCEPT Blood System through our education, marketing and sales activities; • hire, train, deploy, support and maintain a qualified U. S.- based commercial organization and field sales force; • expand the labeled indications of use for the INTERCEPT Blood System and / or design, develop, test and obtain regulatory approval or certification 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~~ **IFC** in the U. S. is subject to a number of risks and uncertainties, including those related to: • the impact of macroeconomic developments, such as general political, health and economic conditions, including the Ukraine- Russia conflict, **the state of war between Israel and Hamas and the risk of a larger regional conflict,** economic slowdowns, recessions, inflation **, bank failures** , rising interest rates and tightening of credit markets on our business ~~; • the COVID- 19 pandemic and its effect on customers, hospitals, suppliers and our employees~~ ; • staffing shortages at blood centers, hospitals, study sites or suppliers; • the highly concentrated U. S. blood collection market that is dominated by a small number of blood collection organizations; • availability of **blood** donors; • regulatory and licensing requirements, including the FDA Center for Biologics Evaluation and Research, or CBER, licensing processes and its BLA requirements, that U. S.- based blood centers are required to follow in order to obtain and maintain the required site- specific licenses to engage in interstate transport of blood components processed using the INTERCEPT Blood System; • changed or increased regulatory restrictions or requirements; • our ability to meet regulatory requirements for any changes to our products, including component composition, manufacturing process, and location; • the amount available for reimbursement pursuant to codes we have obtained under the Healthcare Common Procedure Coding System, or HCPCS, or New Technology Add- On Payment, or NTAP, and pricing for outpatient use of INTERCEPT- treated blood components; • any supply or manufacturing problems or delays arising with any of our suppliers, many of whom are our sole qualified suppliers for the particular product or component they manufacture, including the ability of our suppliers to maintain FDA approval to manufacture the INTERCEPT Blood System and to comply with FDA- mandated current Good Manufacturing Practice, or cGMP, and Quality System Regulation, or QSR, requirements **and foreign equivalents** ; • our and our suppliers ability to produce sufficient quantity of product to meet the growing demand for our products ~~, especially in light of the Final Guidance Document~~ ; • any supply or manufacturing problems or delays arising from our customers third- party suppliers whose products are used in combination and compliance with our products including customers third- party suppliers'

ability to maintain FDA approval to manufacture the INTERCEPT Blood System and to comply with FDA- mandated cGMP and QSR requirements; • ability **to contract with, maintain and add additional blood center manufacturers for the production** of ~~our~~ **IFC and for the** contracted blood center manufacturing partners to produce IFC at sufficient quantities and at acceptable quality levels **; • ability of blood center manufacturing partners to obtain and maintain BLAs allowing produced IFC to be shipped out of state to meet demand** ; • 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, including those third- party suppliers' ability to maintain FDA or other regulatory approvals to manufacture their products and to comply with FDA- mandated cGMP and QSR requirements **and foreign equivalents** ; • our ability to obtain patents, protect trade secrets, prevent others from infringing on our proprietary rights, and operate without infringing the proprietary rights of third parties **; • existing and potential future competitive threats, including complaints, litigation or other such disruptive practices, regardless of merit** ; • 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 order to maintain or 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. Despite having claims elsewhere for use of INTERCEPT- treated platelets up to seven days, we have not been able to satisfy the FDAs requirement to obtain a seven- day storage claim for INTERCEPT- treated platelets. As a result, customers or prospective customers may adopt competing solutions if they perceive that: • the loss of platelets leads to increased costs, or the perception of increased costs for our customers; • the use of our product in any way constrains the availability of platelets due to platelet loss; • our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusable unit; ~~or~~ • our process requires changes in blood center collection processes or clinical regimens to address platelet loss **; or • our products may never receive approval for storage of platelets beyond five days** . Additionally, existing customers may not believe they can justify any perceived operational change or inefficiency either generally or in conjunction with a blood component availability shortage. This concern may be exacerbated during **any** ~~the current~~ blood shortage crisis **, which the U. S. is currently facing** . Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post- transfusion platelet counts (according to a measurement called " corrected count increment ") and may be more effective than transfusion of INTERCEPT- treated platelets. Although certain other studies demonstrate that INTERCEPT- treated platelets retain therapeutic function comparable to conventional platelets, prospective customers may choose not to adopt our platelet system due to considerations relating to corrected count increment or other factors. **In addition, while our platelet system is used outside of the U. S. to treat whole blood derived, pooled buffy- coat collected platelet units, the FDA does not currently allow buffy- coat platelets and therefore our ability to treat U. S. collected platelets is limited to those collected via apheresis. Given the current shortage of platelets in the U. S., hospitals may not discriminate about which platelet products they receive, which may result in less demand for INTERCEPT- treated products and therefore less urgency for blood centers to adopt or increase INTERCEPT- treated platelets.** The INTERCEPT Blood System does not inactivate all known pathogens, which may limit its market adoption. For example, our products have not been demonstrated to be effective in the reduction of certain non- lipid- enveloped viruses, including hepatitis A and E viruses, and human parvovirus B- 19, due to the biology of these viruses. Although we have shown high levels of reduction of a broad spectrum of lipid- enveloped viruses, INTERCEPT' s inability to inactivate, or limited reduction of certain non- lipid- enveloped viruses may negatively impact the decision to adopt by prospective customers. Similarly, although our products have been demonstrated to effectively inactivate spore- forming bacteria, our products have not been shown to be effective in reducing bacterial spores once formed. Furthermore, due to limitations of detective tests, we cannot exclude that a sufficient quantity of pathogen or pathogens beyond the detection limits may still be present in active form, which could present a risk of infection to the transfused patient. Should INTERCEPT- treated components contain detectable levels of pathogens after treatment, the efficacy of INTERCEPT may be called into question, whether or not any remaining pathogens are the result of INTERCEPT' s efficacy, the limitations of testing methodologies or other factors. Such uncertainties may limit the market adoption of our products. We have conducted studies of our products in both in vitro and in vivo environments using well- established tests that ~~are~~ **were** accepted by regulatory bodies. However, we cannot be certain that the results of these in vitro and in vivo studies accurately predict the actual results in humans in all cases. In addition, strains of infectious agents in living donors may be different from those strains commercially available or for which we have tested and for which we have received approval of the inactivation claims for our products. To the extent that actual results in human patients differ, commercially available or tested strains prove to be different, or customers or potential customers perceive that actual results differ from the results of our in vitro or in vivo testing, market acceptance of our products may be negatively impacted. If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced or delayed. For example, if adverse events arise from incomplete reduction of pathogens, improper processing or user error, or if testing of INTERCEPT- treated blood samples fails to reliably confirm pathogen reduction, whether or not directly attributable to the INTERCEPT Blood System, customers may refrain from purchasing our products. We have recently learned of instances where, following treatment with INTERCEPT, mishandling of the treated blood components has introduced environmental bacterium. We must help our blood center customers to remain **vigilant** or increase their vigilance in adopting best practices regarding blood component handling. Failure to adequately address this risk may call into question the efficacy of using

pathogen reduction. **We must report safety events to regulatory authorities, regardless of the imputability of 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 **. Hospital or other blood center customers may purchase IFC as a biologic from us or other blood centers which would be produced by blood center manufacturing partners of ours or another blood center. Should we receive product complaints on the produced IFC product, we may not be able to determine if a problem exists, or from where the problem originated** . Should customers feel that INTERCEPT treatment has a negative impact on the number of transfusable platelet units able to be manufactured from available donors, our ability to educate a blood center on the benefits of treating increasing proportions of its platelet units may be negatively impacted. Moreover, there is a risk that further studies that we or others may conduct, including the post- approval studies we ~~are~~ **were** required to conduct as a condition to the FDA approval of the platelet system, will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease using our products. In addition, some hospitals may decide to purchase and transfuse both INTERCEPT- treated blood components and conventional blood components, including IFC which we have very limited 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~~ **Hospitals may not have adequate staffing levels or may have competing priorities which could delay such system updates, perhaps indefinitely. Management of complex inventories** may require coordination between hospital suppliers, blood centers, or us, which in turn may cause delays in market adoption. In addition, customers may require certain changes to our products for any number of reasons. Complying with such requests may prove costly, and may create complexities surrounding the manufacturing of disposable kits, compliance with regulatory authorities, blood center usage, or inventory management. Conversely, failure to comply with such requests from customers may result in damage to our relationship or the potential loss of customer business. Market adoption of our products is also affected by blood center and healthcare facility budgets and the availability of coverage and adequate reimbursement from governments, managed care payors, such as insurance companies, and / or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT- treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the federal and, in some cases, state levels, regulators, healthcare facilities and third- party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, commercial use of our products may not be covered by governmental or commercial third- party payors for health care services and may never be covered. In addition, the costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third- party payors, the costs and expenses specific to the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and / or products at the site of patient care. Governmental or third- party payors may change reimbursement rates, year- over- year, or in reaction to submitted claims for reimbursement of costs and expenses related to blood components treated with INTERCEPT. If the costs to the hospital for INTERCEPT processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, or if reimbursement rates are insufficient or decreased in any given year for blood components treated with INTERCEPT, hospital billing and / or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products. In addition, even if we are able to achieve market acceptance in the U. S. or newly commercialized markets, we have provided and may in the future provide adoption incentives which may negatively impact our reported sales. The market for the INTERCEPT Blood System is highly concentrated with few customers, including often- dominant regional or national blood collection entities. Failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. Moreover, the market for pathogen reduction systems in the U. S. is highly concentrated and dominated by a small number of blood collection organizations. In the U. S., the American Red Cross represents the largest single portion of the blood collection market. Our ability to gain and maintain significant market penetration in the U. S. is largely dependent on utilization of INTERCEPT and distribution of INTERCEPT- treated blood components by the American Red Cross. The American Red Cross is a large organization. Given the large relative size of the American Red Cross, 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. Furthermore, should the American Red Cross order our products on an inconsistent basis, either by increasing or reducing overall utilization of the INTERCEPT Blood System or by building or depleting inventory levels they hold, our results of operations will be difficult to predict and may fall short of investor expectations. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption are made on a regional or even blood center- by- blood center basis, but depend on both local approvals and centralized regulatory approvals from the Paul Ehrlich Institute, or PEI. Obtaining these approvals requires

support and coordination from local blood centers, and may take a significant period of time to obtain, if ever. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other parts of the EU and other ~~third~~ countries where we rely on CE Certificates of Conformity and the CE Mark, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. Following the inclusion of pathogen- inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using our products. The review period for a new MAA can be 12 months or longer following submission and we cannot assure that any of the potential German customers submitting a new MAA will obtain it. We have invested in substantial commercial resources in Germany. Without approvals of MAA applications obtained by potential German customers, **or willingness of hospitals to seek reimbursement for pathogen-reduced platelets or for insurers to submit for the approved incremental reimbursement for pathogen- reduced platelets,** our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect our business, results of operations and financial condition and we may never realize a return on the investments we have made building out our commercial team in Germany. In addition, the reimbursement awarded to INTERCEPT in Germany may not be considered by German blood centers as attractive enough to implement pathogen reduction or cover the entirety of their blood center platelet collections which may in turn limit the market acceptance in Germany. Similar to the U. S., German blood centers will need to successfully market and sell to their hospital customers and understand and assist with the steps that are needed at the hospital level in Germany to administer pathogen- reduced platelets. While we have entered into agreements with Établissement Français du Sang, or EFS, to supply illuminators and platelet and plasma disposable kits and maintenance services for illuminators to EFS, we cannot provide any assurance that the national deployment of the platelet system in France will be sustainable or that we will be able to secure any contracts subsequent to our existing contract with EFS. If we are unable to continue to successfully support EFS' national adoption of the platelet system, EFS' use of the plasma system, our business, results of operations and financial condition may be adversely impacted. Our contracts with EFS do not contain purchase volume commitments and as such, ~~we may see variability in~~ **it is challenging to forecast with precision the** purchase levels ~~or an~~ **and** ~~altogether cessation~~ **product demand and fulfill EFS' orders** . In addition, we understand that EFS is inspecting and testing samples of each lot that it purchases from us prior to accepting the products shipped to fulfill orders. We have little insight into the time to test, testing conditions or ultimate results. Other customers may require similar conditions of purchase. Testing may have a negative impact on our ability to recognize product revenue either due to the time it takes to test and approve the release of a shipment or if the customer experiences problems with testing or if testing results are outside of the customer acceptance criteria. In Japan, the Japanese Red Cross controls a significant majority of blood transfusions and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. Before the Japanese Red Cross would consider our products, we understand that we may need to commit to making certain product configuration changes, which are currently under development but may not be economically or technologically feasible for us to accomplish. Significant increases in demand may occur given the concentrated nature of many of the largest potential customers and the potential for a mandate by public health agencies to adopt pathogen reduction technologies. Should those customers choose to adopt and standardize their production on the INTERCEPT Blood System or be required to adopt and standardize on the INTERCEPT Blood System, our ability to meet associated increases in demand will likely be constrained due to a variety of factors, including production capacity at approved manufacturing sites, supply issues, manufacturing disruptions, availability of disposable kits manufactured from the obsolete plastic materials in jurisdictions that have not approved the use of alternate plastics for our disposable kits, or other obsolescence of parts, among others. If we encounter sustained growth or accelerated growth, our production capacity may be strained, at least temporarily or should we encounter disruptions, supply shortages, or shipping delays, we may have to allocate available products to customers, which could negatively impact our business and reputation or cause those customers to adopt competing products. We may be unable to develop and maintain an effective and qualified U. S.- based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our products in the U. S. Successfully commercializing our products in the U. S. has taken more time than anticipated and has required us to continue to invest in commercialization efforts to build and maintain relationships, additional routine- use data and trust from the industry. We continue to need to attract, retain, train and support sales, marketing and scientific and hospital affairs personnel and other commercial talent. **Our** ~~For example, we still need to attract and retain~~ hospital affairs professionals ~~to help~~ **may be ineffective in** ~~educate~~ **educating** 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 **and / or effective** hospital affairs, sales and marketing capabilities for the U. S. market and we also may not be able to devote sufficient **effective** resources to the advertising, promotion and sales efforts for the platelet, plasma or cryoprecipitation systems in the U. S ~~. The current labor shortage in the U. S. and in many countries where we have commercialized our products has exacerbated the challenge of attracting and retaining these personnel~~ . In any event, if we are unable to develop and maintain an effective and qualified U. S. based commercial organization ~~in a timely manner or at all~~ , we may fail to realize the full sales potential of our commercial products in the U. S. which would materially and adversely affect our business, financial condition, results of operations and growth ~~prospectus~~ **prospects** . We have very limited experience selling directly to hospitals nor do we have prior experience or expertise complying with regulations governing finished biologics. The introduction of 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. **Furthermore** ~~In this regard~~ , ~~our~~ **contracting with individual hospitals is time consuming and is often a protracted and bespoke process. Our** blood center customers may view the sale of biologics directly to hospitals as a competitive threat, which may adversely affect our customer relationships, could negatively impact our business prospects and could result in loss of business and revenue. Conversely, we may also sell the disposable kits directly to blood centers for the manufacture of IFC for their own account or for hospitals with whom they already have contracts in place. As a result, we may be directly competing with these blood centers for the sale of IFC. These blood centers have more experience and existing contracts with hospitals and may be able to offer synergies that we cannot, each of which may negatively impact our ability to compete successfully. In addition, until we are successful in selling INTERCEPT Blood System for Cryoprecipitation kits to blood centers or affiliate organizations or hospitals with in- house blood centers, our ability to directly commercialize finished IFC throughout the U. S. is dependent on the approval of manufacturing site BLAs by the FDA **or the addition of an increased number of IFC manufacturing collaborations** . While certain sites have received their BLAs, we cannot be sure that all of the sites will receive such authorizations in a timely manner, if at all **. For instance, despite having several sites already with their BLAs, we understand one site submitted for a BLA over six months before hearing back from the FDA, who in their response, indicated it would take at least another twelve months to rule on the BLA. Such delays may impact our ability to supply IFC in sufficient quantities** . In addition, in order to market and sell finished IFC to hospital customers throughout the U. S., we may need to identify and validate additional manufacturing partners or sell INTERCEPT Blood System for Cryoprecipitation kits to blood centers or affiliate organizations or hospitals with in- house blood centers. We cannot guarantee that we will be able to successfully negotiate additional agreements with manufacturing partners on terms that are acceptable to us. IFC is a product derived from our INTERCEPT Blood System for plasma. As such, any supply disruptions or failures that could impact our plasma system will have a direct negative impact on the production of IFC. Such supply disruptions could negatively impact our ability to fulfill customer orders, which will have an adverse effect on our business reputation and the successful introduction and adoption of our new products. Further, unless or until we negotiate committed volume purchase agreements with our customers, we can provide no assurance that sales of IFC product will occur in a consistent or predictable manner. If we are unable to successfully market the **IFC** ~~INTERCEPT Blood System for cryoprecipitation~~ to hospitals or comply with unique regulations governing finished biologics, our ability to monetize and deliver the **IFC** ~~INTERCEPT Blood System for cryoprecipitation~~ will be negatively impacted which would materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, we may never achieve market acceptance and adoption of IFC by U. S. hospitals to generate product revenue sufficient to cover its costs. We may be liable and we may need to withdraw our products from the market if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials. Our insurance coverage may be inadequate to offset losses we may incur. We are exposed to potential liability risks inherent in the testing and marketing of medical devices and biologic products. We may be liable if any of our products cause injury, illness or death. Although we complete preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen ~~,~~ rare reactions or adverse side effects related to long- term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in preclinical and clinical testing could be discovered after a marketing approval, or CE Certificate of Conformity has been received or after affixing the CE Mark to our products. For example, in cases where we have obtained regulatory approval or have affixed the CE Mark to our products, we have demonstrated pathogen reduction to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. In addition, even if our products inactivate all pathogens in a blood product, it is often difficult to determine if pathogens are introduced after treatment with INTERCEPT due to blood center or hospital mishandling, shipping or other possibilities. For example, we have recently learned of instances where, following treatment with INTERCEPT, mishandling of the treated blood components has introduced environmental bacterium. We must help our blood center customers to remain **vigilant** or increase their vigilance in adopting best practices regarding blood component handling. Failure to adequately address this risk may call into question the efficacy of using pathogen reduction. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient or was a result of a potential defect or lack of efficacy of our products. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease **. We must report safety events to regulatory authorities, regardless of the imputability of our products** . 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. Although, we maintain an active safety monitoring platform with trained personnel, we cannot predict when, if ever, a safety event will occur or be able to timely or satisfactorily determine whether or not our product was a cause. We maintain product liability insurance, but do not know whether the insurance will provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis viruses. Although we believe that our safety procedures for handling and disposing of hazardous materials are adequate and comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result. A recall of

our products, either voluntarily or at the direction of the FDA, the competent authorities of an EU Member State, or another governmental authority, including foreign regulatory authority or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us. Any adverse event involving our products, whether in the U. S. or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. Under the FDA' s reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. We may initiate a product recall under our own initiative if any material deficiency in our product is found, such as a component failure, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues, or withdraw a product to improve device performance or for other reasons. If we do not adequately address problems associated with our products, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. Similar actions and obligations may be imposed by the competent authorities of an EU Member State, or a foreign regulatory authority. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future. Such events could impair our ability to supply our products in a cost- effective and timely manner in order to meet our customers' demands. We expect our products will continue to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use and may compete with future products that may be developed by others. Our success depends in part on our ability to respond quickly to customer and prospective customer needs, successfully receive and maintain regulatory approvals, and adapt to medical and technological changes brought about by the development and introduction of new products. Competitors' products or technologies may make our products obsolete or non- competitive. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. If competitive pathogen reduction products experience significant problems, customers and potential customers may question the safety and efficacy of all pathogen reduction technologies, including the INTERCEPT Blood System. Such questions and concerns may impair our ability to market and sell the INTERCEPT Blood System. Several companies have, or are developing, technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen reduction systems. A number of companies are specifically focusing on alternative strategies for pathogen reduction in platelets and plasma. These alternative strategies may be more effective in reducing certain types of pathogens from blood products, including certain non- lipid- enveloped viruses, such as hepatitis A and E viruses or human parvovirus B- 19, which our products have not demonstrated an ability to inactivate or have not demonstrated a high level of inactivation. If our customers determine that competitor' s products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community, market adoption of our platelet and plasma products may be adversely impacted. In addition, customers and prospective customers may believe that our competitors' products are safer, more cost effective or easier to implement and incorporate into existing blood processing procedures than INTERCEPT Blood System products. Moreover, regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets. In addition, while we believe that IFC has many advantages over competitors, traditional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Even if we are able to generate compelling data regarding the use of IFC over other products or traditional cryoprecipitate, hospitals may not perceive the advantage of IFC over the competing products and we may be ineffective in selling biological agents directly to hospitals or be unable to demonstrate the economic or patient advantages to customers relative to the competitors. Further, competitors may have more experience marketing and selling products directly to hospitals **and may try to impede the marketability of our products. In late 2023, we learned that Octapharma filed a complaint against the FDA regarding BLAs received by our manufacturing partners. While we understand that the complaint has been settled, it has and may continue slowing the licensure of additional BLAs. Until additional BLAs are issued to our manufacturing partners, we may not have enough production capacity to supply demand, especially in states outside of the home states of our manufacturing partners. A byproduct of producing IFC is pathogen reduced cryoprecipitate poor plasma. If we are unable to find a commercial outlet for pathogen reduced cryoprecipitate poor plasma, we will continue to incur costs to discard the byproduct, which negatively impact our operating results** . 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. **, though it represents the minority of collections. Outside of the U. S., our platelet systems are used to treat both apheresis and buffy coat collected platelets. Although there is currently a shortage of platelets in the U. S.,**

until buffy coat platelets are accepted by the FDA, use of our platelet system in the U. S. will be limited to apheresis collected platelets. Our platelet system is designed to work with platelets collected and stored in storage solutions, called InterSol and SSP , and for platelets suspended in 100 % plasma. Fresenius is the exclusive manufacturer of InterSol and MacoPharma of SSP , both widely- used PAS. Many of our customers and prospective customers use InterSol or SSP in connection with INTERCEPT treatment. Similarly, some of our customers combine multiple platelet or plasma components before treating the combined product with INTERCEPT. Further, blood centers using INTERCEPT must have access to those certain devices, blood bags, assays or platelet additive solutions that are compatible with our products. We have recently learned of concerns about manufacturers' ability to provide an uninterrupted supply of PAS solutions to our blood center customers. Should such a supply disruption occur, our customer' s ability to treat platelets using INTERCEPT may be negatively impacted or may require us to secure approval for and supply PAS, for which we do not currently have regulatory approval. We understand that several third- party manufacturers of pooling sets are planning to discontinue producing pooling sets due to the requirement to comply under the new European Union Regulation (EU) 2017 / 745, the Medical Device Regulation, or MDR. Our customers' ability to use our INTERCEPT products may be impaired should manufacturers of those products cease production or if our customers are unable to find an alternate pooling set meeting their quality and production requirement for their production of INTERECEPT- treated blood components. Moreover, in order to alleviate any disruption to our customers, we have chosen to stockpile pooling sets, which required use of capital for a marginally profitable non- core product. In addition, should other manufacturers of collection devices, compatible assays and blood bags, pooling sets or platelet additive solutions fail to obtain or maintain regulatory approval or a CE Certificate of Conformity necessary for affixing the CE Mark to ~~our~~ **their** ~~product~~ **products** under the MDR, experience unexpected production disruption, or decide to cease distribution of those respective products to customers and prospective customers, or prohibitively increase costs, our ability to sell the INTERCEPT Blood System may be impaired and acceptance within 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 **, known as triple dose collections** . While we have trained many customers to break down such donations to volumes and doses compatible with our products other prospective customers may not want to modify their operating practices and may therefore choose alternative compliant practices. In order to ~~address~~ **enable** these customers **to treat triple dose collections** , we would need to develop future configurations of the platelet system ~~to treat platelet donations with such processing parameters~~ , which is not in our current plans. We estimate that the majority of platelets used in the U. S. are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. **Some** ~~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 **the use of INTERCEPT in** a **manner** ~~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 may also need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations. Until we pursue and obtain approval of these additional product configurations, we will not be able to fully address those portions of the market, which limits our product revenue and adversely impacts our financial results** . In the U. S, our approved labels for the platelet system from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100 % plasma. While we are seeking to generate acceptable data for Amicus collected platelets stored in 100 % plasma, we cannot assure you that the data will be acceptable to the FDA or that we will receive timely approval, if ever. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U. S. market that can use our products. In addition, given that there is some loss of platelets using our product, blood centers may need to increase collection volumes in order to use our product. Given the current blood component shortage, increased collection volumes may not be achievable or use of INTERCEPT may be considered less efficient than other operating practices, particularly in regions such as the U. S. where we do not maintain a seven day platelet storage claim. **Platelet dose requirements vary greatly between regulatory agencies around the world. In areas where approved platelet dosage levels are relatively high, such as the U. S., any loss of platelets by using INTERCEPT may result in a lower produced yield at blood centers. Given the current shortage of platelets in the U. S., blood centers may not want to adopt or increase production of INTERCEPT- treated platelets if they feel it will impact their ability to comply with the relatively high dosage requirements required by the FDA.** Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the ~~platelet and~~ plasma systems. In addition, we will need to continue to generate acceptable data in order to conform with the evolving collection practices such as automated whole- blood collection. If we are unable to conform to evolving collection practices our ability to address those portions of the market may be compromised. ~~We may also need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations.~~ In any event, any failures or delays in obtaining FDA, CE Certificates of Conformity and other regulatory approvals for any new configurations **or product improvements** would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could materially harm our product revenue and prospects for potential future profitability. We are currently conducting multiple clinical trials for our products and product candidates and plan to commence additional clinical trials of our products and product candidates in the future. We cannot be certain that the design or conduct of, or data collected from, these trials will be sufficient to support FDA **approval** , a CE Certificate of Conformity prior to affixing a CE Mark or any

other regulatory approvals outside the U. S. If we fail to produce positive results in our ongoing or planned clinical trials, the development timeline and regulatory approval and commercialization prospects for our products and our product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, would be materially adversely affected. We do not know whether we will begin or complete clinical trials on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board, ministry of health or ethics committee approval to conduct a study at a prospective clinical site, delays in recruiting subjects to participate in a study, delays in the conduct of the clinical trial by personnel at the clinical site or due to our inability to actively and timely monitor clinical trial sites because of travel restrictions, extreme weather or other natural forces, terrorist activity or general concerns over employee safety. **For example** ~~In this regard~~, we ~~have~~ experienced delays in our RedeS and ReCePI studies related to the COVID- 19 pandemic ~~and other factors~~. ~~For example~~ **In addition**, some clinical sites for the RedeS study are located in areas that are subject to disruption by severe weather such as flooding, hurricanes or other natural forces such as earthquakes, which have delayed enrollment and progress of the RedeS study in the past. In addition, our ReCePI study in complex cardiovascular surgery patients had been slower to enroll due to a variety of factors including low frequency of administering red blood cells to the patient population and reticence to participate in research studies. If we are unable to enroll a sufficient number of patients ~~from~~ **for** the ~~ReCePI~~ **RedeS** study to generate the data needed for licensure, we will need to reach agreement with the FDA on a new pathway to generate sufficient data for the red blood cell system, including the potential for additional Phase 3 clinical trials beyond what is currently contemplated ~~with the RedeS and ReCePI studies~~. In any event, we cannot be certain that further delays in the RedeS ~~study, the ReCePI~~ study or other clinical trials will not occur. Criteria for regulatory approval in blood safety indications are evolving, reflecting competitive advances in the standard of care against which new product candidates are judged, as well as changing market needs and reimbursement levels. Clinical trial design, including enrollment criteria, endpoints and anticipated label claims are thus subject to change, even if original objectives are being met. As a result, we do not know whether any clinical trial will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical studies and clinical trials and products emerging from any successful trial may not reach the market for several years. Enrollment criteria for certain of our clinical trials may be quite narrow, further delaying the clinical trial process. For instance, clinical trials previously conducted using INTERCEPT- treated plasma for patients with thrombotic thrombocytopenic purpura lasted approximately four years due in part to the difficulties associated with enrolling qualified patients. In addition, enrollment criteria impacted the speed with which we were able to enroll patients in our European Phase 3 red blood cell system trial in chronic anemia patients, and may impact other studies. Given the need to phenotypically match donations and patients and the existing burden of managing the production and supply to sickle- cell anemia patients, donor recruitment in chronic anemia patients may be difficult or impractical, which may be costly or significantly delay or preclude our ability to obtain any FDA approval of our red blood cell system. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later and larger clinical trials or in the results of routine use. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful. We have conducted many toxicology studies to demonstrate the safety of the platelet and plasma systems, and we have conducted and plan to conduct toxicology studies for the red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities or Notified Bodies may require further toxicology or other studies to further demonstrate our products' safety, which could delay or preclude regulatory approval and commercialization. Furthermore, any major changes to components used in our products or configuration changes to our products may require additional toxicology studies which may not produce acceptable results. Beyond toxicology studies, changes to our products or the manufacturing process of our products may require additional aging and stability data in order to satisfy regulators and maintain historical label claims. For instance, despite having 24 month aging for our products in many territories around the world, the FDA has limited the shelf life of our platelet product to six months for any platelet kit produced using a new solvent for the manufacture of a component. **While we have produced and submitted stability data to support the shelf life of our products beyond six- months, until the FDA approves such data and allows for a longer shelf life, we will need to manage our supply chain closely which is time consuming and costly.** 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 **additional** ~~one or more~~ post- approval clinical or in vitro studies as a condition of approval ~~, such as~~ **. While we have completed** the **two** post- approval ~~clinical study~~ **studies required by the FDA, there is no guarantee** that we **will be able to** ~~completed~~ **complete** ~~in connection with the~~ **future studies required as a condition of** approval **. The** ~~of the platelet system and the additional~~ post- approval **studies** ~~study that~~ we ~~are~~ **have been** required to ~~conduct on recovery and survival of platelets suspended in 100 % plasma in connection with the expanded label claim that we received for the platelet system. In addition, the FDA has required that we successfully~~ complete ~~a recovery and survival study of platelets suspended in platelet additive solutions stored at five days. Each of these studies~~ and any additional studies that the FDA may require could involve significant expense, may require us to secure adequate funding to complete and may not be successful. In addition, enrollment of post- marketing studies may be

difficult to complete timely if customers of blood centers are reluctant to accept conventional, non- INTERCEPT- treated products once INTERCEPT products become available to them. Other regulatory authorities or Notified Bodies outside of the U. S. may also require post- marketing studies. Failure to successfully complete post- marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals. While we **have submitted** ~~are in the process of submitting~~ an application for a CE Certificate of Conformity prior to affixing a CE Mark to our red blood cell system, it has not been approved for marketing or commercialized anywhere in the world. Significant development and financial resources will be required to progress the red blood cell system into a commercially viable product and to obtain the necessary CE Certificate of Conformity and other regulatory approvals for **the product or any future iterations or changes to** the product. For instance, regulators or Notified Bodies may require clinical data for our red blood cell system under each collection and processing method using various additive or storage solutions before they would grant approval for any such configuration. The clinical data we have generated thus far and submitted for a Certificate of Conformity does not support multiple configurations of collection processes, storage solutions and kits. If we are required to and are ultimately unable to collect data under each configuration or if we limit our pursuit of certain configurations over others, our market opportunity may be limited. In any event, any failure or further delays in completing the development activities for the red blood cell system would prevent or continue to delay its commercialization, which would materially and adversely affect our business, financial condition, results of operations, growth prospects and potential future market adoption of any of our products, including the red blood cell system. In some instances, we are relying on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials and development activities for the red blood cell system. We do not control these third parties and, as a result, they may not treat our activities as their highest priority, or in the manner in which we would prefer, which could result in delays, inefficient use of our resources and could distract personnel from other activities. Additionally, if we, our contract research organizations, other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our trials may be deemed unreliable and the FDA or foreign regulatory agencies or Notified Bodies may require us to perform additional clinical trials before delivering a CE Certificate of Conformity or approving the red blood cell system for commercialization. We cannot assure you that, upon inspection, regulatory agencies will determine that any of our clinical trials comply with good clinical practices. We must also be able to demonstrate stability of our active compounds manufactured under the FDA' s cGMP regulations and similar requirements outside of the U. S. which meets release specifications **. Our contracted manufacturer has had a history of failure in manufacturing the active compound of the red blood cell system** . If we are unable to demonstrate an ability to manufacture according to our specifications under cGMP or similar requirements outside of the U. S. with acceptable stability data, we may be unable to satisfy regulatory questions and requirements which could prevent or delay the potential approval of or our ability to commercialize the red blood cell system. In addition, existing lots of these red blood cell compounds manufactured under cGMP may be dispositioned by regulators or ourselves as unsuitable for clinical use which would impact our ability to produce INTERCEPT- treated red blood cells for ongoing and future clinical trials and may require changes to the manufacturing process of our red blood cell compounds or new production of the compounds, all of which would be costly and time consuming and impact our ability to perform under our BARDA contract **. In addition to the two chemical components of the INTERCEPT RBC System, amustaline and glutathione, there are additional substances contained with the Processing Set (Processing Solution and SAG- M Storage Solution) that contain substances that may be considered as ancillary medicinal substances by either the Notified Body or the Competent Authority. If we are unable to reach resolution on the classification of the additional substances contained with the RBC System, any decision on our CE Certificate of Conformity application would substantially delay the timing of a decision on our CE Certificate of Conformity application, perhaps indefinitely** . In 2003, we terminated Phase 3 clinical trials evaluating a prior generation of the red blood cell system in acute and chronic anemia patients. The trials were terminated due to the detection of antibody reactivity to INTERCEPT- treated red blood cells in two patients in the 2003 chronic anemia trial. Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. While we successfully completed the European Phase 3 acute anemia clinical trial and the European Phase 3 chronic anemia clinical trial, we cannot assure you that the adverse events observed in the terminated 2003 Phase 3 clinical trials of our earlier red blood cell system will not be observed in current and potential future clinical trials using our modified process. We also cannot assure you that patients receiving INTERCEPT- treated red blood cells will not develop allergic reactions to the transfusion. We will need to successfully conduct and complete license enabling Phase 3 clinical trials in the U. S. and to generate sufficient chronic anemia data for licensure. Given the need to phenotypically match donations and patients and the existing burden of managing the production and supply to sickle- cell anemia patients, donor recruitment in chronic anemia patients may be difficult or impractical, which could significantly delay or preclude our ability to obtain any FDA approval of our red blood cell system. In any event, there can be no assurance that we will be able to successfully complete these prerequisite Phase 3 clinical trials or otherwise generate sufficient Phase 3 clinical data. In part, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. If treatment emergent antibody reactions associated with hemolysis are observed in any of our Phase 3 trials, the FDA will require us to place a clinical hold and we will need to investigate the underlying cause. Such investigations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product' s reputation and may force us to suspend or terminate development activities related to the red blood cell system in the U. S., which would have a material adverse effect on our business and business prospects. To date, several S- 303 antibody events without evidence of hemolysis have been detected in the RedeS and ReCePI studies. We do not yet know if the S- 303 antibody events were in the control or test arm, and we cannot provide any assurance that additional S- 303 antibody events will not occur, or if they do

occur, will not be clinically significant. We completed our European Phase 3 clinical trials of our red blood cell system for acute anemia patients and separately for chronic anemia patients. We filed our application for a CE Certificate of Conformity related to the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the resubmission of our application under the new MDR. The Notified Body has reviewed all four modules of our application for CE Certificate of Conformity of the red blood cell system, though delays can occur for multiple reasons, including due to ~~clock stops for~~ questions on our application for a CE Certificate of Conformity or work load for the Notified Body. Furthermore, the Dutch Medicines Evaluation Board ~~(~~**, or** CBG ~~)~~, the competent authority for our red blood cell product, has reviewed the relevant sections of our submission and have asked numerous questions. We ~~will need to satisfactorily respond~~ **cannot predict with certainty, when, if ever, our answers** to those questions ~~timely~~ and ~~with satisfactory data before our application will be considered for approval. We cannot predict when, if ever, we will be able to answer those questions and supply~~ the required data ~~or whether~~ **will support** a decision concerning certification ~~will~~**. In addition, CBG has asked TÜV SÜD to assess the need for consultation of additional substances contained with the INTERCEPT RBC Processing Set (Processing Solution and SAG- M Storage Solution). Should an assessment of the storage solution be required, we may see a delay in the decision concerning certification beyond** ~~occur~~ -- **our expected timing of the second half of 2024** . In addition, we are currently in discussions with our sole supplier of key components of the red blood cell system with respect to a dispute over its willingness to continue to supply us with such components, without changes, throughout the application process for our CE Certificate of Conformity. Because our CE Certificate of Conformity application under the new MDR for the red blood cell system is specific to this supplier' s existing manufacturing site and manufacturing processes, if we are unable to reach satisfactory resolution of this dispute, or if this supplier is otherwise unable or unwilling to supply us with these components using its existing manufacturing site and manufacturing processes, any decision on our CE Certificate of Conformity application would be **impacted and could be** delayed beyond our current expectations, and we may be required to engage and validate a new supplier for these components, which would substantially delay the timing of a decision on our CE Certificate of Conformity application, perhaps indefinitely. ~~Accordingly~~ **We continue to work with our supplier to ensure preparedness for an inspection to support the CE certification and future commercial manufacturing in the event of approval of our CE Certificate of Conformity application. However, the timing of the ultimate decision on our CE Certificate of Conformity application and the related timing at which we may be able to affix the CE Mark to our product, could impact our current supplier' s willingness to continue to supply us with these components, and could hasten our plans to engage and validate a new supplier of these key components, which will be costly and time-consuming. We cannot predict with certainty when we may receive a decision on our CE Certificate of Conformity application, if ever. While we expect we could receive an approval decision in the second half of 2024** , the timing of the ultimate decision on our CE Certificate of Conformity application and the related timing at which we may be able to affix the CE Mark to our product, remains subject to the satisfactory resolution of this dispute, including our current supplier' s willingness to continue to supply us with these components using its existing manufacturing site and manufacturing processes throughout our CE Certificate of Conformity application and afterwards, if obtained, or alternatively, the engagement and validation of a new supplier of these key components, and in any event will be based on questions about our application for a CE Certificate of Conformity and the timing of the responses, and we ~~do not otherwise expect a related~~ **cannot predict with certainty when we may receive an** decision ~~will occur for at least another 12 months~~ , if ever. Moreover, we do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to support a CE Certificate of Conformity, even if limited to a target patient population having chronic anemia. Furthermore, we do not yet know if the clinical data we have generated will be sufficient to satisfy the stricter standards imposed by the MDR. If such data is deemed insufficient, we may need to generate additional safety data in clinical trials to satisfy the MDR standards. We will likely need to generate additional safety and efficacy data in order to achieve broad label claim or market acceptance. In addition, the European Phase 3 clinical trials in acute, and separately, chronic anemia patients, may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. These data may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate non- inferiority of INTERCEPT red blood cells compared to conventional red blood cells and the significantly lower lifespan for INTERCEPT red blood cells compared to conventional red blood cells may limit our ability to obtain any regulatory approvals or certification in certain countries for the red blood cell system. A number of trial design issues that could impact efficacy, regulatory approval, certification and market acceptance will need to be resolved prior to the initiation of further clinical trials. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues, securing commercial manufacturing for sufficient volumes or **if our manufacturers continue to fail to be able to produce sufficient volumes of the active ingredients or if we are unsuccessful** in obtaining subsequent regulatory approvals or certification 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 or certification, our product development costs will increase, which may exceed the budgets or timeframe under our BARDA agreement or which costs may otherwise not be reimbursable to us under the BARDA agreement. Even if we were to successfully complete and receive approval or certification for our red blood cell system, potential blood center customers may object to working with a potent chemical, like amustaline, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system. If the red blood cell system were to face such objections from potential customers, we may choose to pay for capital assets, specialized equipment or personnel for the blood center, which would have a negative impact on any potential contribution margin from red blood cell system sales. Moreover, customers may not accept the manual configuration of the product and require us to develop a more

operationally scalable version of the system which would be expensive and may not be successful. Additionally, the use of the red blood cell system may result in some processing loss of red blood cells. If the loss of red blood cells leads to increased costs, or the perception of increased costs for potential customers, or potential customers believe that the loss of red blood cells reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, potential customers may not adopt our red blood cell system, even if approved for commercial sale. Risks Related to Regulatory Approval, CE Certificates of Conformity, and Oversight, and Other Legal Compliance Matters Our company, our products, and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic authorities, foreign authorities and Notified Bodies. 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 and Notified Bodies. Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer- facing business processes in order for the FDA and international regulatory authorities and Notified Bodies to approve them for commercial use. For our product candidates, we must provide the FDA and international regulatory authorities and Notified Bodies 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 and certifications 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, certifications 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 certifications or may not produce optimal transfusable blood components. For example, jurisdictions differ in the definition of what constitutes a transfusable unit of platelets and in certain jurisdictions, our approved label claims and the definition of a viable platelet unit for transfusion may allow for a significantly lower or higher platelet count per volume than certain jurisdictions may allow. This variability in platelet count per volume may result in differences in platelet quality once processed and stored using INTERCEPT, and if customers experience sub- optimal platelet quality following INTERCEPT treatment, they may limit their adoption of INTERCEPT or consider adoption of competing blood safety technologies over INTERCEPT. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval or certifications and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action. Outside of the U. S., regulations vary by country, including the requirements for regulatory and marketing approvals, certifications or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to technical documentation supporting the certification and CE Marking of our product, countries outside the EU may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, Singapore and elsewhere may require in- country clinical trial data, among other requirements, or that our products be widely adopted commercially in Europe and the U. S., or may delay such approval decisions until our products are more widely adopted. In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the U. S., Germany, Canada, Austria, Australia and other countries, applicable to prospective customers of INTERCEPT Blood System products and the blood centers that process and distribute blood and blood products. In those countries, blood centers and other customers are required to obtain approved license supplements from the appropriate regulatory authorities before making available blood products processed with our pathogen reduction systems to hospitals and transfusing physicians. Our customers may lack the resources or capability to obtain such regulatory approvals. Significant product changes or changes in the way customers use our products may require amendments or supplemental approvals to licenses already obtained. Blood centers that do submit applications, supplements or amendments for manufacturing and sale may face disapproval or delays in approval that could further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products. **We recently** ~~In March 2020, we~~ received ~~extensions of our CE Certificate~~ **certification under** ~~of Conformity for~~ the **MDR for the INTERCEPT Blood System for** ~~platelet~~ **platelets** and plasma ~~systems to 2024 that was issued on the basis of the MDD. We submitted our CE Certificate of Conformity application for approval of the platelet system under the new MDR in November 2021 and subsequently completed our CE Certificate of Conformity submission for the plasma system under the new MDR, but cannot currently assure you that our products will timely meet the requirements of the new MDR prior to the expirations of our CE Certificate of Conformity that was issued on the basis of the MDD. Our failure to meet the requirements of the new MDR could materially and adversely affect our business, financial condition, results of operations and growth prospects~~ . We or our customers have received approval for the sale and / or use of INTERCEPT- treated platelets and plasma within Europe in France, Switzerland, Germany and Austria. **Switzerland has** ~~However, we have recently learned that Swiss regulators will no longer accept~~ **accepted to unilaterally recognized** CE **Marked** ~~Certificates of Conformity issued on the basis of the MDR for EU based~~ medical devices ~~on the basis of the mutual recognition agreement concluded between the parties~~ . While we are currently in the process of completing the requirements to maintain regulatory approval of our products in Switzerland, we cannot assure you that we will be successful in doing so. In addition, we or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE Mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals due to changes in regulatory law, our inability to maintain compliance with regulations or other factors. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing

applications in order to obtain regulatory approval. If we or our customers are unable to obtain or maintain regulatory approvals for the use and sale or continued sale and use of INTERCEPT- treated platelets or plasma, market adoption of our products will be negatively affected and our business, financial condition, results of operations and growth prospects would be materially and adversely impacted. The advertising and promotion of medical devices in the EU is subject to the national laws of EU Member States applying the MDR, Directive 2006 / 114 / EC concerning misleading and comparative advertising, and Directive 2005 / 29 / EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Moreover, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products in the EU. We must comply with medical device reporting requirements, including the reporting of serious incidents including malfunctions related to our products and field safety corrective actions, as well as adverse events occurring during clinical investigations. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation or withdrawal of regulatory clearances, certifications or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. As a condition to the ~~initial~~ FDA approval of the platelet system, we were required to **conduct two** ~~submit data from a~~ post- approval **studies** ~~clinical study~~ of the platelet system – a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT- treated platelets ~~. While that post marketing~~ **; and a recovery and survival** study **of INTERCEPT** ~~was successful, we are also required to conduct a post- approval recovery and survival clinical study in connection with the label expansion approval for the use of the platelet system to treat~~ **treated** platelets suspended in 100 % plasma **and stored for five days. The haemovigilance study** ~~as~~ **was** ~~well~~ **completed, met its primary endpoint and** ~~as~~ **was accepted by FDA, and results have been published in** a **peer- reviewed journal. We have also completed the** recovery and survival study ~~of~~ **for INTERCEPT- treated** platelets suspended in ~~platelet additive solutions~~ **100 % plasma and** stored ~~at~~ **for** five days **and have submitted the study results to the FDA** . Successful enrollment and completion of ~~these additional~~ **any other** post- approval studies will require that we identify and contract with **study sites or** hospitals that have the desire and ability to participate and contribute to the study in a timely manner ~~and who are willing to purchase INTERCEPT- treated platelets from our blood center customers~~ , which we may be unable to do in a timely manner or at all. In addition, the FDA may also require us to commit to perform other lengthy post- marketing studies, for which we would have to expend significant additional resources, which could have an adverse effect on our financial condition and results of operations. In addition, there is a risk that post- approval studies will be unsuccessful or show results inconsistent with our previous studies. Should this happen, potential customers may delay or choose not to adopt the INTERCEPT Blood System and existing customers may cease use of the INTERCEPT Blood System. Failure to successfully complete post- marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals. We are also required to comply with applicable FDA and other regulatory post- approval requirements relating to, among other things, labeling, packaging, storage, advertising, promotion, record- keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory authorities' requirements, including, in the U. S., ensuring that quality control and manufacturing procedures conform to cGMP and current QSR requirements. We must also comply with requirements concerning advertising and promotion for our products. For example, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off- label, use. If the FDA determines that our promotional materials or training constitutes promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off- label use, or a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. In addition, our reputation could be damaged and adoption of the products could be impaired. If a regulatory authority or Notified Body suspects or discovers problems with a product, such as serious incidents, adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory authority may impose restrictions on use of that product, including requiring withdrawal of the product from the market. **For example the FDA has requested information on bacterial contamination of INTERCEPT- treated products in conjunction with their investigation of complaints stemming from contamination of manufacturing sites and blood centers.** Our failure to comply with applicable regulatory requirements could result in enforcement action by regulatory agencies, which may include any of the following sanctions: • adverse publicity, warning letters, fines, injunctions, seizure, consent decrees and civil penalties; • repair, replacement, recall or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products and regulatory strategies; • exclusion from participation in government programs, such as Medicare and Medicaid; • refusal to grant export or import approval for our products or refusal to allow us to enter into government contracts; • additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance; • withdrawing, suspension or variation in marketing approvals or CE Certificates of Conformity that have already been granted, resulting in

prohibitions on sales of our products; and • criminal prosecution. Any of these actions, in combination or alone, could prevent us from selling our products and harm our business. In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Should we obtain approval or a CE Certificate of Conformity for our red blood cell system, we will likely be required by regulators or Notified Bodies to collect additional data in patients receiving INTERCEPT- treated red blood cells. In addition, assuming approval or certification, we will be required to develop a registry of patients receiving INTERCEPT- treated red blood cells for future data collection and evaluation. To commence, enroll and complete such a registry, we may incur significant costs. Further, introducing and implementing use of such a registry may face data collection challenges or resistance from transfusing physicians, hospitals or patients. We cannot ensure that the data collected in such a registry would support continued use of INTERCEPT- treated red blood cells. In addition, the regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, increased operation costs or lower than anticipated sales. For example, complying with the new MDR will require considerable time, attention and effort by our manufacturers and us and may limit or delay any contemplated changes to our products or expansion of label claims. In addition, regulators have been impacted by the global staffing shortage, **as well as the volume of existing and new MDR filings, all of which** further ~~constraining~~ --- **constrain** their ability to review submissions timely. If we or our third- party suppliers fail to comply with the FDA' s or other regulatory authorities' or foreign regulatory authorities' good manufacturing practice regulations, it could impair our ability to market our products in a cost- effective and timely manner. In order to be used in clinical studies or sold in the U. S., our products are required to be manufactured in FDA- approved facilities. If any of our suppliers fail to comply with FDA' s cGMP regulations or otherwise fail to maintain FDA approval, we may be required to identify an alternate supplier for our products or components. Our products are complex and difficult to manufacture. Finding alternate facilities and obtaining FDA approval for the manufacture of the INTERCEPT Blood System at such facilities would be costly and time- consuming and would negatively impact our ability to generate product revenue from the sale of our platelet, plasma or cryoprecipitation system in the U. S. and achieve operating profitability. Our red blood cell system also needs to be manufactured in FDA- approved facilities, several of which are not currently FDA- approved. Failure of our suppliers to meet cGMP regulations and failure to obtain or maintain FDA approval will negatively impact our ability to achieve FDA approval for our products 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, our third- party suppliers and third- party suppliers of products or components used by our customers in combination with our products 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 products, all of which is costly and may require updating periodically. The FDA and other regulatory authorities, including international regulatory authorities and Notified Bodies, audit compliance with cGMP and QSR requirements through periodic announced and unannounced inspections of manufacturing and other facilities. These audits and inspections may be conducted at any time. The manufacturing facility which produces our platelet and plasma systems was recently audited by the FDA. While there were not objectionable conditions observed during the audit, the FDA or other regulatory authorities, including third country authorities and Notified Bodies, may inspect and audit facilities manufacturing our products or components or products and components of third- party suppliers used by our customers in combination with our products at any time. Complying with and resolving any audit findings may result in additional costs, changes to our manufacturers' quality management systems or both. Failure to timely resolve and comply to audit findings, if any, may result in enforcement actions and may result in a disruption to the supply of our products or other products or components used by our customers in combination with our products. In any event, if we or our suppliers fail to adhere to cGMP and QSR requirements, have significant non- compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA or other regulatory agency could take enforcement action against us, which could delay production of our products and may include: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • unanticipated expenditures to address or defend such actions; • customer notifications or repair, replacement, refunds, recall, detention or seizure of our products; • refusing or delaying our requests for premarket approval of new products or modified products; • withdrawing, suspension or variation of marketing approvals or CE Certificates of Conformity that have already been granted; • refusal to grant export or import approval for our products; or Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects. If we modify our FDA- approved or CE Marked products, we may need to seek additional approvals, or certification, which, if not granted, would prevent us from selling our modified products. Any modifications to the platelet, plasma or cryoprecipitation systems could be determined to significantly affect their safety or effectiveness, including significant design and manufacturing changes, or determined to constitute a major change in their intended use, manufacture, design, components, or technology which would require approval of a new premarket approval application, or PMA, or PMA supplement. Further, any modification to our plasma system may have an impact on the cryoprecipitation system, which may similarly require approval of a new PMA supplement. However, certain changes to a PMA- approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier' s decision. The FDA may not agree with our decisions regarding whether new submissions or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, we are redesigning the illuminators used in the platelet and plasma systems and may need to further redesign the illuminator. We will need to obtain regulatory approval of any future redesign of the illuminator

before it can be commercialized. Generating data from the new illuminator may be time consuming, expensive or unsuccessful. In addition, in order to address the entire market in the U. S., customers will need to change their operating practices to conform to our product specifications or we will need to obtain approval for additional configurations of the platelet system, as discussed in greater detail above under " Risks Related to Our Business and Industry — Our platelet and plasma products and product candidates are not compatible with some collection, production and storage methods or combinations thereof. " Should we decide not to pursue or otherwise fail to obtain FDA and foreign regulatory approvals of any new configurations, our ability to generate product revenue from sales of the platelet system may be impaired and our growth prospects may be materially and adversely affected. In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions or modify existing requirements for safety interventions, including safety interventions involving the use 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. For those products sold in the EU, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. ~~If a significant change is made to products for which CE Certificates of Conformities have been delivered on the basis of the MDD, we would no longer be able to rely on those CE Certificates of Conformities for purposes of placing the products on the EU market and would need to obtain CE Certificates of Conformity on the basis of the MDR.~~ Obtaining certification can be a time- consuming process, and delays in obtaining required future clearances, certifications or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property **, data we collect about trial participants in connection with clinical trials** , and sensitive third- party data. Our data processing activities may subject us to numerous data privacy and security obligations established in various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security, that affect our sales, marketing and other promotional activities by, among other things, limiting the kinds of financial arrangements we may have with hospitals, healthcare providers or other potential purchasers of our products. These laws are often broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. For example, within the EU, the control of unlawful marketing activities is a matter of national law and regulations in each of the EU Member States. There are a variety of organizations and entities within EU Member States which monitor perceived unlawful marketing activities. We could face civil, criminal and administrative sanctions if it is determined that we have breached our obligations in any EU Member State in respect of our marketing activities. Industry associations also closely monitor the activities of member companies. If these organizations or authorities name us as having breached our obligations under their regulations, rules or standards, our reputation would suffer and our business and financial condition could be adversely affected. In addition, there are numerous U. S. federal, state and local healthcare regulatory laws, and ~~equivalent~~ **similar** foreign laws, including but not limited to, anti- kickback laws, false claims laws, antitrust **,** privacy laws, and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, hospitals, blood centers, physicians, other healthcare providers, and our customers are subject to scrutiny under these laws. Violations of these laws can subject us to significant penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs, including the Medicare and Medicaid programs, or equivalent foreign 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 **and biologics** 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 **and biologics** manufacturers **and distributors** 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. Moreover, our business practices are also subject to regulation by national, regional, state and local agencies, including but not limited to the Department of Justice, Federal Trade Commission, HHS Office of Inspector General and other regulatory bodies. For example, on November 29, 2022, we received a civil investigative demand, or the CID, from the U. S. Department of Justice Antitrust Division, or the Division, inquiring regarding contracting and information exchange practices related to our products and services. Although we do not believe that such practices violate antitrust regulations, we are unable to predict how long this investigation will continue or its outcome. At this time, the Division has not initiated any claim or proceeding against us relating to these matters. We are working cooperatively with the Division and are currently in the process of responding to the CID. If the outcome of the CID is unfavorable to us, it may result in changes to our business practices, fines, penalties or administrative sanctions against us, negative publicity and / or other negative actions that could materially harm our financial performance and results of operations, as well as our stock price. In addition, we have incurred and we expect to continue to incur significant costs in connection with this investigation, regardless of the outcome, which could harm our ability to achieve our financial performance objectives. In addition, there has been a trend of increased U. S. federal, state and local regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payments Sunshine Act, imposes annual reporting requirements on device **and biologics** manufacturers **and distributors** 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device **and biologics** manufacturer **and distributor** 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. Outside the United States, interactions between medical devices companies and health care professionals are also governed by strict laws, such as national anti- bribery laws of European countries, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. We are also subject to domestic and foreign laws and regulations covering data privacy and the protection of health- related and other personal information. Domestic privacy and data security laws are complex and changing rapidly. Many states have enacted laws regulating the online collection, use and disclosure of personal information and requiring that companies implement reasonable data security measures. Laws in all states and U. S. territories also require businesses to notify affected individuals, governmental entities and / or credit reporting agencies of certain security breaches affecting personal information. These laws are not consistent, and compliance with them in the event of a widespread data breach is complex and costly. In the U. S., the California Consumer Privacy Act of 2018, or CCPA, gives California residents expanded rights related to their personal information, including the right to access and delete their personal information, and receive details about how their personal information is used and shared. These create an additional burden on us, as do the restrictions on " sales " of personal information that allow Californians to opt- out of certain sharing of their personal information. The CCPA prohibits discrimination against individuals who exercise their privacy rights, provides for civil penalties for violations and creates a private right of action for data breaches that is expected to increase data breach litigation. Similarly, the California Privacy Rights Act, or CPRA, **which** ~~when it becomes~~ **became** effective on January 1, 2023, ~~will restrict~~ **restricts** use of certain categories of sensitive personal information; further ~~restrict~~ **restricts** the use of cross- contextual advertising techniques; ~~establish~~ **establishes** restrictions on the retention of personal information; ~~expand~~ **expands** the types of data breaches subject to the private right of action; and ~~establish~~ **establishes** the California Privacy Protection Agency to implement and enforce the new law, as well as impose administrative fines. Other states have also enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and **also** become effective in 2023. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). In the ~~EU~~ **EEA** , the General Data Protection Regulation, or EU GDPR **and in the UK the United Kingdom' s implementation of the EU GDPR, the UK GDPR** , which ~~is~~ **are** wide- ranging in scope, imposes detailed requirements, in particular, in relation to the control over personal data by individuals to whom the personal data relates, the information that we must provide to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification, the legal bases for processing personal data, the exceptions that allow us to process special categories of personal data and the use of third- party processors in connection with the processing of personal data. The EU GDPR **and UK GDPR** also imposes strict rules on the transfer of personal data out of the ~~EU~~ **EEA and United Kingdom respectively,** and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to ~~€~~ 20 million **euros under the EU**

GDPR, 17. 5 million pound sterling under the UK GDPR, or **, in each case,** 4 % of the annual global revenues of the non- compliant company, whichever is greater. In addition ~~, under the EU GDPR~~, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. **In** ~~Further,~~ the ~~exit~~ **ordinary course** of **business** ~~the United Kingdom~~, **we may** ~~or UK, from the EU on January 1, 2020, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. The UK has implemented legislation similar to the GDPR, the UK GDPR, including the UK Data Protection Act, which provides for fines of up to the greater of 17. 5 million British Pounds or 4 % of a company' s worldwide turnover, whichever is higher. Additionally, the relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear following Brexit, including with respect to regulation of data transfers~~ -- **transfer** ~~between EU Member States and the UK. On June 28, 2021, the European Commission announced a decision of " adequacy " concluding that the UK ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued~~ personal data ~~flows~~ from **Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular,** the European Economic Area ~~, or EEA, to the UK. Some uncertainty remains, however, as this adequacy determination must be renewed after four years~~ and ~~may be modified or revoked in~~ the **United Kingdom have significantly restricted** ~~interim. We cannot fully predict how~~ the **transfer of personal** ~~Data~~ **data to** ~~Protection Act,~~ the **United States** ~~UK GDPR,~~ and other ~~UK data protection~~ **countries whose privacy** laws ~~or regulations may develop in~~ **it generally believes are inadequate.** ~~the~~ **Other** ~~medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the UK will be regulated. Certain~~ jurisdictions ~~have enacted~~ **may adopt similarly stringent interpretations of their** data localization ~~laws~~ and cross- border ~~personal~~ data transfer laws **. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law** , **such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (** which **allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we** could ~~make it more difficult~~ **face significant adverse consequences, including the interruption or degradation of our operations, the need** to ~~transfer information across~~ **relocate part of or all of our business or data processing activities to other** jurisdictions (such as **Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or** transferring **of** ~~or receiving~~ personal data **necessary to operate our business. Additionally, companies** that ~~originates in~~ **transfer personal data out of** the EEA ~~)~~ **and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups** . **Some** ~~Recent legal developments in Europe~~ **European regulators** have **ordered** ~~created complexity and compliance uncertainty~~ ---- **certain** ~~regarding~~ **companies to suspend or permanently cease** certain transfers ~~of personal data from the EEA. For example, on July 16, 2020, the Court~~ -- **out** of ~~Justice of the European~~ -- **Europe** ~~Union, or~~ **for allegedly violating** ~~CJEU, invalidated~~ the ~~EU~~ **GDPR' s cross** - **border** ~~U. S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to United States entities who had self- certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses, or SCCs, (a standard form of contract approved by the European Commission as an adequate personal~~ data transfer **limitations** ~~mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of SCCs must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK. The UK is not subject to the European Commission' s new SCCs but has published its own transfer mechanism, the International Data Transfer Agreement (" IDTA "), which enables transfers from the UK. In addition, additional measures may be required even when relying on SCCs or the IDTA, where the laws of the importer' s country do not offer an adequate level of protection, such as the United States~~ . The CCPA, CPRA and similar laws in other states, the EU GDPR, the UK GDPR and other international privacy laws have increased our responsibility and potential liability in relation to personal data that we process compared to prior law, including in clinical trials and employee data, and we may be required to put in place additional mechanisms to ensure compliance with these laws, which could divert management' s attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the EU GDPR and the UK GDPR, we may not be successful either due to various factors within our control or other factors outside our control. It is also possible that local courts and data protection authorities may have different interpretations of applicable law, leading to potential inconsistencies in application of these laws. If we are unable to implement sufficient safeguards to ensure that our transfers of personal information from the EEA or the UK are lawful, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal information from the EEA or the UK. Complying with our obligations under applicable privacy laws, regulations, amendments to or re- interpretations of existing laws and regulations, and contractual or other requirements relating to privacy, data protection, data transfers, data localization, or information security may require us to make changes to our services to enable us or our customers to meet new legal requirements, incur substantial operational costs, modify our data practices and policies, and restrict or otherwise impact our business operations. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data security, marketing or communications) by us or by the third parties on which we rely 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 enforcement actions, including investigations litigation, fines, audits, inspections and other penalties or adverse publicity, additional reporting requirements and / or oversight, bans on processing personal data and orders to destroy or not use personal data. Any of these events could have an adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; or substantial changes to our business model or operations. In addition, new regulations, legislative actions or changes in interpretation of existing laws or regulations regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. We are also subject to the U. S. Foreign Corrupt Practices Act and anti- corruption laws, and similar laws with a significant anti- corruption intent in foreign countries. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement. Any violation of these laws by us or our agents, distributors or joint venture partners could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. We currently operate in many countries where the public sector is perceived as being more or highly corrupt. Our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption activity, such as China, India and Russia. Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly. In addition, failure by us or our agents, distributors or joint venture partners to comply with these laws, rules and regulations could delay our expansion into high- growth markets, could damage market perception of our business and could adversely affect our existing business operations. Increased business in higher risk countries could also subject us and our officers and directors to increased scrutiny and increased liability. To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which have led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. In addition, most of these laws apply to not only the actions taken by us, but also actions taken by our distributors and other third- party agents, and healthcare providers with whom we interact. We have limited knowledge and control over the business practices of our distributors and agents, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition. Legislative, regulatory, or other healthcare reforms may make it more difficult and costly for us to obtain regulatory approval or CE Certificates of Conformity for our products and to produce, market and distribute our products after approval or certification 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 or certification 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 Patient Protection and Affordable Care Act, or ACA, continues to significantly impact the health care industry. Among other things, the ACA: • established a Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and • implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. There have been executive, judicial and Congressional challenges to numerous provisions of the ACA. For example, ~~legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA~~ on ~~certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate ". On~~ June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ~~PPACA~~ -- **ACA** marketplaces through plan year 2025. The IRA also eliminates the ~~"~~ **"** donut hole ~~"~~ **"** under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a manufacturer discount program. It is unclear how any such challenges and the healthcare reform efforts of the Biden administration will impact ACA and our business. The implementation of new health care legislation could result in significant changes to the health care system, which could have a material adverse effect on our business, results of operations, financial condition and growth prospects. ~~In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, triggering the legislation' s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect until 2031, unless additional congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.~~

More recently, there has been heightened governmental scrutiny in the U. S. to control the rising cost of healthcare. Such scrutiny has resulted in several recent presidential executive orders, congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to pricing and reform government program reimbursement methodologies for healthcare products. State legislatures are also increasingly passing legislation and implementing regulations designed to control the cost of healthcare, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. We expect that additional U. S. federal and state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. The changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre- market assessment of safety and performance, new classifications to indicate risk levels, requirements for third- party testing by Notified Bodies, additional requirements for the quality management system, traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of **the MDR or continued certification under** the MDR. Moreover, in the EU some countries may require the completion of additional studies that compare the cost- effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medical devices, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025 onward. Risks Related to Government Contracts A significant portion of the funding for the development of the red blood cell system **has come and** is expected **to continue** to come from our BARDA agreement, and if BARDA were to eliminate, reduce, delay, or object to extensions for funding of our agreement, it would have a significant, negative impact on our government contract revenues and cash flows, and we may be forced to suspend or terminate our U. S. red blood cell development program or obtain alternative sources of funding. **Our ability to be paid by the DoD is predicated on our ability to achieve the stated milestones in the agreement and for the DoD to agree with the successful completion of each.** We anticipate that a significant portion of the funding for the development of the red blood cell system in the United States will come from our agreement with BARDA. The agreement, including its subsequent modifications, provide for reimbursement of certain expenses incurred by us for up to approximately $ ~~245~~ **270** . ~~9~~ **2** 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 $ ~~148~~ **185** . ~~9~~ **5** million under the base period of the agreement and associated options. Accordingly, our ability to receive any of the unexercised $ ~~97~~ **84** . ~~0~~ **7** million in additional funding provided for under the BARDA agreement is dependent on BARDA exercising additional options under the agreement, which it may do or not do at its sole discretion. In addition, BARDA is entitled to terminate our BARDA agreement for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. In addition, activities covered under the base period and exercised options may ultimately take longer than is allowed or cost more than is covered by the BARDA contract. Exercised and unexercised options under the BARDA contract will likely require a longer performance period to complete than is remaining on our agreement; if we are unable to secure additional funding or allow for additional time for completion, we would have to bear the cost to complete the activities or terminate the activities before completion. In addition, should there be a temporary funding shortfall with any of the activities contemplated, we may need to cease, delay or defer completion of the activities until the funding shortfall is resolved, if ever. For example, we know that certain options are expected to run out of approved amounts under the agreement in the near- term. Should BARDA be unable to secure additional funds to support those ongoing costs timely, or at all, we will have to cease, delay, defer or pay for ongoing activities. We are uncertain how the current U. S. debt ceiling will affect BARDA funding. We have hired and maintain staffing, as well as having entered into agreements with third parties to perform activities associated with the BARDA contract. Should we be unable to fully utilize the personnel or third parties as planned, either because of BARDA funding or time limitations, or other reasons, we may be forced to bear costs that we had anticipated would be covered under the contract. Moreover, the continuation of our BARDA agreement depends in large part on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. BARDA may suspend or terminate the agreement should we fail to achieve key milestones, or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. The uncertainty regarding the after effects of the COVID- 19 pandemic, and its impact on participating blood centers, hospitals and their patients, severe weather or other natural disaster impacts to sites enrolling our clinical trials may all negatively impact our ability to complete our clinical trials. Our ability to meet the expectations of BARDA under our contract is largely dependent on our ability to attract, hire and retain

personnel with competencies that are in short supply. In addition, in many instances we must identify third- party suppliers, negotiate terms acceptable to us and BARDA and ensure ongoing compliance by these suppliers with the obligations covered by our BARDA agreement. If we are unable to provide adequate supplier oversight or if suppliers are unable to comply with the requirements of the agreement, our ability to meet the anticipated milestones may be impaired. There can also be no assurance that our BARDA agreement will not be terminated, that our BARDA agreement will be extended for existing exercised options or through the exercise of subsequent option periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under our agreement with BARDA. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U. S. Congress. The general economic environment and uncertainty, coupled with tight federal budgets, and the lack of congressional unanimity on the national debt ceiling and budget, has led to a general decline in the amount available for government funding. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of pathogen reduction technology. While BARDA has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID- 19, the availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. Furthermore, funding limitations may require certain activities to slow or be deferred which may be impractical to do. In addition, if we are unable to generate sufficient prerequisite Phase 3 clinical data, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U. S. may require additional capital beyond which we currently have. If our BARDA agreement is terminated or suspended, if there is any reduction or delay in funding under our BARDA agreement, or if BARDA determines not to exercise some or all of the options provided for under the agreement, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non- dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, or if we determine that the cost of alternative available capital is too high, we may be forced to suspend or terminate development activities related to the red blood cell system in the U. S. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed by BARDA, our cash flows would be negatively impacted, or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. This in turn would impair our ability to complete ongoing studies or commence new studies. In addition, under the BARDA agreement, BARDA will regularly review our development efforts and clinical activities. Under certain circumstances, BARDA may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such BARDA advice, overall red blood cell program delays and costs associated with additional resources for which we had not planned may result. Also, the costs associated with following such advice may or may not be reimbursed by BARDA under our agreement. Finally, we may decide not to follow the advice provided by BARDA and instead pursue activities that we believe are in the best interests of our red blood cell program and our business, even if BARDA would not reimburse us under our agreement **. We are reimbursed for costs and are compensated by the DoD based on achievement of stated milestones in the agreement. In order for the DoD to pay for our claimed costs and compensation, they must agree on the successful completion of each milestone. Should we be unsuccessful in satisfactorily completing the stated milestones or if we encounter delays or disputes with the DoD, our cash flows and anticipated results of operations will be negatively impacted** . 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~~ **agreements** with BARDA, **the** FDA and **the** DoD, 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 any of our government

contracts are 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. Our ability to receive funding under our contract with DoD for the development of pathogen reduced, lyophilized cryoprecipitate is based on achievement of milestones which cannot be guaranteed. If we are unable to achieve any of those milestones, funding may be limited, less than expected, or non- existent for that particular milestone, which in all cases would negatively impact our cash flows and financial results. 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 government contracts. 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 government contracts. 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 government contracts. 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 government contracts. To ensure proper administration of our government contracts, including management of third- party suppliers, consultants or contractors, we must invest and commit resources to undertake significant compliance activities. The diversion of resources from our development and commercial programs to these compliance activities, as well as the exercise by the U. S. government of any rights under these provisions, could materially harm our business. Laws and regulations affecting government contracts, including our agreements with BARDA, FDA and DoD, make it more costly and difficult for us to successfully conduct our business. Failure to comply with laws and regulations could result in significant civil and criminal penalties and adversely affect our business. We must comply with numerous laws and regulations relating to the administration and performance of our agreements. Among the most significant government contracting regulations are: • the FAR and agency- specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts; • the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti- Kickback Statute, the Procurement Integrity Act, the False Claims Act and the U. S. Foreign Corrupt Practices Act; • export and import control laws and regulations; and • laws, regulations and executive orders restricting the exportation of certain products and technical data. In addition, as a U. S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U. S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U. S. government may adjust our agreement- related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event that the government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, the government would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U. S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. In addition, under U. S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U. S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to **solely** private sector commercial companies. Risks Related to Our Reliance on Third Parties We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain and maintain any necessary in- country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may adversely affect our financial condition and results of operations. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of product revenue and our ability to accurately forecast our product supply needs. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, initial purchases of illuminators or INTERCEPT disposable kits by these third parties may not lead to follow- on purchases of platelet and plasma systems' disposable kits. We have a finite number of illuminators that can be produced under the current approved configuration before a redesigned and approved illuminator is available. Agreements with our distributors typically require the distributor to maintain quality standards that are compliant with standards generally accepted for medical devices. We may be unable to ensure that our distributors are compliant with such standards. Further, we have limited visibility into the identity and requirements of blood

banking customers these distributors may have. Accordingly, we may be unable to ensure our distributors properly maintain illuminators sold or provide quality technical services to the blood banking customers to which they sell **. In Russia and Belarus, our illuminators and related spare parts are subject to sanctions. We have a number of installed illuminators in Russia and Belarus that require routine maintenance and replacement of spare parts in order to remain in service. We recently obtained licensure in the U. S. to resume supplying new illuminators and spare parts to service existing illuminators installed in Russia and Belarus, under certain conditions and requirements. If we are unable to maintain our license or comply with the conditions and requirements in the license, we will be unable to sell new illuminators or provide spare parts to maintain the installed devices in Russia and Belarus, which would impact our financial results. Additionally, if new sanctions restrictions are placed on our ability to continue to support our business in Russia, Belarus, or other CIS countries, then we may decide to cease that business which would have a detrimental impact on our financial results, our reputation in those countries, and the eligibility of our Russian and Belarussian distributors to participate in public contracts** . Currently, a fairly concentrated number of distributors contribute a meaningful minority 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. In certain territories there may not be an alternate distributor capable of covering the entirety of the geography, in which case we may need to contract and manage multiple distributors for a region or a distributor and sub- distributor system. Such complexities will dilute our attention and may result in customer dissatisfaction. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in a particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end- user accounts directly rather than through distributors, we incur additional expense, our working capital is negatively impacted due to longer periods from cash collection from direct sales customers when compared to the timing of cash collection from our former distribution partners and we may be exposed to additional complexity including local statutory and tax compliance. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. In addition, in territories where new distributors are responsible for servicing end- user accounts, there will be a period of transition in order to properly qualify and train these new distributors, which may disrupt the operations of our customers and adversely impact our reputation and operating results. In certain cases where a terminated distributor holds title to illuminators placed in the field, we may choose to buy back the illuminators from the distributor to ensure continuity of service to those customers. If this were to occur, our recognizable product revenue would be negatively impacted. In February 2021, we entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd., or ZBK, to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD., or the JV, for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood system for platelets and red blood cells in the People' s Republic of China. We own 51 % of equity in the JV and consolidate the JV. The JV will need to obtain regulatory approval for the INTERCEPT Blood System for Platelets and Red Blood Cells before it can begin commercializing in China. In order to obtain that regulatory approval, the JV may need to run additional clinical studies in China. We cannot assure you the JV will be successful in meeting the endpoint, once defined, or be successful in meeting any other requirements or that it will ever receive regulatory approval. **If the JV is unable to obtain regulatory approval to sell INTERCEPT in China, our ability to grow our business and achieve significant revenues in China will be negatively impacted. We may be unable to realize a return on any investment in the JV or we may not be able to monetize any profit or otherwise generate meaningful value from our ownership of the JV.** We do not own our own manufacturing facilities, but rather manufacture our products using a number of third- party suppliers, many of whom are our sole suppliers for the particular product or component that we procure. We rely on various contracts and our relationships with these suppliers to ensure that the sourced products are manufactured in sufficient quantities, timely, to our exact specifications and at prices we agree upon with the supplier. For example, Fresenius is our sole supplier for the manufacture of finished disposable kits for the platelet and plasma systems. We also rely on other third- party suppliers for other components

and products that are currently our sole qualified suppliers for such components and products. In the event Fresenius or any of our other sole qualified suppliers refuses or is unable to continue operating under our supply agreements with them, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected. **Fresenius may have financial constraints or impose additional financial conditions on us.** We may also encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. Until we are able to generate data satisfactory to the FDA regarding the stability of platelet products using a component manufactured with a new solvent, our platelet product shelf life **is** ~~will be~~ limited to six months in the U. S., straining our supply chain and distribution to customers to supply product with sufficient remaining available shelf life. ~~Any unforeseen logistical issues may result in~~ **In some cases, our customers have experienced** increased outdated product which ~~would~~ negatively ~~impact~~ **impacts** our results of operations. In addition, our product supply chain requires us to purchase certain components in minimum quantities or make last time purchases of obsolete components and may result in a production cycle of more than one year. Significant disruptions to any of the steps in our supply chain process may result in longer productions cycles which could lead to inefficient use of cash or may impair our ability to supply customers with product. Moreover, the price that we pay to some of our suppliers is dependent on the volume of products or components that we order. If we are unable to meet the volume tiers that afford the most favorable pricing, our gross margins will be negatively impacted. Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons or may unilaterally change the formulations of certain commercially available reagents that we use, causing at least temporary interruptions in supply. Furthermore, suppliers producing third- party components which are used by our customers and are compatible for use in combination with our products may not be available for a variety of reasons, including manufacturing problems, regulatory delays or audit deficiencies. Should that happen, customers may not be able to use our product with alternate components for which our products are compatible, which in turn, may damage our business. In addition, we may need to identify, validate and qualify additional manufacturing capacity with existing or new suppliers. Further, customer demand for our platelet kits is likely to fully utilize the production capacity of our third- party manufacturer (s). Under the terms of our ~~new~~ 2022 Agreement, Fresenius will expand manufacturing of the components and disposable sets to multiple production facilities, following qualification and licensure of such additional facilities. If Fresenius experiences any delays in the qualification and licensure for its new production facilities, then our ability to continue to grow the platelet business will be impaired and our supply and mix of platelet kits or plasma kits will be adversely impacted. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill and potentially irreversible loss of momentum in the marketplace. Although we are actively evaluating alternate suppliers and **have** ~~working with suppliers to make~~ **made** ~~the~~ **and plan to continue making** capital investments to operationalize additional sites within our existing supplier' s networks for certain components and finished kits, we do not have qualified additional sites or suppliers or capacity beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. In addition, suppliers from whom our contract manufacturers source components and raw materials may cease production or supply of those components to our contract manufacturers. Identification and qualification of alternate suppliers is time consuming and costly, and there can be no assurance that we will be able to demonstrate equivalency of alternate components or suppliers or that we will receive regulatory approval in the U. S. or other jurisdictions. If we conclude that supply of the INTERCEPT Blood System or components from suppliers is uncertain, we may choose to build and maintain inventories of raw materials, work- in- process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient. We have purchased a last time build of our current model illuminator, which is being phased out of manufacture due to obsolescence of certain components. As a result, we will not be able to continue manufacturing the current model illuminator. We are currently developing the new illuminator which **may** ~~is expected to potentially~~ take ~~more than twelve months~~ **an extended period of time** to complete and obtain regulatory approval. Until such time as we obtain approval for the redesigned illuminator, if ever, the demand for illuminators may be higher than the remaining number of illuminators in inventory, resulting in possible customer allocations or loss of sales. We anticipate that we will need to continue investing in subsequent versions of the illuminator to enhance functionality and manage obsolescence. We and our customers rely on the availability of spare parts and replacement components to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts or replace components during 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 understand that components used in the current model illuminator are no longer commercially available beyond what we 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 components become unavailable or obsolete, we may be required to identify and qualify replacement components for the current model illuminator 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. 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. We recently signed an agreement with a supplier to produce the new redesigned illuminator. ~~We must transfer over the design documentation and validate our new supplier, as well as secure components for the new redesigned illuminator.~~ Some ~~on~~ **of** the new components require long order lead times and have required that we procure the components in advance of receiving regulatory approval in

order to satisfy demand for our products. Until we are able to validate our new supplier, obtain regulatory approvals and sell our newly designed illuminator, sales of illuminators will be limited to the quantity of the current model illuminator that we have on hand **. Furthermore, our ability to maintain the existing installed base of current model of illuminators is limited, in some cases, to the existing stockpiled components that we have on hand and our ability to calibrate light dose on such illuminators is limited to maintaining the bulbs required to operate a calibration station and external radiometers** . Any failure to, or delays in, receiving regulatory approvals for the redesigned illuminator, or increased costs associated with mitigating any such delays, could materially and adversely affect our business, financial condition, results of operations and growth prospects and impair our sales and ability to penetrate new markets. To meet the growing demand for our products, we are likely to invest in manufacturing capacity at existing or alternative manufacturing sites with existing and alternative suppliers, which could be costly and disruptive to our business. In order to increase and diversify manufacturing capacity, our manufacturing partners have in the past, and may in the future, require us to pay for capital investments in whole or in- part in order to offset the impact of cash flows and risk. In the event that alternate manufacturers or alternate manufacturing sites are identified and qualified, we will need to transfer know- how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers and manufacturing sites; however, certain of our supplier' s materials, manufacturing processes and methods are proprietary to them, which will impair our ability to establish alternate sources of supply, even if we are required to do so as a condition of regulatory approval. We may be unable to establish alternate suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Moreover, the inclusion of components manufactured by new suppliers or by alternate sites within our current network of suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms more favorable to us than those that we currently have with our manufacturers. Many of the existing agreements we have with suppliers contain provisions that we have been operating under for an extended period of time, including pricing. Should we enter into agreements or amend agreements with any manufacturer with less favorable terms, including pricing, our results of operations may be impacted, our recourse against such manufacturers may be limited, and the quality of our products may be impacted. Furthermore, we do not have experience working with partners that are producing our products in multiple sites globally. Should we need to oversee our manufacturers producing components or finished goods for our products in multiple global plants, we may be unsuccessful in providing an adequate level of oversight, may be unable to manage the complexity of such operations, including quality, incur additional costs in managing the global supply chain including capital investments in those plants or become less efficient with our use of cash and working capital. Raw materials, components or finished product may not meet specifications or may be subject to other non- conformities. In the past, non- conformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. Similarly, we have experienced non- conformities and out of specification results in certain component manufacturing needed for clinical use, commercial sale and regulatory submissions. Non- conformities can increase our expenses and reduce gross margins or result in delayed regulatory submissions or clinical trials. Any quality failure in manufacturing by our suppliers may result in a significant write down and impact to our reported gross margins. Should non- conformities occur in the future, we may be unable to manufacture products to support our red blood cell clinical trials, or to meet customer demand for our commercial products, which would result in delays for our clinical programs, or lost sales for our commercial products, and could cause irreparable damage to our customer relationships. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. In addition, we may not receive timely or accurate demand information from distributors or direct customers, or may not accurately forecast demand ourselves for the INTERCEPT Blood System. Should actual demand for our products exceed our own forecasts or forecasts that customers provide, we may be unable to fulfill such orders timely, if at all. Should we be unable to fulfill demand, particularly if mandated by a public health authority or as included in the Final Guidance Document for the U. S., our reputation and business prospects may be impaired. Further, certain distributors and customers require, and potential future distributors or customers may require, product with a minimum shelf life. If customers requiring minimum shelf- lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf- lives which may lead to increased write- offs and inefficient use of our cash. Should we choose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs and / or reduced gross margins. In order to meet minimum shelf- life requirements, we may need to manufacture sufficient product to meet estimated forecasted demand. As a result, we may carry excess work- in- process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. Our platelet and plasma systems' disposable kits have 6 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. For instance, until we are able to generate data satisfactory to the FDA regarding the stability of platelet products using a component manufactured with a new solvent, our platelet product shelf life will be limited to six months in the U. S. Given the short shelf life in the U. S. and logistical challenges of producing the products in Europe before shipping to the U. S., we may incur elevated air freight costs **, may receive requests by customers to return expired product** or we may not be able to supply product to customers in the U. S. with sufficient shelf life, ~~both~~ **each of** which would negatively impact our results of operations **. In addition, we may need to impair the value of any purchased inventory if we believe we will not be able to supply product to U. S. customers with**

sufficient shelf life . We and our distributors may be unable to ship product to customers prior to the expiration of the product shelf life, a risk that is heightened if we elect to increase our inventory levels in order to mitigate supply disruptions. We have entered into certain public tenders or may enter into commercial contracts with customers, that call for us to maintain certain minimum levels of inventory. If our suppliers fail to produce components or our finished products satisfactorily, timely, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non- compliance with certain public tenders which may in turn result in penalty fees, permanent harm to our customer relations or loss of customers. In addition, certain large national prospective customers, like those in the UK or Japan, may choose to convert all of their operations to INTERCEPT. Should we or our suppliers encounter any manufacturing issues or if we and our suppliers are not able to build more manufacturing capacity, we may not be able to satisfy all of the global demand or may have to allocate available product to certain customers which may force customers to adopt competing products, which could permanently impact our ability to convert those customers to INTERCEPT users and may negatively impact our customers operations and consequently, our competitive position and reputation. Conversely, we may choose to overstock inventory in order to mitigate any unforeseen potential disruption to manufacturing which could consume our cash resources faster than we anticipate and may cause our supply chain to be less efficient **. The current conflict in the Middle East and impact on shipping routes has resulted in increased costs to ship our products via ocean and meet our supply chain requirements. Should the conflict continue or worsen, or if we are unable to ship products and components to meet our supply chain demand, we may continue to incur increased costs, encounter delays, and / or have to rely on air freight which is significantly more expensive than ocean shipment** . Until we sell sufficient INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations, expand the number of manufacturing partners producing IFC for us, or more of our manufacturing partners for IFC receive approval of their BLAs, our IFC sales will be limited. Additionally, because IFC are products derived from our INTERCEPT Blood System for plasma, any supply disruptions or failures that could impact our plasma system will have a negative direct impact on the production of IFC. We currently have no experience with customer expectations regarding turnover or inventory levels of IFC held at either our blood center manufacturing partners or at the hospitals themselves. Our IFC product has a shelf life of five days from thaw before it expires. To mitigate product expiration, should hospitals require that we use a consigned inventory model whereby unused product at the hospital at expiration is replaced with fresh product at reduced or no cost to the hospital, we may need to keep additional inventory or manufacture IFC above levels generating an economic return, which could adversely affect our results of operations and financial condition. Obsolescence or shortage of raw materials, key components of and accessories to the INTERCEPT Blood System, may impact our ability to supply our customers, may negatively impact the operational costs of our customers and may increase the prices at which we sell our products, resulting in slower than anticipated growth or negative future financial performance. The manufacture, supply and availability of key components of, and accessories to, our products are dependent upon a limited number of third parties and the commercial adoption and success of our products is dependent upon the continued availability of these components or accessories. For example, our customers rely on continued availability of third- party sets, supplied plastics, saline and reagents for processing, storing and manufacturing blood components. If the blood product industry experiences shortages of these components or accessories, or if manufacturers cease production of these components or accessories, the availability and use of our products may be impaired. With respect to the manufacture of our products, our third- party manufacturers source components and raw materials for the manufacture of the INTERCEPT processing sets. Certain of these components are no longer commercially available, are nearing end- of- life or are available only from a limited number of suppliers. We and our third- party manufacturers do not have guaranteed supply contracts with all of the raw material or component suppliers for our products, which magnify the risk of shortage and obsolescence and decreases our manufacturers' ability to negotiate pricing with their suppliers. For example, a solvent used in the manufacture of the plastic beads for the compound adsorption devices used for our products is no longer available. Accordingly, we purchased all remaining existing material. We will need to qualify plastic beads produced with a new solvent prior to consuming available inventory levels. If we are unable to use all of the raw material produced during the final production run, or if the final material produces suboptimal results, we may require customers to modify their operating practices, or run out of material before an alternate material can be qualified. Moreover, we may be required to impair or write- off the value of any unused last- time- buy raw materials or components. Customers may object to changes in operating practices or changes to the instructions for use, and a potential negative impact on their operations as a result of the use of this material, could impair our reputation or customer acceptance of our products. Any shortage or obsolescence of raw materials, components or accessories or our inability to control costs associated with raw materials, components or accessories, could increase our costs to manufacture our products. Further, if any supplier to our third- party manufacturers is unwilling or unable to provide high quality raw materials in required quantities and at acceptable prices, our manufacturers may be unable to find alternative sources or may fail to find alternative suppliers at commercially acceptable prices, on satisfactory terms, in a timely manner, or at all. Furthermore, we do not yet know whether or not certain components used by blood center operators or used in the production of INTERCEPT will comply with the new standards under the MDR. Failure to comply with the new standards timely may result in a disruption to blood center operations or the manufacture of the INTERCEPT Blood System. If any of these events were to occur, our product quality, competitive position, reputation and business could suffer, we could experience cancellations of customer orders, refusal by customers to accept deliveries or a reduction in our prices and margins to the detriment of our financial performance and results of operations. Risks Related to Our Financial Condition and Capital Requirements Our cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. While our net losses ~~are narrowing~~ **have recently narrowed** , at our expected and guided sales levels of the platelet, plasma and cryoprecipitation systems, and of IFC, our costs to manufacture, distribute, market ~~,~~ **and** sell **our products** , support the systems **,** and develop new products ~~are~~ **will** likely ~~to continue to~~ be in excess of our product revenue. In particular, it is expensive and time consuming to continually address

ever- changing regulatory requirements whether those changes are due to changes in the requirements or changes in our products to expand or maintain our products' label claims. **Furthermore, the cost of complying with increased oversight and changing requirements under U. S. GAAP, the SEC and PCAOB and other administrative regulators are expected to continue to increase and may be unsustainable or increase faster than the anticipated revenue growth.** In addition, we expect to incur additional research and development costs associated with the development of different configurations of existing product candidates and products and our **new** illuminator, development of new products, planning, enrolling and completing ongoing clinical and non- clinical studies, including the post- approval studies or registry studies we are and may be required to conduct in connection with the approvals of the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting in vitro studies and clinical development of our red blood cell system in Europe and the U. S., and completing activities to support a potential CE Certificate of Conformity and the CE Marking for our red blood cell system in the EU. These costs could be substantial and could extend the period during which we expect to operate at a loss, particularly if we experience any difficulties or delays in completing the activities. In addition, we may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, or to compete favorably with other blood safety interventions or other pathogen reduction technologies, which may reduce or altogether eliminate any gross profit on sales. Until we are able to generate a sufficient amount of product revenue or limit expenses or capital investments and generate positive net cash flows from operations, which we may never do, meeting our long- term capital requirements is in large part reliant on continued access to funds under our 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~~ **agreements** with BARDA, **the FDA, and the DoD** 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 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. In addition, while our stated goal is to achieve profitability in the future, actual results may be different than our forecasted operating plan and may require that we make certain trade- offs to potentially achieve profitability. Such trade- offs may negatively impact our commercial potential or result in deferrals in development activities. We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to our **Amended and Restated** Credit, Security and Guaranty Agreement (Term Loan), or the **Amended** Term Loan Credit Agreement, and our **Amended and Restated** Credit, Security and Guaranty Agreement (Revolving Loan), or the Revolving Loan Credit Agreement, both with MidCap Financial Trust, or MidCap, or potentially pursuant to new arrangements with different lenders. We **have borrowed and** may **in future** 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, unless we restructure our credit agreements prior to April 1, 2026, the principal amounts outstanding under our Term Loan Credit Agreement will begin amortizing and require us to pay amounts as they come due in cash, which would negatively impact our available working capital beyond the next 12 months.** Should interest rates continue to increase, the rates that we are obligated to pay under our ~~Credit~~ **credit** ~~Agreements~~ **agreements** would likely increase, potentially leading to higher interest expense. 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. **Moreover, recent developments in the financial services industry could cause us to experience liquidity constraints or failures, hinder our ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, and result in further disruptions or instability in the financial services industry or financial markets. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations.** As a result of economic conditions, general global economic uncertainty, political change, **war, the effects of inflationary pressures** and other factors ~~,~~ including ~~uncertainty associated with the COVID- 19 pandemic~~ **recent and potential U. S. bank failures** , we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. As a result of stimulus programs put in place over the past two years, the U. S. and many countries are currently experiencing an inflationary environment. In addition, the U. S. Federal Reserve has raised, and may again raise, interest rates, in response to concerns about inflation **. Moreover, the U. S. Federal**

Reserve may not lower interest rates as quickly as markets expect, if at all , which in turn ~~has~~ **could** negatively ~~impacted~~ **impact** equity values, including the value of our common stock. Furthermore, our vendors and suppliers may raise prices in an inflationary environment, costs to transport our products may increase and access to timely shipping may be limited **. Recent bank failures have also caused increased concerns about liquidity in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time** . If we are unable to generate positive cash flows we may need to raise additional capital to support our operations which may be unavailable if and when needed. Should this occur, 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 or certifications in the EU, which would increase our costs and potentially delay the approval. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials. Covenants in our Term Loan Credit Agreement and Revolving Loan Credit Agreement can restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the Term Loan Credit Agreement and Revolving Loan Credit Agreement. As of December 31, ~~2022~~ **2023** , our total indebtedness under our Term Loan Credit Agreement and Revolving Loan Credit Agreement was approximately $ ~~69~~ **79** . 8 million. All of our current and future assets, except for intellectual **property** and certain investments in subsidiaries and affiliates ~~, are secured~~ , are secured for our borrowings under the Term Loan Credit Agreement and Revolving Loan Credit Agreement. The Term Loan Credit Agreement and Revolving Loan Credit Agreement require that we comply with certain covenants applicable to us and our subsidiary, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the Term Loan Credit Agreement or the Revolving Loan Credit Agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the Term Loan Credit Agreement or the Revolving Loan Credit Agreement **. In addition, our failure to comply with certain financial covenants could result in the lenders obtaining a security interest in our intellectual property** . 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. ~~Our existing~~ **Unless we prepay the principal amount due or meet the requirements for and choose to extend the interest only period of the** Term Loan **we will be** ~~requires~~ **required to make** principal payments beginning in April ~~2023~~ **2026** until March 1, ~~2024~~ **2028 if not repaid sooner** ~~. Should we be unable to refinance the outstanding Term Loan at consistent or better terms than we currently have or generate sufficient cash flow from operations timely, our liquidity could be negatively affected~~ . Risks Related to Managing Our Growth and Other **Business** Risks We are responsible for worldwide sales, marketing, distribution, maintenance and regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties to support us in these areas on a timely basis, our ability to commercialize the INTERCEPT Blood System may be irreparably harmed. We will need to maintain and may need to increase our competence and size in a number of functions, including sales, deployment and product support, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with U. S., EU, 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. Currently, we, third- party suppliers and vendors and customers are experiencing an extremely tight labor market exacerbating our ability to attract and retain talent. Furthermore, a significant component of our employee compensation and retention practice involves stock- based compensation. Given the pull back in our stock price, key talent may not find our stock- based compensation to be a compelling reason to stay employed at Cerus. We **recently enacted a restructuring plan and reduced our workforce by approximately 10 percent. The absence of such employees may require us to reduce the scope of activities we planned for or result in an impact to our operations, including but not limited to our quality systems, ability to timely meet our deadlines, sufficiently service customers, adequately and timely respond to regulatory authorities and maintain an effective internal control structure, among others. We** have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all. In addition, in some cases, the cost of obtaining approval and maintaining compliance with certain regulations and laws may exceed the product revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition. Furthermore, we may choose to seek alternative ways to sell or treat blood components with our products. These may include new business models, which may include selling kits to blood centers,

performing inactivation ourselves, staffing blood centers or selling services or other business model changes. We have no experience with these types of business models, or the regulatory requirements or licenses needed to pursue such new business models. We cannot assure you that we will pursue such business models or if we do, that we will be successful. For example, in early 2021, we formed a joint venture with a Chinese entity with the intent to develop and commercialize blood transfusion products to enhance blood safety in the People' s Republic of China. Our involvement in the joint venture may be a distraction for our management and impair our ability to successfully and timely manage our other operations. Additionally, the operations of the joint venture may require future capital infusion from us and we may never see a return from our investment in the joint venture. Adverse market and economic conditions may exacerbate certain risks affecting our business. Sales of our products are dependent on purchasing decisions of and / or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including the COVID- 19 pandemic, disruptions due to political instability ~~or~~ **,** terrorist attacks **or war** , economies and currencies largely affected by declining commodity prices **, inflationary pressures** or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for the INTERCEPT Blood System, and of which could adversely affect our business, financial condition, results of operations and growth prospects. In the past, a meaningful amount of our product revenue has come from sales to distributors for the Russian and CIS country markets, as well as Middle Eastern markets. While we believe that all patients wanting access to INTERCEPT- treated blood components should have access, Russia' s ongoing war against Ukraine and the elevated U. S. and EU sanctions imposed against Russia **and Belarus** has made servicing our ~~distributor~~ **distributors** in Russia **and Belarus** more difficult. **Additionally, the state of war between Israel and Hamas and the risk of a larger regional conflict may affect our business. We understand that certain of our products are now prohibited to be sold under U. S. sanctions against Russia. While we are applying for a license to continue ensuring that Russian and Belarusian patients can receive INTERCEPT products, we cannot assure you when we will be successful in obtaining such a license, if ever, or for what duration such a license may be effective if we ever receive one.** Furthermore, because of the severe devaluation of the **Russian** ruble in the currency markets, our products have become more costly for the Russian market. Should the situation persist or worsen, including **additional** sanctions in response to the war, we may be unable to service our Russian **and Belarusian** ~~distributor~~ **distributors** . Weakness and / or instability in worldwide oil demand and / or prices, civil, political and economic disturbances and any potential spillover effect may have a negative impact on markets that we service. We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include: • complying with diverse and unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements; • complying with other laws and regulatory requirements to which our business activities abroad are subject, such as the U. S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti- corruption intent in foreign countries (as discussed in greater detail above under " Risks Related to Regulatory Approval, CE Certificates of Conformity and Oversight, and Other Legal Compliance Matters — We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business " and " Risks Related to Our Reliance on Third Parties — We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries "); • differing payor reimbursement regimes, governmental payors and price controls; • changes in the political or economic condition of a specific country or region; • fluctuations in the value of foreign currency versus the U. S. dollar; • adverse tax consequences, including changes in applicable tax laws and regulations; • liabilities for activities of, or related to, our international operations and those of our agents, distributors and joint venture partners; • tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U. S. Department of the Treasury), and other trade barriers; • economic weakness, including inflation, **bank failures,** or political or economic instability in particular economies and markets outside the U. S.; • difficulties in attracting ~~and~~ **,** retaining **, and paying** qualified personnel; and • cultural differences in the conduct of business. For example, product sales of the INTERCEPT Blood System in many countries outside of the U. S. are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Significant fluctuations in the volatility of foreign currencies relative to the U. S. dollar may materially affect our results of operations. In addition, in a period where the U. S. dollar is strengthening / weakening as compared to Euros and other currencies we transact in, our product revenues and expenses denominated in Euros or other foreign currencies are translated into U. S. dollars at a lower / higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility. As our commercial operations grow globally, our operations are exposed to more currencies and as a result our exposure to foreign exchange risk will continue to grow. Additionally, all of the employees of our subsidiary, Cerus Europe B. V., are employed outside the U. S., including in France, where labor and employment laws are relatively stringent and, in many cases, grant significant job protection to certain employees, including rights on termination of employment. In addition, one of our manufacturing partners that we are dependent on is located in France and may have employees that are members of unions or represented by a works council as required by law. These more stringent labor and employment laws to the extent that they are applicable, coupled with the requirement to consult with the relevant unions or works' councils, could increase our operational costs with respect to our own employees and could result in passed through operational costs by our manufacturing partner. If the increased operational costs become significant, our business, financial condition and results of operations could be adversely impacted, perhaps materially. Finally, following the result of a referendum in 2016, the UK left the EU 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 as the UK determines which EU laws to replace or replicate. Altered regulations could add time and expense to the process by which our product candidates receive regulatory approval or certification in the EU. Given the lack of comparable precedent, it is unclear what financial, regulatory, trade and legal implications the withdrawal of the UK from the EU will ultimately have and how such withdrawal will affect us. If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected. We are highly dependent upon our executive management team and other critical personnel, including our specialized research and development, regulatory and operations personnel, many of whom have been employed with us for many years and have a significant amount of institutional knowledge about us and our products. We do not carry " key person " insurance. If one or more members of our executive management team or other key personnel were to retire or resign, our ability to achieve development, regulatory or operational milestones for commercialization of our products could be adversely affected if we are unable to replace them with employees of comparable knowledge and experience. In addition, we may not be able to retain or recruit other qualified individuals, and our efforts at knowledge transfer could be inadequate. If knowledge transfer, recruiting and retention efforts are inadequate, significant amounts of internal historical knowledge and expertise could become unavailable to us. We also rely on our ability to attract, retain and motivate skilled and highly qualified personnel in order to grow our company. **Our depressed stock price negatively impacts our ability to provide perceived valuable equity compensation to our employees, including executive management.** Competition for qualified personnel in the medical device and pharmaceutical industry is very intense. Labor shortages of qualified personnel is expected to persist for the foreseeable future and has required that we broaden our searches and change the way we operate. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, ability to perform under our BARDA agreement, or results of operations and growth prospects could be adversely affected. Even if we are able to identify and hire qualified personnel commensurate with our growth objectives and opportunities, the process of integrating new employees is time consuming, costly and distracting to existing employees and management. Such disruptions may have an adverse impact on our operations, our ability to service existing markets and customers, or our ability to comply with regulations and laws. Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from a single site that may be subject to lengthy business interruption in the event of a severe earthquake. We also may suffer loss of computerized information and may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems. **Much** ~~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 **and are located near a small plane airport** . Should a severe earthquake occur **or a plane crash into our site** , we might be unable to occupy our facilities or conduct research and development and general and administrative activities in support of our business and products until such time as our facilities could be repaired and made operational. Our property and casualty and business interruption insurance in general does not cover losses caused by earthquakes. While we have taken certain measures to protect our scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us. We have also taken measures to limit damage that may occur from the loss of computerized data due to power outage, system or component failure or corruption of data files. However, we may lose critical computerized data, which may be difficult or impossible to recreate, which may harm our business. We may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems, which may subject us to fines or adverse consequences, up to and including loss of our ability to conduct business. Significant disruptions of information technology systems or actual or alleged breaches of data security could adversely affect our business. Our business is increasingly dependent on complex and interdependent information technology systems, including internet-based systems, databases and programs, to support our business processes as well as internal and external communications. These include those that are used directly by our operations and those used by critical service providers and suppliers, including our manufacturing partners. As use of information technology systems has increased, deliberate attacks, attempts to gain unauthorized access to computer systems and networks, and unintentional actions or inactions that expose us to security vulnerabilities and incidents have increased in frequency and sophistication. Our and our supplier' s information technology, systems and networks are potentially vulnerable to breakdown, ransomware, supply chain attacks, malicious intrusion and computer viruses which may result in the impairment of production and key business processes or loss of data or information. We and our suppliers are also potentially vulnerable to data security breaches- whether by (a) intentional or accidental actions or inactions or (b) employees or others- which may expose sensitive data to unauthorized persons. For example, we have in the past and may in the future be subject to " phishing " attacks in which third parties send emails purporting to be from reputable sources. Phishing attacks may attempt to obtain personal information, infiltrate our systems to initiate wire transfers or otherwise obtain proprietary or confidential information. Although we have not experienced any losses as a result of such attacks or any other breaches of data security, such breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others. We may be subject to contractual, regulatory, or legal requirements that obligate us to use industry- standard or reasonable security measures to safeguard personal information. A security breach could lead to claims by our customers or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages, and in some cases our customer agreements do not limit our remediation costs or liability with respect to data breaches. Litigation resulting from security incidents may adversely affect our business. Actual or alleged unauthorized access to our platform, systems, networks, or physical facilities, or those of our vendors, could result in litigation with our customers or

other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management' s time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our products and / or platform capabilities in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur, and the confidentiality, integrity, or availability of personal information was disrupted, we could incur significant liability, or our platform, systems, or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation. We know that certain of our suppliers have been successfully attacked by certain malware aimed at extracting a ransom. Should such ransomware breaches occur in the future, production may be impacted, information exfiltrated or other records and information compromised or lost. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures designed to protect our data security and information technology systems, such measures may not prevent such events. Notifications and follow- up actions related to a security breach of one of our suppliers could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations. Further, the costs to respond to a security breach and / or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these problems may not be successful, and these problems could result in interruptions, delays, cessation of service, negative publicity, loss of customer trust, less use of our products and services as well as other harms to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses, which may result in potential regulatory inquiries, litigation or other investigations, and can affect our financial and operational condition. While we have attempted to limit our liability in our contracts, there can be no assurance that contractual limitations of liability are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims **. Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate. The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U. S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows. The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one- time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a " permanent establishment " under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions** . Our ability to use our net operating loss carryforwards and certain other tax attributes is uncertain and may be limited. Our ability to use our federal and state net operating loss, or NOL, carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards (if any), and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. Under current law, U. S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes (such as research and development credit carryforwards) to offset its post- change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. Although we have completed studies to provide reasonable assurance that an ownership change limitation would not apply, we cannot be certain that a taxing authority would reach the same conclusion. If, after a review or audit, an ownership change limitation were to apply, utilization of our domestic NOL and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being utilized to reduce future income tax liabilities. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows. Risks Related to Our Intellectual Property Our

commercial success will depend, in part, on obtaining and maintaining patent protection on our products and successfully defending our products against third- party challenges. Our technology will be protected from unauthorized use only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to: • obtain patents; • protect trade secrets; • operate without infringing upon the proprietary rights of others; and • prevent others from infringing on our proprietary rights. We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, we are aware of an expired U. S. patent issued to a third- party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to have infringed any valid claim of this patent, we may, among other things, be required to pay damages. Our patents expire at various dates between ~~2022~~ **2025** and ~~2038~~ **2040** . 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~~ in ~~2023 and~~ 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents. We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third- party patents and intellectual property to continue development and commercialization of our products. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products. Our patents do not cover all of the countries in which we are selling, and planning to sell, our products. We will not be able to prevent potential competitors from using our technology in countries where we do not have patent coverage. Further, the laws of some foreign countries may not protect intellectual property rights to the same extent as the laws of the U. S., including the CIS countries, China and other jurisdictions where we are currently expanding or seeking to expand our commercialization efforts through distributors or otherwise. For example, we recently formed a joint venture with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China. The prosecution of intellectual property infringement and trade secret theft in China is more difficult and unpredictable than in the United States, and we may also have limited legal recourse in the event our intellectual property rights are infringed. In any event, our inability to adequately enforce or protect our intellectual property rights to INTERCEPT in China and other foreign jurisdictions where we are currently expanding or seeking to expand our commercialization efforts could adversely impact our potential commercial success and harm our business. In certain countries, including EU Member States, China and India, compulsory licensing laws exist that may be used to compel a patent owner to grant licenses to third parties, for reasons such as non- use of the patented subject matter within a certain period of time after patent grant or commercializing in a manner that is cost- prohibitive in the country. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license for the INTERCEPT Blood System to a third- party, which could materially diminish the value of such patents. This could adversely impact our potential product revenue opportunities. We may face litigation requiring us to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know- how or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings before the U. S. Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights. We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees, consultants and contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know- how and inventions **. Risks Related to Our Common Stock Our stock price is volatile and your investment may suffer a decline in value. The market price for our common stock has varied between a high of $ 4. 05 on January 5, 2023, and a low of $ 1. 21 on October 9, 2023, in the twelve- month period ended December 31, 2023. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described in this " Risk Factors " section. The market price of our common stock may also be dependent upon the valuations and recommendations of the analysts who cover our business. If the results of our business do not meet these analysts' forecasts, the expectations of investors or the financial guidance we provide to investors in any period, the market price of our common stock could decline. In addition, the stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations have in the past and may in the future adversely affect the trading price of our common stock. In the past, following periods of volatility in the market or significant price declines, securities class- action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management' s attention and resources, which could materially and**

adversely affect our business, financial condition, results of operations and growth prospects. The exclusive forum provisions in our amended and restated bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or any of our directors, officers or employees, or our stockholders, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims. Our amended and restated bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for: • any derivative claim or cause of action or proceeding brought on our behalf; • any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees, or our stockholders, to us or to our stockholders; • any claim or cause of action against us or any of our current or former directors, officers or other employees, or our stockholders, arising out of or pursuant to any provision of the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws; • any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; • any claim or cause of action as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; and • any claim or cause of action against us or any of our current or former directors, officers or other employees, or our stockholders, governed by the internal affairs doctrine or otherwise related to our internal affairs. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act of 1933, as amended, or the Securities Act, or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. The application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions, and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such an instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions, which costs could be borne by stockholders, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to the exclusive forum provisions in our amended and restated bylaws, including the Federal Forum Provision. These provisions could limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers or other employees, or our stockholders, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Furthermore, if a court were to find the exclusive forum provisions contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material and adverse impact on our operating results and our financial condition. Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Additionally, any cash dividends declared or paid would require prior written consent under the terms of our Term Loan Credit Agreement and Revolving Loan Credit Agreement. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future . General Risk Factors We are obligated to develop and maintain proper and effective internal control over financial reporting. In the future, we may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weakness identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting. Complying with Section 404 requires a rigorous compliance program as well as adequate time and resources. As a result of expanding our commercialization efforts, developing, improving and expanding our core information technology systems as well as implementing new systems to support our sales, supply chain activities and reporting capabilities, all of which require significant management time and support, we may not be able to complete our internal control evaluation, testing and any required remediation in a timely fashion. For example, with respect our joint venture formed with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China, we had no

prior experience designing and maintaining effective internal control over financial reporting for joint ventures or for economic entities in China. Failure to adequately maintain an effective internal control structure over the joint venture' s financial results may result in significant deficiencies or material weaknesses in our internal control over financial reporting. Additionally, if we identify one or more material weaknesses in our internal control over financial reporting, we will not be unable to assert that our internal controls are effective. Should our internal controls be deemed ineffective, our ability to obtain additional financing, or obtain additional financing on favorable terms, could be materially and adversely affected which, in turn, could materially and adversely affect our business, our financial condition and the value of our common stock. If we are unable to assert that our internal control over financial reporting is effective in the future, or if our independent registered public accounting firm is unable to express an opinion or expresses an adverse opinion on the effectiveness of our internal controls in the future, investor confidence in the accuracy and completeness of our financial reports could be further eroded, which would have a material adverse effect on the price of our common stock. Provisions of our charter documents, our compensatory arrangements and Delaware law could make it more difficult for a third- party to acquire us, even if the offer may be considered beneficial by our stockholders. Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti- takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third- party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third- party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine. In addition, our executive employment agreements, change of control severance benefit plan and equity incentive plans and agreements thereunder provide for certain severance benefits in connection with a change of control of us, including single- trigger equity vesting acceleration benefits with respect to outstanding stock options, which could increase the costs to a third- party acquirer and / or deter such third- party from acquiring us.