UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission file number 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock listed on the Nasdaq Global Market, was $240 million. [(1)]

As of February 6, 2025, there were 185,789,815 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement in connection with the registrant's 2025 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

[(1)] Based on a closing sale price of $1.76 per share on June 28, 2024. Excludes 49.0 million shares of the registrant's common stock held by executive officers, directors and stockholders that the registrant has concluded were affiliates at June 30, 2024.

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For the Fiscal Year Ended December 31, 2024

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- ***the impact of macroeconomic developments, including escalating trade tensions and the ongoing conflict between Ukraine and Russia on our business and operations as well as the business or operations of our customers, manufacturers, research partners, and other third parties with whom we conduct business;***
- ***future sales of and anticipated demand for, and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT™ Blood System, including our ability to comply with applicable United States, or U.S., and foreign laws, regulations and regulatory requirements;***
- ***our ability to successfully complete the development of, receive regulatory approvals for and commercialize the red blood cell system;***
- ***our strategy and the potential therapeutic applications for the INTERCEPT Blood System;***
- ***our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the U.S., as well as our ability to manage the risks attendant to our international operations;***
- ***the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions, including whether we will submit a new application for conformity assessment to obtain a CE Certificate of Conformity to affix the CE Mark to the red blood cell system, whether data exist to support a classification of compounds for approval, whether existing clinical data would be sufficient to either submit or potentially obtain approval of any such new application, and whether our planned modular premarket approval, or PMA, application for the red blood cell system will be submitted to the U.S. Food and Drug Administration, or FDA, on the timeline we anticipate or at all;***
- ***our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System;***
- ***our ability to obtain adequate clinical and commercial supplies of the INTERCEPT Blood System from our sole source suppliers for a particular product or component they manufacture;***
- ***the initiation, scope, rate of progress, results and timing of our ongoing and proposed preclinical and clinical trials of the INTERCEPT Blood System;***
- ***the successful completion of our research, development and clinical programs and our ability to manage cost increases associated with preclinical and clinical development of the INTERCEPT Blood System;***
- ***the amount and availability of funding we may receive under our government contracts with the Biomedical Advanced Research and Development Authority, or BARDA, the U.S. Department of Defense, or DoD, and the FDA;***
- ***our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;***
- ***the ability of our products to inactivate the emerging viruses and other pathogens that we may target in the future;***
- ***our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;***
- ***our estimates regarding the sufficiency of our cash resources, our ability to continue as a going concern and our need for additional funding; and***
- ***our plans, objectives, expectations and intentions and any other statements that are not historical facts.***

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

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

RISK FACTOR SUMMARY

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

- 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 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.
- 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.
- 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.

- 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 agreements, and if BARDA were to eliminate, reduce or delay, or object to extensions for funding of our agreements, 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 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 may continue to generate losses and 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 continued 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 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 and your investment may suffer a decline in value.

Item 1. *Business*

Overview

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

Our INTERCEPT Blood System is intended for use with blood components and certain of their derivatives: 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, and 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 or maintain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including in the U.S., we will have difficulties achieving and maintaining 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 a Phase 3 clinical trial - the RedeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional, un-treated, red blood cells. With respect to our MDR application in the European Union, or EU, we announced in October 2024 that the Dutch Medicines Evaluation Board, or CBG, the Competent Authority for the red blood cell system, reviewed the active pharmaceutical ingredient module of our MDR application and concluded that the data included in the module were insufficient to support the proposed classification of the impurity profile of the final product, necessitating the closure of our MDR application without an approval. In collaboration with TÜV-SÜD, our Notified Body for the red blood cell system, we are assessing strategies for a potential new MDR application, including data to address the classification questions raised by CBG. We cannot predict with certainty when, if ever, we will be able to satisfactorily address CBG's conclusions and as such, cannot predict if or when we will submit a new MDR application for the red blood cell system and, if submitted, when a decision concerning certification would occur. In addition, as a result of the failure to obtain approval of our MDR application, our product development costs will be ongoing. 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.

Contribution margins from our sales is likely 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 CE Certificate of Conformity under MDR in December 2023
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 CE Certificate of Conformity under MDR 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, completed in 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 • Resubmission of application for CE Certificate of Conformity under MDR would be required in order to potentially obtain marketing approval in Europe

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 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 have received CE Certificates of Conformity to affix the CE Mark in accordance with the MDR for our INTERCEPT platelet and plasma systems which allows us to continue to place our platelet and plasma systems on the European Union market under the new regulatory requirements of the MDR. 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 completed 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 as well as a recovery study of platelets treated with the platelet system. 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 2025 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 plan to 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 sell directly to hospitals and to other blood centers. Of the blood centers that we have contracted with to produce IFC for us, all have received their interstate licenses, or BLAs. 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. We also understand that we will need to obtain new PMAs for our INTERCEPT platelet and plasma systems for use with our new LED-based illuminator. 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 initially filed an 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 our application for a CE Certificate of Conformity under the new MDR. In October 2024, we announced CBG, the Competent Authority for the red blood cell system, concluded that the data provided regarding the medicinal product or active pharmaceutical ingredient of our MDR application were insufficient to support the proposed classification of the impurity profile of the final product, necessitating the closure of our MDR application without an approval. In collaboration with TÜV-SÜD, we are assessing strategies for a potential new MDR application, including data to address the classification questions raised by CBG. We cannot predict with certainty when, if ever, we will be able to satisfactorily address CBG's conclusions and as such cannot predict if or when we will submit a new MDR application for the red blood cell system and, if submitted, when a decision concerning certification would 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.

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 of INTERCEPT-treated RBCs. 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 are now 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, if positive, are expected to support our chronic use assessment in our planned modular premarket approval, or PMA, application for the red blood cell system that we plan to submit to the FDA.

In March 2024, we announced positive topline results from a Phase 3 clinical trial in the U.S., known as the ReCePI study, that was designed to evaluate the efficacy and safety of INTERCEPT-treated red blood cells in patients requiring transfusion for acute blood loss during surgery. The ReCePI study met its primary efficacy endpoint, demonstrating non-inferiority for INTERCEPT RBCs compared to conventional RBCs as measured by the incidence of acute kidney injury (AKI) following transfusion of study RBCs. A total of 581 patients were enrolled and randomized across 18 clinical study sites. The modified intention-to-treat, or mITT, population included 321 patients requiring RBC transfusions in the trial. Not all enrolled patients required RBC transfusions. Subjects were randomized on a 1:1 basis either to the treatment arm transfused with INTERCEPT RBCs or to the control arm transfused with conventional RBCs. The primary efficacy endpoint was 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. The ReCePI study was and the RedeS study is being funded as part of our initial agreement with BARDA. In addition to successfully conducting and completing the RedeS and ReCePI studies, we also understand that an additional Phase 3 clinical trial including chronic anemia subjects, *in vitro* studies, and other necessary activities will be required to be successfully completed and submitted to the FDA before the FDA will consider our red blood cell product for approval.

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. In December 2024, we and Porex have entered into a second amended and restated manufacturing and supply agreement that became effective January 1, 2025, or the 2025 Agreement, for the continued supply of the compound adsorption devices. Porex is currently our sole supplier for compound adsorption devices. Under the 2025 Agreement, we and Porex agreed to extend the term of the prior agreement until December 31, 2027. Under the terms of the 2025 Agreement, unit pricing for platelet wafers and plasma disks are set at certain amounts for the first twenty-four months, starting January 1, 2025 with volume based pricing after the first twenty-four months. 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 would have expired in April 2025, however it has automatically renewed for an additional year as neither party has delivered notice of its intent to terminate the agreement. The agreement will continue to automatically renew for one year periods unless either party provides notice not to renew at least two years prior to the expiration. Under the terms of the amended agreement, pricing is volume based and is subject to annual, prospective adjustments based on a Producer Price Index subject to an annual cap.

We have completed the manufacturing for the current model of illuminator and maintain an inventory of those final devices. We have submitted a new application for conformity assessment to obtain a CE Certificate of Conformity to affix the CE Mark to a new illuminator. In the U.S., we will be required to file a new PMA for our INTERCEPT Blood System for both platelets and plasma for use with our new illuminator. Although data is still being developed for the required PMAs, we have completed the redesign of the new illuminator. If we successfully generate the data required for the new PMAs, we cannot predict when, if ever, we will receive approval for use of the platelet and plasma systems with the new illuminator. 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 have contracts for certain critical components and for the manufacture of our new illuminator. However, we do not know if those agreements 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 automatically renewed for two years until December 31, 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 affords 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 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 agree on any 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. Our agreements with EFS to supply platelet disposable kits and plasma disposable kits will both expire in October 2025. We also have an agreement with EFS for maintenance services for illuminators that will expire in October 2025. We are discussing new contract terms with EFS for the supply of platelet disposable kits, plasma disposable kits, and maintenance services for illuminators. 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 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, though most of these agreements do not contain stated minimum manufacturing commitments of the blood centers. 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 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. Furthermore, if our contracted manufacturing partners do not produce IFC in sufficient quantities, or at all, we may not be able to meet hospital or blood center demand which would limit our commercial efforts and may impact customer perception of our reliability in the marketplace.

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. 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 educate adequate numbers of blood center customers 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 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, 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 four contracts with U.S. Federal Agencies, two with BARDA, one with the FDA, and another with the 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 obtaining approval on audited indirect costs or rates and is subject to 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, 2024, 2023 and 2022. 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 blood 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, may perceive the cost of adopting IFC as prohibitive relative to its advantages or compared to competitive products, we may be ineffective in selling blood components directly to hospitals.

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 III CE Certificate of Conformity under the MDR 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 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. for platelets 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 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, 2024, we owned 16 issued or allowed U.S. patents and approximately 166 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2025 and 2042. Recent patent applications will, if granted, result in patents with later expiration dates. 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.

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 12 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 an 18 month shelf life. 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 is not customary for our turnover cycle for finished 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 forecasted demands. Any write-down of our inventory to net realizable value establishes a new cost basis 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. To the extent that our blood center manufacturing partners do not produce sufficient quantities, or at all, we may choose to buy treated IFC from other blood centers to meet demand from hospitals or other blood centers that do not make IFC, which may negatively impact our gross profit and overall operating returns.

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 maintaining compliance with regulatory requirements and obtaining 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 a new PMA for both the platelet and plasma systems for use with the new LED-based illuminator and licensure of the red blood cell system including the RedeS study, an additional Phase 3 clinical trial including chronic anemia subjects, *in vitro* studies, and other activities necessary 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, 2024, 2023 and 2022.

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 the MDD for our platelet system and separately for our plasma system in 2002 and 2006.

In December 2023, we received CE Certificates of Conformity in accordance with the MDR to affix the CE Mark to our platelet and plasma systems. We must receive a separate CE Certificate of Conformity in accordance with the MDR 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 under the MDR in June 2021. In October 2024, we announced the CBG, the Competent Authority for the red blood cell system, concluded that the data provided regarding the medicinal product or active pharmaceutical ingredient of our MDR application were insufficient to support the proposed classification of the impurity profile of the final product, necessitating the closure of our MDR application without an approval. In collaboration with TÜV-SÜD, we are assessing strategies for a potential new MDR application, including data to address the classification questions raised by CBG. We cannot predict with certainty when, if ever, we will be able to satisfactorily address CBG's conclusions and as such cannot predict if or when we will submit a new MDR application for the red blood cell system and, if submitted, when a decision concerning certification would occur. 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 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 was completed, met its endpoint, and results published in a peer-reviewed journal. We have also completed the recovery and survival study of the platelet system and have submitted the data to the FDA. 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. We will need to obtain new PMA approvals for our platelet and plasma systems for use with our new illumination device. We cannot predict whether or not we will be successful in generating the data required for the new PMAs, or predict when, if ever, we will receive approval for use of the platelet and plasma systems with the new illuminator. 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. 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 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 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.

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 also sell the finished IFC made by our manufacturing blood center partners directly to hospitals and in some cases, other blood centers. 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 all of our manufacturing partners have received a BLA from CBER, we plan to continue working with any other U.S.-based blood centers producing IFC to support their licensure applications and any delay in obtaining these licenses would adversely impact the nationwide availability of our finished IFC in the U.S. Furthermore, most of our agreements with blood center manufacturing partners do not contain minimum production requirements. If our blood center manufacturing partners do not produce sufficient quantities of IFC, or at all, our commercialization efforts will be negatively impacted. 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. In addition, we have entered into certain agreements with blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation kits which will allow those blood centers and blood center affiliate organizations to produce finished IFC for their own sales efforts to hospitals.

We 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, a consultation of additional substances contained within the INTERCEPT RBC Processing Set (Processing Solution and SAG-M Storage Solution) was required and ultimately determined to not support licensure of our application for CE Mark approval. Should we be required to generate data for these ancillary solutions, our resubmission of our application for CE Mark approval and an eventual 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. 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 legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; limiting the 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 in certain circumstances.

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 amendments and judicial and Congressional challenges to numerous provisions of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed 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 second Trump 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, 2024, we had 281 employees representing at least 38 nationalities which includes 7 dedicated commercial consultants. Approximately 62% of our global employees are women. In addition, of our U.S. employees, approximately 50% identify as non-white.

Below is additional demographic information about our current employee base as of December 31, 2024.

Cerus Employees	**2024**
Salaried workforce	267
Managers and above	73
Part-time employees	16

Average age	46.6 years
Average length of service in years	6.5 years
Employee turnover rate December 31, 2023 to 2024 (voluntary)	8.3%

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.

Compensation and Benefits

We strive to provide pay, benefits, and services that are competitive with local markets and create incentives to attract and retain employees 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 leave, tuition reimbursement, among others.

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. Our employees receive 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. In 2024, we implemented learning paths within the LinkedIn Learning platform, to drive more specialized and focused development for all employees.

Hybrid Workforce

Beyond providing offices and infrastructure for our employees to work, we also allow for remote work and have adopted a hybrid workplace policy. 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 well-being.

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 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

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

Our business is dependent on our ability to grow and sustain commercialization of the INTERCEPT Blood System for platelets, plasma, and cryoprecipitation 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, increase use of INTERCEPT, or sustain current levels of INTERCEPT adoption. 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, upon adoption, U.S. blood centers may 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 broad 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 IFC in the U.S. will depend on our ability to:

- 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 the sale of INTERCEPT-treated products into 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 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 escalating trade tensions and the Ukraine-Russia conflict, economic slowdowns, recessions, inflation, bank failures, rising interest rates and tightening of credit markets on our business;
- 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, 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;
- 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 IFC and for the contracted blood center manufacturing partners to produce IFC at sufficient quantities and at acceptable quality levels or for other blood centers to contract with us for the purchase of kits and to produce IFC for their own sales efforts;
- 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.

The INTERCEPT Blood System may not achieve or be able to sustain broad market adoption.

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;
- 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 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 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 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. Hospitals may not have adequate staffing levels or may have competing priorities which could delay such system updates, perhaps indefinitely. Similarly, blood centers may have staffing or budgetary constraints or have competing priorities which may delay adoption of our products, including onboarding or producing IFC. 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 or continued use of technologies, including our products. In some jurisdictions, commercial use of our products may not be covered by governmental or commercial third-party payors for health care services and may never be covered. In addition, the costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third-party payors, the costs and expenses specific to the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. Governmental or third-party payors may change reimbursement rates, year-over-year, or in reaction to submitted claims for reimbursement of costs and expenses related to blood components treated with INTERCEPT. If the costs to the hospital for INTERCEPT processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, or if reimbursement rates are insufficient or decreased in any given year for blood components treated with INTERCEPT, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products. In addition, even if we are able to achieve market acceptance in the U.S. or newly commercialized markets, we have provided and may in the future provide adoption incentives which may negatively impact our reported sales.

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

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. Moreover, the market for pathogen reduction systems in the U.S. is highly concentrated and dominated by a small number of blood collection organizations. In the U.S., the American Red Cross represents the largest single portion of the blood collection market. Our ability to achieve 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. We understand that the American Red Cross has competing priorities which are currently preventing them from producing IFC for their own accounts. Until the American Red Cross can produce IFC for their own accounts, they will be dependent on us or other blood centers to supply IFC for sale to their accounts and our ability to source and produce sufficient IFC for the American Red Cross is limited. 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. The American Red Cross or other customers may impose business continuity requirements or Environmental, Social and Governance requirements to its suppliers. Should the American Red Cross or other customers impose such requirements to our business, we may be unable to satisfy the requirements without significant disruption to our operations and incurrence of costs, if at all.

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 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 authorization will first need to obtain one before using our products. The review period for a new authorization can be 12 months or longer following submission and we cannot assure that any of the potential German customers submitting a new application for authorization will obtain it. We have invested in substantial commercial resources in Germany. Without approvals 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, platelet and plasma disposable kits, maintenance services for illuminators and ancillary pooling sets 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, it is challenging to forecast with precision the purchase levels and product demand and fulfill EFS' orders. Furthermore, EFS contracts are entered into as part of a public procurement process and generally extend for multiple years with little ability to adjust pricing. Our operating margins may be negatively impacted should inflation rise faster than our contracted pricing. 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 obsolete plastic materials, 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 hospital affairs professionals may be ineffective in 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. 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. In any event, if we are unable to develop and maintain an effective and qualified U.S. based commercial organization, 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 prospects.

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.

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 our IFC business to be fully operational. Furthermore, 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. Furthermore, most of our agreements with blood center manufacturing partners do not contain minimum production requirements. If our blood center manufacturing partners do not produce sufficient quantities of IFC, or at all, our commercialization efforts will be negatively impacted. 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 IFC to hospitals or comply with unique regulations governing finished biologics, our ability to monetize and deliver IFC 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.

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.

We expect our products will continue to encounter significant competition. The INTERCEPT Blood System products and IFC 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. If additional BLAs are delayed or are never 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 will continue to negatively impact our operating results.

If competitors receive regulatory approval, certification, or are able to receive advantageous label claims sooner or less costly than we are able to, the marketability of our products in those geographies will be at a disadvantage. Regulators may not apply the same criteria for our products or competitive products which may require us to incur additional costs, may delay or preclude approval decisions by such regulators, or provide competitors with a market advantage over our products, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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. In the past, we have 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 their 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 enable these customers to treat triple dose collections, we would need to develop future configurations of the platelet system, which is not in our current business plan. 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 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 compatible with triple dose collections, and random donor platelets, we would need to perform additional product development and testing, including the possibility of 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. Unless and until we decide to pursue and potentially obtain approval of these additional product configurations, we will not be able to fully address those portions of the market, which will continue to limit our product revenue. 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. Given the scarcity of platelets in the U.S., hospitals may choose to take any available and useful platelet unit, whether or not it is treated with INTERCEPT and which blood centers may choose to defer adoption or increased usage of INTERCEPT due to a perceived lack of demand from their hospital customers. 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 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. 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.

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.

We are currently conducting 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, interruptions or delays in blood center production of the blood components used for the clinical trial, delays in recruiting subjects to participate in a study, delays in obtaining institutional review board, ministry of health or ethics committee approval to conduct a study at a prospective clinical site, 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, we experienced delays in our RedeS and ReCePI studies related to the COVID-19 pandemic. 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. Moreover, clinical trial enrollment at additional RedeS clinical trial sites have commenced later than previously anticipated, and we are continuing to assess the potential impact of that delay on the anticipated timing for completion of the RedeS study which, if that anticipated timing is delayed, would delay the timing of our planned final PMA module submission. If we are unable to enroll a sufficient number of patients for the RedeS study to generate the data needed for licensure, we will need to reach agreement with the FDA on sufficiency of fewer patients, or a new pathway to generate sufficient data for the red blood cell system, including the potential for additional Phase 3 clinical trials beyond what we are currently contemplating. If we see any treatment emergent antibodies with amustaline specificity without evidence of hemolysis in patients receiving INTERCEPT-treated RBCs 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, which would cause delay. In any event, we cannot be certain that further delays in the RedeS 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, foreign regulatory authorities, or Notified Bodies. 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 18 months for any platelet kit produced using a new solvent for the manufacture of a component. 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 post-approval clinical or *in vitro* studies as a condition of approval. While we have completed the two post-approval studies required by the FDA, there is no guarantee that we will be able to complete future studies required as a condition of approval. The post-approval studies we have been required to complete and any additional studies that the FDA may require could involve significant expense, may require us to secure adequate funding to complete and may not be successful. In addition, enrollment of post-marketing studies may be difficult to complete timely if customers of blood centers are reluctant to accept conventional, non-INTERCEPT-treated products once INTERCEPT products become available to them. Other regulatory authorities or Notified Bodies outside of the U.S. may also require post-marketing studies. Failure to successfully complete post-marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals.

The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity.

The red blood cell system has not been approved for marketing or commercialization 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. In this regard, in October 2024, we announced that the Dutch Medicines Evaluation Board, or CBG, the Competent Authority for the red blood cell system, reviewed the medicinal product or active pharmaceutical ingredient data of our MDR application for conformity assessment and a CE Certificate of Conformity to affix a CE Mark to our red blood cell system and concluded that the data included in the module were insufficient to support the proposed classification of the impurity profile of the final product, necessitating the closure of our MDR application without an approval. In collaboration with TÜV-SÜD, our Notified Body for the red blood cell system, we are assessing strategies for a potential new MDR application, including data needed to address the classification questions raised by CBG and the associated timeline. We cannot predict with certainty when, if ever, we will be able to satisfactorily address CBG's conclusions and as such, cannot predict if or when we will submit a new MDR application for the red blood cell system and, if submitted, when a decision concerning certification would occur. In any event, given the closure of our MDR application without an approval, we do not expect to receive CE Mark approval of the red blood cell system for at least eighteen months from a potential submission, if ever. Moreover, 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 for the red blood cell system 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 demonstrate to the FDA an ability to define, test, and meet acceptable specifications for our current manufactured compounds used to prepare INTERCEPT-treated red blood cells before we can initiate our planned modular PMA application submission to and seek regulatory approval of the red blood cell system from the FDA. This may require that we can demonstrate stability of our active compounds manufactured under the FDA's cGMP regulations and similar requirements outside of the U.S. to meet 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 agreements.

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 which are considered as ancillary medicinal substances by either the Notified Body in the EU. If we are unable to provide data on the use of these ancillary medicinal substance with INTERCEPT red blood cells, our ability to satisfy the requirements for CE Certificate of Conformity under a potential new MDR application will be impaired.

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 the ongoing RedeS study in the U.S. and continue to believe that we will also need to conduct and complete, and generate acceptable data from, an additional Phase 3 clinical trial including chronic anemia patients in the U.S., *in vitro* studies, and other necessary activities before the FDA will consider our red blood cell system for potential approval. 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 submit and complete our planned modular PMA application submission on the anticipated timeline or at all and to otherwise 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 the RedeS study or generate acceptable Phase 3 clinical data from chronic anemia patients in the U.S. We anticipate the final PMA module submission upon the completion of the RedeS study, assuming that we have generated acceptable Phase 3 chronic anemia data. While we previously anticipated that the completion of the RedeS study and the planned final PMA module submission would occur in the second half of 2026, clinical trial enrollment at additional RedeS clinical trial sites commenced later than previously anticipated and we are continuing to assess the potential impact of that delay on the anticipated timing for completion of the RedeS clinical trial and the planned final PMA module submission. Any delay on the planned final PMA module submission would potentially increase our development costs and delay the potential commercialization of the red blood cell system in the U.S. In any event, for our planned modular PMA application, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. In addition, if we are unable to enroll a sufficient number of patients for the 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 we are currently contemplating. Moreover, 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. Though we have not seen any clinical significance to date, we have seen antibody formation to S-303 treated red blood cells, and we will need to continue to generate data related to S-303 treatment emergent antibodies. In addition, even though we reported positive topline results from the ReCePI study in the first quarter of 2024, this does not ensure that any other clinical trials of the red blood cell system will be successful, including the RedeS study, nor does it ensure that the data from the ReCePI study will be deemed supportive of regulatory approval by the FDA. In this regard, because non-clinical and clinical data are often susceptible to varying interpretations and analyses, regulatory authorities, including the FDA, may disagree with our interpretation of the data from any of our completed clinical or non-clinical trials and may require additional clinical testing and/or further analyses from completed clinical or non-clinical trials before we can obtain regulatory approval and begin commercialization of the red blood cell system, if at all, any of which could result in increased costs to us, limit our ability to generate revenue and adversely affect our commercial prospects.

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 conformity assessment and 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. In October 2024, we announced that CBG, the Competent Authority for the red blood cell system, reviewed the medicinal product or active pharmaceutical ingredient data of our MDR application and concluded that the data included in the module were insufficient to support the proposed classification of the impurity profile of the final product, necessitating the closure of our MDR application without an approval. In collaboration with TÜV-SÜD, our notified body for the red blood cell system, we are assessing strategies for a potential new MDR application and the associated timeline. We cannot predict with certainty when, if ever, we will be able to satisfactorily address CBG's conclusions and as such, cannot predict if or when we will submit a new MDR application for the red blood cell system and, if submitted, when decision concerning certification would occur. In any event, given the closure of our MDR application without an approval, we do not expect to receive CE Mark approval of the red blood cell system for at least eighteen months from a potential submission, if ever. However, we do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to support a potential new MDR application or a CE Certificate of Conformity, even if limited to a target patient population having chronic anemia. We do not know if data from the ReCePI Phase 3 clinical trial will be accepted by TÜV or whether such data would be supportive of expanding the target patient population beyond chronic anemia patients or whether such data will be accepted at all. In addition, the European Phase 3 clinical trials in acute, and separately, chronic anemia patients, may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate 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, providing satisfactory data surrounding additional medicinal substances and classification of the medicinal product or active pharmaceutical ingredient, 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, including those resulting from the failure to obtain approval of our MDR application for the red blood cell system, 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 agreements or which costs may otherwise not be reimbursable to us under the BARDA agreements. 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 may not be successful. Currently, our contract with BARDA contemplates development of a more operationally scalable version. If we are unable to access funds contemplated under our BARDA contract for this purpose, for any reason, the development of a more operationally scalable version may require capital investment which may be beyond our means. 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 or issue related CE Certificates of Conformities. 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 have obtained approval under the CE Certificate of Conformity based on the MDR for the INTERCEPT Blood System for platelets and plasma. 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 accepted to unilaterally recognize CE Marked medical devices. 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 industry 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 Europe. 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, CE Certificates of Conformity or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

The FDA and other regulatory agencies have in the past, and may in the future, require post-approval studies to be successfully completed to maintain licensure. Successful enrollment and completion of 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, 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 understand that we will be required to obtain new PMAs for our INTERCEPT Blood System for Platelets and for Plasma with our new LED-based illuminator. We are currently working with the FDA to understand the data requirements for those PMAs. If we are unable to generate the required data for new PMAs, use of INTERCEPT in the United States will be limited to continued use with the existing illuminator, which we have a limited number of devices available and for which we have a limited time that we can continue to support and maintain.

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 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;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing, 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
- criminal prosecution.

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

If we modify our FDA-approved 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.

We understand that we will be required to obtain new PMAs for our INTERCEPT Blood System for Platelets and for Plasma with our new LED-based illuminator. We are currently working with the FDA to understand the data requirements for those PMAs. If we are unable to generate the required data for new PMAs, use of INTERCEPT in the United States will be limited to continued use with the existing illuminator, which we have a limited number of devices available and for which we have a limited time that we can continue to support and maintain.

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. Obtaining new related CE Certificates of Conformity or variation of existing Certificates 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.

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.

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 largely 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 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. 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; laws that require device and biologics companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government or otherwise restrict payments that may be made to healthcare providers; 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 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. The Division closed its investigation on January 15, 2025 without initiating any claim or proceeding against us relating to these matters. We are currently and may again in the future become subject to similar investigations by other state or federal government agencies. If the outcome of the CID or any such similar investigation 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 incurred significant costs in connection with the CID, and we could incur significant costs in connection with potential future similar investigations, 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.

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in countries outside of the U.S.

In the European Economic Area ("EEA") (comprised of the 27 EU Member States, plus Iceland, Lichtenstein and Norway), Regulation (EU) 2017/745 on Medical Devices, or the Medical Device Regulation ("MDR") and its associated guidance documents and harmonized standards govern many aspects of the regulation of medical devices. This includes device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance.

Medical devices must comply with the General Safety and Performance Requirements ("GSPRs"), set out in Annex I to the Medical Device Regulation. Compliance with these requirements is a prerequisite to affixing the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the Medical Device Regulation and obtain the right to affix the CE mark, medical devices manufacturers must conduct a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low-risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires review by a Notified Body. A Notified Body is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical device. Following a successful assessment process, the Notified Body issues a CE Certificate of Conformity. This Certificate and completion of the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must include the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical investigations conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical investigations and scientific literature. Moreover, after a device is placed on the market, it remains subject to significant regulatory requirements that must commonly be fulfilled by the manufacturer or on their behalf.

The Medical Device Regulation includes a number of transitional provisions. Manufacturers of medical devices may only benefit from the transitional provisions if certain conditions are fulfilled. If we or our products fail to comply with the requirements of MDR, then our products may not be permitted to be sold in the EU or other jurisdictions that recognize CE Certificate of Conformity and our results of operations and financial projections would be adversely affected.

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 became effective on January 1, 2023, restricts use of certain categories of sensitive personal information; further restricts the use of cross-contextual advertising techniques; establishes restrictions on the retention of personal information; expands the types of data breaches subject to the private right of action; and 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 became effective in 2023. We are or may become subject to new, additional, different or changed data privacy laws, at the state or other levels of government, and correspondingly the risk of enforcement action against us could increase because we have or 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 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 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 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, 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 the ordinary course of business, we may transfer personal data 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 and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border 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 face significant adverse consequences, including the interruption or degradation of our operations, the need to 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 personal data necessary to operate our business. Additionally, companies that 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 European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

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 amendments and executive, judicial and Congressional challenges to numerous provisions of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed 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 manufacturer discount program. It is unclear how any such challenges and the healthcare reform efforts of the second Trump 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.

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 EU Member states may, after a medical device is CE marked, 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. In December 202, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which has applied as of January 12, 2025, is intended to boost cooperation among EU Member States in assessing health technologies, and, where the medical device is a class IIb or class III medical device or an in-vitro diagnostic medical device of class D, providing the basis for cooperation at EU level for joint clinical assessments in these areas. If the conclusion of these assessments are negative, or compare our products unfavorably with competing products, this may impact our pricing and reimbursement status. If we are unable to obtain or maintain favorable pricing and reimbursement status in EU Member States for our medical devices or medical devices that we may successfully develop and for which we may obtain certification, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

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 agreements, and if BARDA were to eliminate, reduce, delay, or object to extensions for funding of our agreements, 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 agreements with BARDA. The original agreement that we entered into in 2016, or the 2016 Agreement, including its subsequent modifications, provides for reimbursement of certain expenses incurred by us for up to approximately $270.2 million to support the development of the red blood cell system. However, the 2016 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 2016 Agreement and the potential exercise of subsequent option periods. To date, BARDA has exercised approximately $185.5 million under the base period of the 2016 Agreement and associated options. BARDA will no longer exercise any of the remaining options under the 2016 BARDA Agreement. In September 2024, we entered into a new agreement with BARDA, the 2024 Agreement, which includes potential funding of up to approximately $188.4 million under a base period and subsequent option periods, similar to the 2016 Agreement. Our ability to access the full amount available under the 2024 Agreement is dependent on our success in completing required tasks under the base period and each option period, if and to the extent any option periods are exercised by BARDA, which it may do or not do in its sole discretion. In addition, BARDA is entitled to terminate either of our BARDA agreements 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. We understand that the 2016 Agreement with BARDA will expire in 2026 and the 2024 Agreement with BARDA will expire in 2030. Under both BARDA agreements, activities covered under the base period and

exercised option periods may ultimately take longer than is allowed or cost more than is covered by the respective BARDA agreements, and 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 2016 Agreement in the near-term. We are uncertain how future U.S. government budgets, executive actions, and debt ceiling negotiations 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 our BARDA agreements. 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 our BARDA agreements. Moreover, the continuation of our BARDA agreements 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 our agreements 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. Our ability to meet the expectations of BARDA under our agreements 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 agreements. If we are unable to provide adequate supplier oversight or if suppliers are unable to comply with the requirements of the agreements, our ability to meet the anticipated milestones may be impaired.

There can also be no assurance that our BARDA agreements will not be terminated, that our BARDA agreements 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 agreements 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 ambiguity regarding the amount available for government funding. The U.S. Federal Government has imposed a standardized indirect cost rate on grants administered by the National Institutes of Health. The standardized rates are significantly lower than our current audited indirect rates. While our contracts with BARDA are not currently impacted by these orders, should the U.S. Federal government impose similar restrictions, we would have to absorb many of our indirect costs which would adversely affect our operating results. 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, 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 successfully complete contemplated milestones, our agreements 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 agreements are terminated or suspended, if there is any reduction or delay in funding under our BARDA agreements, or if BARDA determines not to exercise some or all of the options provided for under the agreements, 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 our BARDA agreements, 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 agreements. 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 agreements.

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 us, 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.

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

U.S. government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our agreements 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 agreements based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA agreements and may, under certain circumstances involving public health and safety, license such inventions to third parties without our consent;
- impose restrictions on indirect rates that may be applied to contracts with the federal government;
- cancel, terminate or suspend our BARDA agreements based on violations or suspected violations of laws or regulations;
- terminate our BARDA agreements 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 agreements;
- decline to exercise an option to continue the BARDA agreements;
- 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 agreements 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 agreements.

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. 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 agreements, 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 agreements, 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. Moreover, as a U.S. government contractor, we maintain plans to ensure compliance with nondiscrimination and regulatory requirements for qualified employees on the basis of gender, race, disability and veteran status. Consequently, we may be subject to executive orders and regulatory changes affecting various aspects of our operations, including compliance with nondiscrimination plans. Any required elimination or modification of such plans in response to new executive orders could pose challenges in hiring or retaining employees and may lead to other adverse operational impacts. Failure to comply with these requirements could expose us to administrative, civil, or criminal liabilities, including fines, penalties, repayments or suspension or debarment from eligibility from future U.S. government 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 rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries.

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain and maintain any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may adversely

affect our financial condition and results of operations. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of product revenue and our ability to accurately forecast our product supply needs. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, initial purchases of illuminators or INTERCEPT disposable kits by these third parties may not lead to follow-on purchases of platelet and plasma systems' disposable kits. We have a finite number of illuminators that can be produced under the current approved configuration before a redesigned and approved illuminator is available. Our ability to continue to support and provide spare parts for the existing illuminators is limited. Accordingly, distributors may need to purchase and either sell or own an equivalent number of new LED-based illuminators that are used in their geographies in order to continue servicing their customers. Distributors may be unable to afford to purchase that many new illuminators, which may require us to provide financing, or may choose to no longer sell INTERCEPT to customers in their geographies. 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 are currently permitted to supply illuminators and spare parts to service existing illuminators installed in Russia and Belarus, under certain conditions and requirements under a special license exception. If the special license exception becomes unavailable to us or if we are unable to meet the conditions and requirements under the special license exception in the future, 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 Belarusian 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. Furthermore, the JV will need to demonstrate compliance with cybersecurity regulations to obtain approval of the illuminator in China. The current illuminator was not designed with current cybersecurity standards and safeguards. Should the JV be unsuccessful in demonstrating compliance with the contemporary cybersecurity requirements, the ability to obtain approval for INTERCEPT platelets in China may also be impaired. 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.

Our manufacturing supply chain exposes us to significant risks.

We do not own our own manufacturing facilities, but rather manufacture our products using a number of third-party suppliers, many of whom are our sole suppliers for the particular product or component that we procure. We rely on various contracts and our relationships with these suppliers to ensure that the sourced products are manufactured in sufficient quantities, timely, to our exact specifications and at prices we agree upon with the supplier. For example, Fresenius is our sole supplier for the manufacture of finished disposable kits for the platelet and plasma systems. We also rely on other third-party suppliers for other components and products that are currently our sole qualified suppliers for such components and products. In the event Fresenius or any of our other sole qualified suppliers refuses or is unable to continue operating under our supply agreements with them, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected. 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. 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. Certain equipment used by manufacturing partners are only used to manufacture our products and are significantly aged and maintained by a limited number of vendors. Should our partners be unable to service and maintain this equipment, production volume and quality of our products may be limited. 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 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 made 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 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 take an extended period of time to complete and obtain regulatory approval. Until such time as we obtain approval for the new LED-based

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 may seek to obtain regulatory approval in certain geographies with the current model illuminator prior to the new model illuminator becoming available. Should regulators require cybersecurity safeguards of the current model illuminator, we may be unable to satisfy such requirements. 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 currently approved illuminator design 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 have signed an agreement with a supplier to produce the new LED-based illuminator. Some 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. While we have validated this new supplier for the new LED-based illuminator, until we obtain regulatory approvals and sell those, 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. Our inability to efficiently and timely convert the existing illuminators in the field to the new illuminator, if approved, could negatively impact our ability to maintain the existing installed base.

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. To meet the growing demand for our products and to invest in future quality improvements and gross margin expansion, we have invested in capital equipment, capacity expansion and cost reduction projects with many of our suppliers. These projects may cost more than anticipated, may not produce the anticipated benefits or may be delayed, any of which would potentially limit our expected return on investment and affect our operations. 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. Furthermore, in order to gain access to certain markets, local or regional manufacturing may be required for certain production aspects of our products. Such requirements will require additional oversight from a quality and supply chain perspective and will potentially dilute any economies of scale we would have otherwise been able to generate from existing supplier sites.

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, our reputation and business prospects may be impaired.

Further, certain distributors and customers require, and potential future distributors or customers may require, product with a minimum shelf life. If customers requiring minimum shelf-lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf-lives which may lead to increased write-offs and inefficient use of our cash. Should we choose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs and/or reduced gross margins. In order to meet minimum shelf-life requirements, we may need to manufacture sufficient product to meet estimated forecasted demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. Our platelet and plasma systems' disposable kits have 18 to 24 months shelf lives from the date of manufacture. Should we change or modify any of our product configurations or components, such future configurations of our products may not achieve the same shelf life that existing products have. Given the 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. timely. In addition, our supply chain has been impacted by worker strikes and other disruptions at ports in which we ship product from and into. Should we encounter such disruptions in the future, we may choose to incur air-freight costs which are much more expensive than ocean shipment and often result in more damage to our products than ocean shipment. 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 may result in increased costs to ship our products via ocean and meet our supply chain requirements. Should the conflict continue or worsen, or if it begins to impact our costs or ability to secure shipping, or if we are unable to ship products and components to meet our supply chain demand, we may 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 or expand the number of manufacturing partners producing IFC for us, 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. The pricing for plasma derived products has become increasingly competitive and has placed a strain on the availability of plasma for production of IFC. Should this constraint escalate or be prolonged, our costs may increase, or we may be unable to meet the demand we and others have generated for IFC. Should that occur, the dependability of a consistent supply may be called into question and customers and prospective customers may choose not to use IFC for their operations. To minimize this risk, we may meet hospital or blood center demand and choose to purchase IFC from blood centers outside of our current manufacturing partners which may not be economical. We currently have limited 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. Changes in environmental, safety or other regulations may require change to our products which would result in increased distraction of personnel and increased cost. For instance, certain plasticizers may be phased out. Should that occur, finding, validating and demonstrating comparability of an alternative may be time consuming and costly, if feasible at all. Any shortage, obsolescence or discontinuation 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 or increase our costs to supply our customers. 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 or accessories used by blood center operators or used in the production of INTERCEPT will comply with the new standards under the MDR. Failure to comply with the new standards timely may result in a disruption to blood center operations or the manufacture of the INTERCEPT Blood System. If any of these events were to occur, our product quality, competitive position, reputation and business could suffer, we could experience cancellations of customer orders, refusal by customers to accept deliveries or a reduction in our prices and margins to the detriment of our financial performance and results of operations.

Risks Related to Our Financial Condition and Capital Requirements

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

Our cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. While our net losses 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 may be in excess of our 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 may be unsustainable or increase faster than the anticipated revenue growth. In addition, we expect to incur additional research and development costs associated with inflationary pressures on labor and study costs, the development of different configurations of existing product candidates and products and our illuminator, development of new products, planning, enrolling and completing ongoing clinical and non-clinical studies, including the post-approval studies or registry studies we are and may be required to conduct in connection with the approvals of the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., performing the agreed-upon activities under our government agreements, legal compliance, and creating, maintaining and defending our intellectual property. Moreover, both our near and long-term capital requirements will require that we continue to invest in capital purchases to support ongoing and proposed studies, in addition to manufacturing capacity expansion to support our growing business. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for CE Certificates of Conformity in the EU, if costs are higher than anticipated or we encounter further delays. In this regard, our product development costs

will be ongoing in connection with our failure to obtain approval of our MDR application and the potential submission of a new MDR application and would also increase if existing clinical data is insufficient for us to either submit or potentially obtain approval of any such new application. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our government contracts, 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. These costs could be substantial and could extend the period during which we expect to operate at a loss, particularly if we experience any difficulties or delays in completing the activities. In addition, we may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, or to compete favorably with other blood safety interventions or other pathogen reduction technologies, which may reduce or altogether eliminate any gross profit on sales.

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

While we have recently been able to generate a sufficient amount of revenue and generate positive net cash flows from operations, we may be unable to sustain those results in the future. If we are unable to continue to produce positive operating cash flows or at sufficient levels, meeting our long-term capital requirements will be, 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, if at all, and interest income earned on the investment of our cash balances. While we believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our agreements with BARDA, the FDA, and the DoD, will be sufficient to meet our capital requirements for at least the next 12 months, if we are unable to generate sufficient product revenue, or access sufficient funds under our government contracts or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, including inflationary assumptions, 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 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, or qualify for and exercise our option to delay amortization to April 1, 2027, the principal amounts outstanding under our Term Loan Credit Agreement will begin amortizing on April 1, 2026 and will 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 increase, the rates that we are obligated to pay under our credit agreements would increase, 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, including those resulting from new tariffs and escalating trade tensions, and other factors including past and potential future U.S. bank failures, we do not know whether additional capital will be available when needed, or that, if available, whether we will be able to obtain additional capital on reasonable terms. Specifically, monetary policies of many countries, as well as recent bank failures, have

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. 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 could negatively 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. We may not be able to offset price increases from vendors with price increases to customers at sufficient levels, if at all, which would harm our results of operations. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for CE Certificates of Conformity in the EU, if costs are higher than anticipated or we encounter further delays. In this regard, our product development costs not reimbursed by our BARDA agreements will be prolonged in connection with our failure to obtain approval of our MDR application and the potential submission of a new MDR application. Development costs not covered by our BARDA agreements may increase if existing clinical data is insufficient for us to either submit or potentially obtain approval of any such new application. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our government contracts, 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, 2024, our total indebtedness under our Term Loan Credit Agreement and Revolving Loan Credit Agreement was approximately $84.2 million. All of our current and future assets, except for intellectual property and certain investments in subsidiaries and affiliates, 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. 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 required to make principal payments beginning in April 2026 until March 1, 2028 if not repaid sooner.

Risks Related to Managing Our Growth and Other Business Risks

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

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

We will need to maintain and may need to increase our competence and size in a number of functions, including sales, deployment and product support, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with U.S., 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 join or stay employed at Cerus. 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, disruptions due to political instability, 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 distributors in Russia and Belarus more difficult. Additionally, the resumption of war between Israel and Hamas, the conflict between Israel and Hezbollah, 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 have received a license to continue ensuring that Russian and Belarusian patients can receive INTERCEPT products, we cannot assure you that the license will be effective for an extended period of time, if at all. Even though we obtained the license, banking restrictions have made transacting with Russian and Belarusian customers much more difficult. If these challenges persist or worsen, we may not be able to continue transacting with those customers. 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 distributors. Furthermore, a larger portion of the Russian economy may be spent fighting the war against Ukraine which may have a negative impact on overall healthcare budgets. 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.

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

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

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

- complying with diverse and unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- complying with other laws and regulatory requirements to which our business activities abroad are subject, such as the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti-corruption intent in foreign countries (as discussed in greater detail above under "*Risks Related to Regulatory Approval, 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, 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.

Moreover, the new Trump administration has called for substantial changes to foreign trade policy and has recently imposed tariffs on certain imports. Canada, China and other countries have responded with retaliatory tariffs on certain U.S. exports. If trade restrictions and tariffs increase our operating costs in the future, and we are not able to recapture those costs from our customers, or if such restrictions or tariffs make it more difficult for us to compete in overseas markets, our business, financial condition and results of operations could be adversely impacted.

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 agreements, 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 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 NOL carryforwards incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year. 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 such 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 NOL 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 NOL carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Risks Related to Our Intellectual Property

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

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

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

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, we are aware of an expired U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to have infringed any valid claim of this patent, we may, among other things, be required to pay damages. Our patents expire at various dates between 2025 and 2042. 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 $2.42 on March 6, 2024, and a low of $1.52 on November 1, 2024, in the twelve-month period ended December 31, 2024. 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.

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

None.

Item 2. ***Properties***

Our corporate headquarters, which includes our principal executive offices, is located in Concord, California. We lease this facility, which includes 84,631 square feet and includes laboratory space for blood safety research and supports general administrative, marketing and technical support functions. Of the 84,631 square feet, we sublease 14,908 square feet to a subtenant under a three-year lease ending March 31, 2025 and ceased using approximately 15,000 square feet of rentable area of corporate office building in the third quarter of 2023. We are currently marketing our vacant space and subleased space for lease after March 31, 2025. We also lease an office facility

in Amersfoort, the Netherlands, which is used for selling and administrative functions. We believe that our current and future facilities will be adequate for the foreseeable future.

Item 1C. ***Cybersecurity***

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property and confidential information that is proprietary, strategic or competitive in nature or Information Systems and Data.

Our information security function, led by our Senior Director, IT & Facilities and our Senior Manager, IT Infrastructure and Operations, helps identify, assess and manage our cybersecurity threats and risks. Our information security function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods and resources including, for example automated tools, internal and external audits, external intelligence feeds and third-party threat assessments; conducting scans of the threat environment, threat assessments for internal and external risk and vulnerability assessments to identify vulnerabilities; evaluating our and our industry's risk profile and threats reported to us; subscribing to reports and services that identify cybersecurity threats; analyzing reports of threat and threat actors and coordinating with law enforcement concerning threats; and internal tabletop incident response exercises.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response plan, disaster recovery/business continuity plans and cybersecurity insurance; incident detection and response, risk assessments, systems monitoring and penetration testing; encryption of data, network security controls, access controls, physical security and asset management, tracking and disposal; and employee training.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, cybersecurity risk is addressed as a component of our enterprise risk management process; the information security function works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional service firms, threat intelligence service providers, cybersecurity software providers, managed cybersecurity service providers, penetration testing firms and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as third-party distributors for our products in certain countries and third-party suppliers for the manufacture of our products, as well as third-party application providers and third-party hosting companies. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, we may impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under "Item 1A—*Risk Factors*" in Part I of this Annual Report on Form 10-K, including the risk factor captioned, "*Significant disruptions of information technology systems or actual or alleged breaches of data security could adversely affect our business*."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by members of management, including our Senior Director, IT & Facilities and our Senior Manager, IT Infrastructure and Operations. Our Senior Director, IT & Facilities has over 26 years of experience in systems engineering, network design and security and is a Certified Information Systems Security Professional, or CISSP. Our Senior Manager, IT Infrastructure and Operations has over 24 years of experience in network administration, security administration and incident response and remediation.

Our Senior Director, IT & Facilities and our Senior Manager, IT Infrastructure and Operations are responsible for helping to integrate cybersecurity risk considerations into our overall risk management strategy and communicating key priorities to relevant personnel. Our Senior Director, IT & Facilities and our Senior Manager, IT Infrastructure and Operations are responsible for helping prepare for cybersecurity incidents, approving cybersecurity processes and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including Senior Director, IT & Facilities, Chief Legal Officer, Chief Financial Officer, Chief Executive Officer and others. Those individuals work with our incident response team to help us mitigate and remediate cybersecurity incidents of which

they are notified. In addition, our incident response plan includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee of the board of directors receives periodic reports from our Senior Director, IT & Facilities and third-party experts concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The board of directors also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 3. ***Legal Proceedings***

None.

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

Not applicable.

PART II

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

Our common stock is traded on the Nasdaq Global Market under the symbol "CERS". On February 6, 2025, we had 115 holders of record of our common stock.

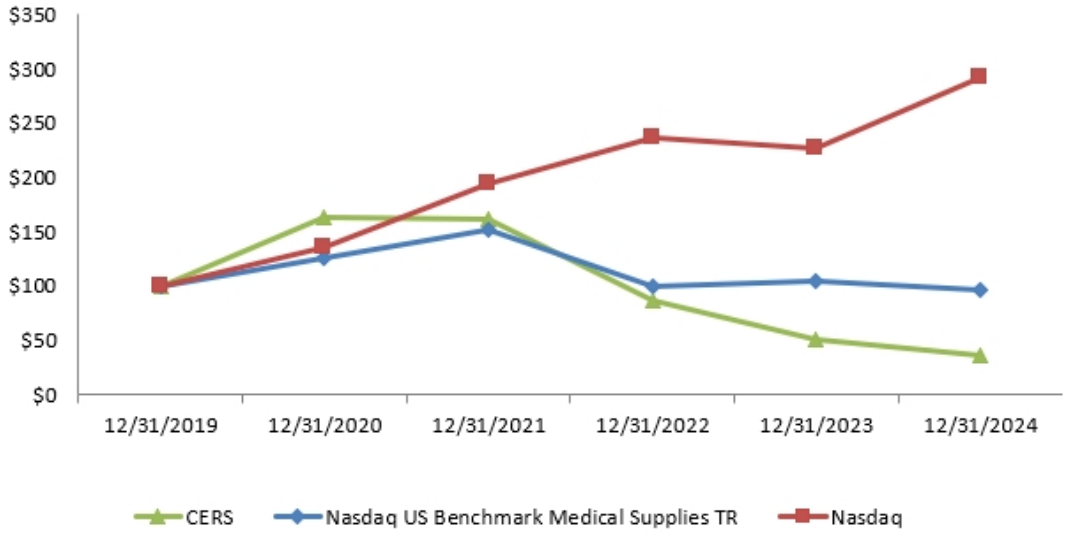
Dividends

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

Stock Performance Graph [(1)]

The following graph shows the total stockholder return of an investment of $100 in cash (and the reinvestment of any dividends thereafter) on December 31, 2019, and tracked the performance through December 31, 2024, for (i) our common stock, (ii) the US Benchmark Medical Suppliers TR, and (iii) the Nasdaq Stock Market (United States) Index. Our stock price performance shown in the graph below is based upon historical data and is not indicative of future stock price performance.

Comparison of 5-year Cumulative Total Return on Investment



	December 31,					
	2019	2020	2021	2022	2023	2024
Cerus Corporation	$ 100.00	$ 163.98	$ 161.37	$ 86.49	$ 51.18	$ 36.49
Nasdaq US Benchmark Medical Supplies TR	100.00	125.26	151.98	99.65	105.43	95.87
Nasdaq	100.00	135.23	194.24	235.78	226.24	291.03

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

Item 6. ***Reserved***

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

This discussion and analysis should be read in conjunction with our audited consolidated financial statements and the accompanying notes included in this Annual Report on Form 10-K for the year ended December 31, 2024. Operating results for the year ended December 31, 2024, are not necessarily indicative of results that may occur in future periods. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that impact our business, including but not limited to the risks and uncertainties described in "Risk Factors" in Part I, Item 1A in this Annual Report on Form 10-K. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends.

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of the INTERCEPT Blood System. Our INTERCEPT Blood System is intended for use with blood components and certain of their derivatives: plasma, platelets, red blood cells and to produce INTERCEPT Fibrinogen Complex, or IFC, and pathogen reduced plasma, cryoprecipitate reduced. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals and certifications, 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 which 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 we sell IFC or disposable kits to manufacture IFC in the U.S. using our direct sales force.

The platelet system is approved by the FDA in the U.S. for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in 100% plasma or InterSol in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease or TA-GVHD. The plasma system is approved by the FDA in the U.S. for ex vivo preparation of pathogen-reduced, whole blood derived or apheresis plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion, and as an alternative to gamma irradiation for prevention of TA-GVHD. Outside of the U.S., we have received CE Certificates of Conformity issued by our Notified Body in accordance with the European Union Medical Devices Regulation 2017/745, or MDR, for the platelet system and the plasma system and affixed the CE Mark to these products.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development and has not been commercialized anywhere in the world. We filed our application for conformity assessment to obtain a CE Certificate of Conformity to affix the CE Mark to the red blood cell system in December 2018 under the Medical Device Directive 93/42/EEC, or MDD, and in June 2021, we completed the resubmission of our application under the MDR. In October 2024, we announced that TÜV-SÜD's, our Notified Body for the red blood cell system, in consultation with the Dutch Medicines Evaluation Board, or CBG, the Competent Authority for the red blood cell system, reviewed information regarding the medicinal product or active pharmaceutical ingredient of our MDR application and concluded that the data provided were insufficient to support the proposed classification of the impurity profile of the final product, necessitating the closure of our MDR application without an approval. In collaboration with TÜV-SÜD, we are assessing strategies for a potential new MDR application, including data to address the classification questions raised by CBG. We cannot predict with certainty when, if ever, we will be able to satisfactorily address CBG's conclusions and as such cannot predict if or when we will submit a new MDR application for the red blood cell system and, if submitted, when a decision concerning certification would occur. In addition, as a result of the failure to obtain approval of our MDR application, our product development costs will be ongoing. See also the risk factor entitled "The red blood cell 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. In 2017, we initiated a Phase 3 clinical, double-blind study in the U.S., known as the RedeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional, red blood cells. We also recently announced positive topline results from a Phase 3 clinical trial in the U.S., known as the ReCePI study, that was designed to evaluate the efficacy and safety of INTERCEPT-treated red blood cells in patients requiring transfusion for acute blood loss during surgery. We announced that the ReCePI study met its primary efficacy endpoint, demonstrating non-inferiority for INTERCEPT RBCs compared to conventional RBCs as measured by the incidence of acute kidney injury (AKI) following transfusion of study RBCs. We continue to believe that we will need to conduct and complete, and generate acceptable data from an additional Phase 3 clinical trial in chronic anemia patients in the U.S., *in vitro* studies, and other necessary activities before the FDA will consider our red blood cell system for potential approval. We anticipate initiating a modular PMA application to the FDA upon the anticipated completion of the RedeS clinical trial. While we previously anticipated that the completion of the RedeS clinical trial and the planned final PMA module submission would occur in the second half of 2026, clinical trial enrollment at additional RedeS clinical trial sites recently commenced later than previously anticipated and we are continuing to assess the potential impact of that delay on the anticipated timing for completion of the RedeS clinical trial and the planned final PMA module submission. In any event, for our planned modular PMA application, we will seek to introduce supplemental clinical data we

obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. In addition, if we are unable to enroll a sufficient number of patients for the RedeS study to generate the data needed for licensure, we will need to reach agreement with the FDA on sufficiency of fewer patients, or a new pathway to generate sufficient data for the red blood cell system, including the potential for additional Phase 3 clinical trials beyond what we are currently contemplating. We must also demonstrate to the FDA an ability to define, test and meet acceptable specifications for our current manufactured compounds used to prepare INTERCEPT-treated red blood cells before we can initiate our planned modular PMA application submission to and seek regulatory approval of the red blood cell system from the FDA. We do not know whether or not the FDA will have a similar perspective on the information regarding the medicinal product as CBG, or that we will be able to answer such questions satisfactorily, should they arise.

We have agreements with Biomedical Advanced Research and Development Authority, or BARDA, part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, under which we receive funding from BARDA to support the development of our red blood cell system, including clinical and regulatory development programs in support of potential licensure, and development, manufacturing and scale-up activities, as well as activities related to broader implementation of all three INTERCEPT systems in areas of emerging pathogens. The initial agreement currently expires in September 2026 and the new agreement currently expires in September 2030. The ReCePI study was funded and the RedeS and other studies are being funded as part of our initial BARDA agreement and BARDA reimburses us for allowable direct contract costs, as such costs are incurred, and for allowable indirect costs under both agreements. If we are unable to access all of the activities and associated reimbursement amounts for the remaining options available under our new BARDA agreement, we will need to fund the activities required to satisfy the requirements for PMA licensure in the U.S. See the discussion under "Government contracts" below for more information. Should those amounts be inaccessible and should we be unable to self-fund the remaining initiatives, successful completion of the development of the red blood cell system may require us to obtain additional capital in order to obtain any regulatory approvals for and commercialize this product. In addition, if we are unable to obtain from our suppliers sufficient clinical quantities of the active compounds for our red blood cell system meeting defined quality and regulatory specifications, if our suppliers are not able to maintain regulatory compliance or if we experience additional delays in enrollment or completion of the RedeS study, our product development costs would likely increase.

In November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. We commercialize and sell finished IFC made by our manufacturing blood center partners and other blood centers directly to hospitals and indirectly through certain blood centers. Similar to our platelet and plasma products, any blood center manufacturing IFC will need to complete its process validations and obtain site-specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, before we or they can sell finished IFC in interstate commerce. While all of our manufacturing partners have now received their Biologics License Application, or BLAs, from CBER, we plan to continue working with any other U.S.-based blood centers producing IFC to support their licensure applications. Delays in obtaining these licenses have adversely impacted and additional delays will adversely impact the nationwide availability of IFC in the U.S. In addition, we have also entered into certain agreements with blood centers who will purchase the finished IFC from us to sell to their hospital customers, and with blood center and blood center affiliate organizations to sell INTERCEPT Blood System for Cryoprecipitation kits to produce finished IFC for their own sales efforts to hospitals. Furthermore, most of our agreements with blood center manufacturing partners do not contain minimum production requirements. If our blood center manufacturing partners do not produce sufficient quantities of IFC, or at all, our commercialization efforts will be negatively impacted. However, 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 blood centers producing IFC receive approval of their BLAs, our IFC sales will be limited.

We have borrowed and, in the future, may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to the Amended and Restated Credit, Security and Guaranty Agreement (Term Loan), or the Term Loan Credit Agreement, and Amended and Restated Credit, Security and Guaranty Agreement (Revolving Loan), or the Revolving Loan Credit Agreement, as described below, or potentially pursuant to new arrangements with different lenders. We have borrowed and may in the 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, or qualify for and exercise our option to delay amortization to April 1, 2027, the principal amounts outstanding under our Term Loan Credit Agreement will begin amortizing on April 1, 2026 and will require us to pay amounts as they come due in cash, which would negatively impact our available working capital. Should interest rates increase, the rates that we are obligated to pay under our credit agreements would increase, 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, including through the Controlled Equity Offering[SM] Sales Agreement, as mended, or the Sales Agreement. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty, political change, war, the effects of inflationary pressures, including those resulting from new tariffs and escalating trade tensions, and other factors including past and potential future U.S. bank failures, we do not know whether additional capital will be available when needed, or that, if available, whether we will be able to obtain additional capital on reasonable terms. Specifically, monetary policies of many countries, as well as recent bank failures, have 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 and global events over the past few years, the U.S. and many countries are currently experiencing an inflationary environment. In addition, the U.S. Federal Reserve in the past 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 could negatively impact equity values, including the value of our common stock. Furthermore, our vendors and suppliers may raise prices in an inflationary environment, including as a result of new tariffs imposed by the new Trump administration and retaliatory tariffs imposed by China and other countries, costs to transport our products may increase and access to timely shipping may be limited. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for CE Certificates of Conformity in the EU, if costs are higher than anticipated or we encounter further delays. In this regard, our product development costs will be ongoing in connection with our failure to obtain approval of our MDR application and the potential submission of a new MDR application and would also increase if existing clinical data is insufficient for us to either submit or potentially obtain approval of any such new application. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our government contracts, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time our existing operations provide sufficient cash flow to conduct these trials.

Although we received FDA approval of our platelet and plasma systems in December 2014, our U.S. commercial efforts continue to be largely focused on enabling blood centers that are using INTERCEPT to optimize production and increase the number of platelet units produced and made available to patients and continuing to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. In addition, to address the entire market in the U.S., customers will need to modify their operating practices, or we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. All U.S. blood centers must be compliant with the FDA guidance document, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U.S. blood centers for compliance, we cannot predict if U.S. customers will continue to adopt INTERCEPT over other options or at what levels. Should we be unable to manufacture INTERCEPT in sufficient quantities in a timely manner, or have adequate resources to assist customers with implementing the INTERCEPT Blood System, U.S. blood centers may be forced to use alternate options allowed by the guidance document, which could permanently impact our ability to convert those blood centers to INTERCEPT users.

We understand that we will be required to obtain new PMAs for our INTERCEPT Blood System for Platelets and for Plasma with our new LED-based illuminator. We are currently working with the FDA to understand the data requirements for those PMAs. If we are unable to generate the required data for new PMAs, use of INTERCEPT in the United States will be limited to continued use with the existing illuminator, which we have a limited number of devices available and for which we have a limited time that we can continue to support and maintain.

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

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

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

In addition to the anticipated product revenues from sales of our platelet and plasma systems and sales of IFC, we anticipate that we will continue to recognize revenue from our government contracts. We recognize government contract revenue associated with the government contracts as qualified costs are incurred for reimbursement over the performance period or as a percentage of the overall contract price based on the extent of progress towards completion.

Fresenius

Fresenius Kabi AG, Fenwal France SAS, and Fenwal International, Inc., or collectively, Fresenius, manufactures and supplies the platelet and plasma systems to us under our Second Amended and Restated Supply and Manufacturing Agreement, or the 2022 Agreement, until December 31, 2031. Fresenius is obligated to sell, 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. 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. Each party has 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. For a discussion of the risks presented to our supply chain, see "Item 1A—*Risk Factors*" of this Annual Report on Form 10-K.

See Note 14, *Development and License Agreements*, to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for further information regarding the 2022 Agreement.

Government contracts

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

The 2016 BARDA Agreement provides for the reimbursement of certain amounts incurred by us in connection with our satisfaction of certain contractual milestones. Under the 2016 BARDA Agreement, we are reimbursed and recognize revenue as qualified direct contract costs are incurred plus capped indirect costs, which permit partial recovery of fringe benefits, overhead and general and administrative expenses. As of September 30, 2024, BARDA has committed to reimburse certain of our expenses related to the clinical development of the red blood cell system during a base period, or the 2016 Base Period, and under exercised option periods, or 2016 Option Periods, in an aggregate amount of up to $185.5 million. BARDA will no longer exercise any unexercised options under the 2016 BARDA Agreement.

In September 2024, we entered into a new agreement with BARDA, or the 2024 BARDA Agreement. The 2024 BARDA Agreement builds on the 2016 BARDA Agreement and aims to further advance the development of the red blood cell system. The 2024 BARDA Agreement includes access to funding that is intended to support a planned FDA modular premarket approval application and potential post-approval studies, accelerate development of an improved version of the red blood cell system, and scale up chemistry, manufacturing, and controls activities to enable a broad product launch, if approved. The six-year agreement with BARDA includes a base period, or the 2024 Base Period, with committed funding of up to $32.1 million, and subsequent option periods, or 2024 Option Periods, that, if exercised by BARDA and completed, would bring the total funding opportunity of $188.4 million as of September 30, 2024. We could be responsible for cost sharing of up to $60.1 million which we would satisfy by agreeing to utilize lower fringe, overhead, and G&A rates for select options than we are otherwise allowed to use as supported by audited indirect cost submissions. BARDA will make periodic assessments of our progress, and the continuation of the 2024 BARDA Agreement is based on our success in completing the required tasks under the 2024 Base Period and each 2024 Option Period (if and to the extent any 2024 Option Periods are exercised by BARDA). BARDA has rights under certain contract clauses to terminate the 2024 BARDA Agreement, including the ability to terminate for convenience at any time. Under the contract, we will be reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. The U.S. Federal Government has imposed a standardized indirect cost rate on grants administered by the National Institutes of Health. The standardized rates are significantly lower than our current audited indirect rates. While our contracts with BARDA are not currently impacted by these orders, should the U.S. Federal Government impose similar restrictions, we would have to absorb many of our indirect costs which would adversely affect our operating results. See Note 14, *Development and License Agreements*, to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for further information regarding our agreements with BARDA.

In September 2020, we entered into a five-year agreement with the FDA for the development of next-generation compounds to optimize pathogen reduction treatment of whole blood to reduce the risk of transfusion-transmitted infections. Under the agreement, we are reimbursed and will recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. The total contract value is $11.1 million. See Note 14, *Development and License Agreements*, to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for further information regarding the agreement with the FDA.

In September 2022, we entered into an agreement with the U.S. Department of Defense, or DoD, for the development of pathogen reduced, lyophilized cryoprecipitate to treat bleeding due to trauma. In May 2023, we entered into an amendment to the agreement with the DoD to extend the agreement to February 2027 and increased the total contract value from $9.1 million to $17.8 million. Under the agreement, we are paid upon completion of each milestone and will recognize revenue 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 overall contract price based on the extent of progress towards completion. See Note 14, *Development and License Agreements*, to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for further information regarding the agreement with the DoD.

Equity Agreements

See Note 11, *Stockholders' Equity*, to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for further information regarding the Amended Sales Agreement.

Debt Agreements

See Note 8, *Debt,* to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

Comparability

This Management's Discussion and Analysis of Financial Condition and Results of Operations generally discusses December 31, 2024 and December 31, 2023 items and year-to-year comparisons between 2024 and 2023, respectively. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 5, 2024.

Critical Accounting Policies and Management Estimates

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

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

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

The main source of our revenue is product revenue from sales of the INTERCEPT Blood System for platelets and plasma, or the platelet and plasma systems or disposable kits, UVA illumination devices, or illuminators, maintenance services of illuminators, and IFC. We sell the platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. We sell IFC directly to hospital customers in the U.S. using a direct sales force and indirectly through certain blood centers, though we may in the future sell INTERCEPT Blood System for Cryoprecipitation disposable kits to strategic blood centers that are not manufacturing partners for our distribution and sale of IFC. For all sales of our INTERCEPT Blood System products, we use a binding purchase order or signed sales contract as evidence of a contract and satisfaction of our policy. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. The contracts with customers can include various combinations of products, and to a much lesser extent, services. In contracts where we sell both products and services, we must determine whether these products or services are capable of being distinct and accounted for as separate performance obligations, or are accounted for as a combined performance obligation. We

must allocate the transaction price to each performance obligation on a relative standalone selling price, or SSP basis, and recognize the revenue when the performance obligation is satisfied. We determine the SSP by using the historical selling price of the products and services. If the amount of consideration in a contract is variable, we estimate the amount of variable consideration that should be included in the transaction price. Product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration that we expect to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, spare parts, storage solutions and IFC are recognized upon the transfer of control of the products to the customer. Product revenue from maintenance services is recognized ratably on a straight-line basis over the term of maintenance as customers simultaneously consume and receive benefits. Freight costs charged to customers are recorded as a component of product revenue. Taxes invoiced to our customers and remitted to governments are recorded on a net basis, which excludes such tax from product revenue.

• **Government contract revenue**—Revenue related to the cost reimbursement provisions under our government contract agreements is recognized as the allowable direct contract costs plus allowable indirect costs are incurred based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. The U.S. Federal Government has imposed a standardized indirect cost rate on grants administered by the National Institutes of Health. The standardized rates are significantly lower than our current audited indirect rates. While our contracts with BARDA are not currently impacted by these orders, should the U.S. Federal Government impose similar restrictions, we would have to absorb many of our indirect costs which would adversely affect our operating results. Revenue on our milestone-based DoD contract will be recognized 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 total contract price based on the extent of progress towards completion. Direct costs incurred under cost reimbursable contracts are recorded as research and development expenses or general and administrative expenses. Payments to us pursuant to our government contract agreements are provisional payments subject to adjustment upon audit by the government. These audits could result in an adjustment to revenue previously reported, which adjustments potentially could be significant. We believe that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

Results of Operations

Years Ended December 31, 2024, 2023 and 2022

Revenue

	Year Ended December 31,			% Change	
(in thousands, except percentages)	**2024**	**2023**	**2022**	**2024 to 2023**	**2023 to 2022**
Product revenue	$ 180,270	$ 156,367	$ 162,048	15%	(4%)
Government contract revenue	21,051	30,430	26,267	(31%)	16%
Total revenue	$ 201,321	$ 186,797	$ 188,315	8%	(1%)

Product revenue increased during the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily due to year-over-year sales volume increase of disposable platelet kit sales to U.S. customers. We expect product revenue for INTERCEPT disposable kits to increase in future periods driven by growth in our platelet business due in part to increased market acceptance of the INTERCEPT Blood System and adoption of the INTERCEPT Blood System in geographies where commercialization efforts are underway.

Government contract revenue decreased during the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily due to the completion of the ReCePI study in the first quarter of 2024. We anticipate that for some finite period of time, government contracts revenue will increase in future periods as multiple contracts are active and as activities supporting those contracts ramp up.

Cost of Product Revenue

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

	Year Ended December 31,			% Change	
(in thousands, except percentages)	**2024**	**2023**	**2022**	**2024 to 2023**	**2023 to 2022**
Cost of product revenue	$ 80,748	$ 69,967	$ 74,954	15%	(7%)

Cost of product revenue increased during the year ended December 31, 2024, compared to the year ended December 31, 2023, consistent with the increase in product revenue for the same comparative periods. We expect cost of product revenue for INTERCEPT disposable kits to increase in future periods as our product revenue grows.

Our gross margin on product sales was 55% during both the years ended December 31, 2024 and December 31, 2023. Margins were impacted by the mix of geographies into which products were sold, with higher U.S. kit sales over sales in other regions and, to a lesser extent product mix. Changes in our gross margin on product sales are affected by various factors, including prices of products sold, the volume of product manufactured, pricing with suppliers, the timing of inventory purchases related to the underlying exchange rate of the Euro relative to the U.S. dollar, manufacturing and supply chain costs, including transportation costs, the mix of product sold, the mix of customers to which products are sold, and the reserves for excess and obsolete inventory. Furthermore, we may experience cost pressures due to the current inflationary environment, tariffs and escalating trade tensions, increased transportation costs and adverse impacts on the efficiency of our supply chain. Additionally, we may encounter unforeseen manufacturing difficulties, which, at a minimum, may lead to higher than anticipated costs, scrap rates, delays in manufacturing products, or lower production levels of manufacturing than would be needed to meet demand. We may also decide to make investments with our manufacturing partners to identify longer-term efficiencies, but result in near-term increased costs. To meet the growing demand for our products and to invest in future quality improvements and gross margin expansion, we have invested in capital equipment, capacity expansion and cost reduction projects with many of our suppliers. These projects may cost more than anticipated, may not produce the anticipated benefits or may be delayed, any of which would potentially limit our expected return on investment and affect our operations. In addition, we may face competition which may limit our ability to maintain existing selling prices for our products which in turn would negatively affect our reported gross margins on product sales. Our gross margins on product sales may be impacted in the future based on all of these and other factors.

We expect to build inventory levels that we believe will be sufficient to meet forecasted demand. At times, we may purchase quantities of materials, components or finished products that are expected to be on-hand for longer than one year. We may procure and carry this inventory to mitigate obsolescence, supply chain disruption and for business continuity reasons.

Research and Development Expenses

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

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2024	2023	2022	2024 to 2023	2023 to 2022
Research and development	$ 58,907	$ 67,639	$ 64,107	(13%)	6%

Research and development expenses decreased during the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily driven by decreased headcount due to our reduction in force implemented in the second quarter of 2023 and the completion of the ReCePI study in the first quarter of 2024.

We expect to incur additional research and development costs associated with inflationary pressures on labor and study costs, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., any activities in support of any potential new MDR application for our red blood cell system in the EU, new product development and product enhancements, including potential new label claims, design efforts on our new illuminator, and costs associated with performing the activities under our government contracts. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, the impact of macroeconomic developments, including escalating trade tensions and the ongoing conflict between Ukraine and Russia, the uncertainty of future preclinical studies and clinical trial results and the uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under "Item 1A—*Risk Factors*" in Part I of this Annual Report on Form 10-K.

Selling, General and Administrative Expenses

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

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2024	2023	2022	2024 to 2023	2023 to 2022
Selling, general and administrative	$ 75,891	$ 75,516	$ 83,335	0%	(9%)

Selling, general, and administrative expenses increased slightly during the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily driven by non-cash stock-based compensation expense.

Restructuring

In June 2023, we began implementing a restructuring plan to pursue greater efficiency and to realign our business and strategic priorities, which included a reduction in force of our employee base during the second quarter of 2023. The restructuring also included a facilities consolidation strategy to cease the use of a part of our corporate office building which occurred during the third quarter of 2023. We recognized certain charges related to our facilities consolidation. A summary of our restructuring charges is as follows (in thousands):

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2024	2023	2022	2024 to 2023	2023 to 2022
Restructuring	$ —	$ 3,728	$ —	N/A	N/A

See Note 7, *Restructuring* to our audited consolidated financial statements included in Part IV, Item 15, *"Exhibits and Financial Statement Schedules"* of this Annual Report on Form 10-K for further information regarding the restructuring charges related to one-time termination benefits.

Non-Operating Expense, Net

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

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2024	2023	2022	2024 to 2023	2023 to 2022
Foreign exchange gain (loss)	$ 370	$ (648)	$ (690)	(157%)	(6%)
Interest expense	(8,877)	(8,386)	(5,831)	6%	44%
Other income (expense), net	1,976	1,765	(1,735)	12%	(202%)
Total non-operating expense, net	$ (6,531)	$ (7,269)	$ (8,256)	(10%)	(12%)

Foreign Exchange Gain (Loss)

We had foreign exchange gain during the year ended December 31, 2024, compared to foreign exchange loss during the year ended December 31, 2023. These were primarily due to foreign exchange variations between the Euro and the U.S. dollar.

Interest Expense

Interest expense increased during the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily due to the draw down of $5.0 million under Tranche 3 of our Term Loan Credit Agreement in March 2024, and due to the increase in interest rates on our Term Loan. Should interest rates increase, the rates that we are obligated to pay under our credit agreements would increase, leading to higher interest expense.

Other Income (Expense), Net

Other income, net increased during the year ended December 31, 2024, compared to the year ended December 31, 2023.

Provision for Income Taxes

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2024	2023	2022	2024 to 2023	2023 to 2022
Provision for income taxes	$ 205	$ 325	$ 488	(37%)	(33%)

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

Due to our history of cumulative operating losses, management has concluded that, after considering all of the available objective evidence, it is not likely that all our net deferred tax assets as of December 31, 2024, will be realized. Accordingly, substantially all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of December 31, 2024.

Liquidity and Capital Resources

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

As of December 31, 2024 and December 31, 2023, we had the following cash and cash equivalents, short-term investments and restricted cash (in thousands):

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 20,266	$ 11,647
Short-term investments	60,186	54,205
Restricted cash	1,095	1,712
Total	$ 81,547	$ 67,564

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

As of December 31, 2024 and December 31, 2023, we had the following indebtedness (in thousands):

	December 31, 2024	December 31, 2023
Debt – current	$ 19,297	$ 20,000
Debt – non-current	64,862	59,796
Total	$ 84,159	$ 79,796

Operating Activities

	Year Ended	
(in thousands)	**December 31, 2024**	**December 31, 2023**
Net cash provided by (used in) operating activities	$ 11,359	$ (43,168)

We had net cash provided by operating activities for the twelve months ended December 31, 2024 compared to net cash used in operating activities during the same period in 2023. The change was primarily related to the significant reduction in our net loss, the decrease in inventory related purchases, and a net increase in cash related to the timing of cash collections and payments, during the twelve months ended December 31, 2024, compared to the same period in 2023.

Investing Activities

	Year Ended	
(in thousands)	**December 31, 2024**	**December 31, 2023**
Net cash (used in) provided by investing activities	$ (8,130)	$ 8,624

We had net cash used in investing activities for the twelve months ended December 31, 2024 compared to net cash provided by investing activities during the same period in 2023. The change was primarily due to higher purchases of investments offset by higher proceeds from the maturity and sale of our investments during the twelve months ended December 31, 2024, compared to the same period in 2023.

Financing Activities

	Year Ended	
(in thousands)	**December 31, 2024**	**December 31, 2023**
Net cash provided by financing activities	$ 4,964	$ 10,673

The decrease in net cash provided by financing activities for the twelve months ended December 31, 2024 was primarily due to payments related to the Revolving Loan Credit Agreement during the twelve months ended December 31, 2024 compared to proceeds from the Revolving Loan Credit Agreement during the twelve months ended December 31, 2023. See Note 8, *Debt,* to our audited consolidated financial statements included in Part IV, Item 15 *"Exhibits and Financial Statement Schedules"* of this Annual Report on Form 10-K for more information.

Working Capital

(in thousands)	**December 31, 2024**	**December 31, 2023**
Working capital	$ 88,890	$ 78,392

Working capital increased as of December 31, 2024, compared to December 31, 2023, primarily due to proceeds from increased product sales, collections, and increase in short-term investments and decrease in our accounts payable as a result of the timing of payments to our vendors. Contract liabilities related to DoD of $0.5 million and $1.5 million as of December 31, 2024 and December 31, 2023, respectively, are excluded from working capital.

Capital Requirements

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with developing and commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercialization of our platelet, plasma systems and IFC, costs to develop different configurations of existing product candidates and products, costs associated with the development of new products, including our illuminator, costs associated with 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, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., costs associated with performing the agreed-upon activities under our government agreements, costs related to legal compliance, and costs related to creating, maintaining and defending our intellectual property. In addition, both our near and long-term capital requirements will require that we continue to invest in capital purchases to support ongoing and proposed studies, in addition to manufacturing capacity expansion to support our growing business. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities, required post-approval studies, market preparedness and product launch activities for any of our product candidates and products in geographies where we do not currently sell our products, and regulatory factors. While we have recently been able to generate a sufficient amount of revenue and generate positive net cash flows from operations, we may be unable to sustain those results in the future. If we are unable to continue to produce positive operating cash flows or at sufficient levels, 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, if at all, and interest income earned on the investment of our cash balances. We believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our government contracts, will be sufficient to meet our capital requirements for at least the next 12 months. However, 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, including inflationary assumptions, 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 take certain actions to potentially achieve profitability, which 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 the Term Loan Credit Agreement and Revolving Loan Credit Agreement, or potentially pursuant to new arrangements with different lenders. We have borrowed and in the future may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, unless we restructure our credit agreements prior to April 1, 2026, or qualify for and exercise our option to delay amortization to April 1, 2027, the principal amounts outstanding under our Term Loan Credit Agreement will begin amortizing on April 1, 2026 and will 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 increase again, the rates that we are obligated to pay under our credit agreements would increase, leading to higher interest expense. See Note 8, *Debt*, to our audited consolidated financial statements included in Part IV, Item 15—*Exhibits and Financial Statement Schedules* of this Annual Report on Form 10-K for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

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.

In March 2023, we entered into an amendment to our Sales Agreement under which we may issue and sell up to $96.8 million of our common stock through or to Cantor Fitzgerald & Co. or Stifel, Nicolaus & Company, Incorporated, as sales agent or principal. During the year ended December 31, 2024, we did not sell shares of our common stock under the Amended Sales Agreement.

While we expect to receive significant funding under our agreements with BARDA, our ability to obtain the funding we expect to receive under both agreements is subject to various risks and uncertainties, including with respect to BARDA's ability to terminate the agreements for convenience at any time and our ability to achieve the required milestones under the agreements, including the completion of the RedeS study. 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, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreements, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed by BARDA, our cash flows would be negatively impacted or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. In addition, if we are unable to meet the requisite milestones in our agreements, including generating sufficient prerequisite Phase 3 clinical data, our agreements 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. The availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If alternative sources of funding are not available, or if we determine that the cost of alternative available capital is too high, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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

As a result of economic conditions, general global economic uncertainty, political change, war, the effects of inflationary pressures, tariffs and escalating trade tensions, and other factors including past and potential future U.S. bank failures, we do not know whether additional capital will be available when needed, or that, if available, whether we will be able to obtain additional capital on reasonable terms. Specifically, monetary policies of many countries, as well as recent bank failures, have 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 and global events over the past few 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 could negatively impact equity values, including the value of our common stock. Furthermore, we expect that the costs of our business may increase as labor rates and prices rise in the current inflationary environment, transportation costs increase, and global supply chain constraints impact availability of our products. We may not be able to offset prices increases from vendors with price increases to customers at sufficient levels, if at all, which would harm our results of operations. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities.

In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for CE Certificates of Conformity in the EU, if costs are higher than anticipated or we encounter further delays. In this regard, our product development costs will be ongoing in connection with our failure to obtain approval of our MDR application and the potential submission of a new MDR application and would also increase if existing clinical data is insufficient for us to either submit or potentially obtain approval of any such new application. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our government contracts, 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.

Commitments

See *Note 8, Debt,* to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

See *Note 10, Commitments and Contingencies*, to our audited consolidated financial statements included in Part IV, Item 15, "*Exhibits and Financial Statement Schedules*" of this Annual Report on Form 10-K for more information on the operating leases and purchase commitments.

We did not have any off-balance sheet arrangements as of December 31, 2024.

Financial Instruments

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our available-for-sale securities related to corporate debt and U.S. government agency securities are classified as Level 2 in the fair value hierarchy, which uses observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. We did not record any credit losses during the years ended December 31, 2024, 2023 and 2022. Adverse global economic conditions have had, and may continue to have, a negative impact on the market values of potential investments.

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

Interest Rate Risk

At December 31, 2024, we held cash, cash equivalents, short-term investments and investments in marketable equity securities of $80.5 million. We do not believe our exposure to interest rate risk to be material given we held cash in interest-bearing accounts with financial institutions and the short-term nature of our investment portfolio consisted of highly liquid money market instruments and corporate debt and U.S. government agency securities with short-term maturities. The weighted average interest rate of our cash and cash equivalents at December 31, 2024, was 4.4%.

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

With respect to the Term Loan Credit Agreement and Revolving Loan Credit Agreement, we are exposed to risks associated with changes in interest rates in connection with our related borrowings. Based on our indebtedness under the Term Loan Credit Agreement of $65.0 million and Revolving Loan Credit Agreement of $19.3 million as of December 31, 2024, and the interest rate on such borrowings then in effect, a hypothetical 100 basis point increase in interest rates could increase our net interest expense in 2024 by approximately $0.8 million subject to certain limitations in each agreement.

Foreign Currency Risk

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

Product sales for our blood safety products are predominantly made in Europe and generally are invoiced to customers in Euro. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems. These inventory purchases and operating expenses are generally paid in Euro and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of non-operating expense, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. An unfavorable 10% change in foreign currency exchange rates for our cash, accounts receivable, accounts payable and accrued liabilities that are denominated in foreign currencies at December 31, 2024, would have negatively impacted our annual financial results by $1.0 million. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

Item 8. ***Financial Statements and Supplementary Data***

Our consolidated financial statements, together with related notes and report of Ernst & Young LLP, independent registered public accounting firm, are listed in Item 15(a) and included herein.

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

None.

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act, Rule 13a–15(e) and 15d-15(e)), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our CEO and CFO have concluded that as of December 31, 2024, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

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

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2024, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles. Our independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which is included below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act which occurred during our fiscal quarter ended December 31, 2024, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerus Corporation

Opinion on Internal Control over Financial Reporting

We have audited Cerus Corporation's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Cerus Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 26, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Ernst & Young LLP

San Mateo, California

February 26, 2025

Item 9B. ***Other Information***

On November 14, 2024, Richard Benjamin, Chief Medical Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense conditions of rule 10b5-1(c) for the sale of up to 85,301 shares of the Company's stock until November 14, 2025.

On November 15, 2024, Kevin Green, Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense conditions of rule 10b5-1(c) for the sale of up to 60,656 shares of the Company's stock until May 15, 2025.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections***

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2025 annual meeting of stockholders, or the Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

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

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

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

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

Code of Ethics

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

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

Item 11. *Executive Compensation*

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

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

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

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

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

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

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

(1) Financial Statements.

(2) Financial Statement Schedules.

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

(3) Exhibits

Exhibit Number	Description of Exhibit
3.1(7)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(7)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(9)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.4(20)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(26)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(27)	Description of securities registered under Section 12 of the Exchange Act of 1934.
	Supply and/or Manufacturing Agreements
10.1(27)††	Amended and Restated Supply Agreement, dated April 21, 2014, by and between Cerus Corporation and Purolite Corporation.
10.2(19)	First Amendment to Amended and Restated Supply Agreement, dated December 1, 2020, by and between Cerus Corporation and Purolite Corporation.
10.3††	Second Amended and Restated Supply and Manufacturing Agreement, dated December 9, 2024, by and between Cerus Corporation and Porex Corporation.
10.4(27)††	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.5(21) ††	Second Amended and Restated Manufacturing and Supply Agreement, by and between Cerus Corporation and Fresenius Kabi AG, Fenwal France SAS, and Fenwal International, Inc, effective as of January 1, 2022.
	Loan and Security Agreements

10.6(22)††	Amended and Restated Credit, Security and Guaranty Agreement (Term Loan), dated March 31, 2023, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.7(27)††	Amendment No. 1 to Amended and Restated Credit, Security and Guaranty Agreement (Term Loan), dated September 1, 2023, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.8(27)††	Amendment No. 2 to Amended and Restated Credit, Security and Guaranty Agreement (Term Loan), dated January 5, 2024, by and among Cerus Corporation, the lenders party thereto and MidCap Financial Trust.
10.9(22) ††	Amended and Restated Credit, Security and Guaranty Agreement (Revolving Loan), dated March 31, 2023, by and among Cerus Corporation, the lenders party thereto and MidCap Financial IV Trust.
10.10†(27)†	Amendment No. 1 to Amended and Restated Credit, Security and Guaranty Agreement (Revolving Loan), dated January 5, 2024, by and among Cerus Corporation, the lenders party thereto and MidCap Financial IV Trust.
	Real Estate Lease Agreements
10.11(13) †	Lease, dated February 16, 2018, between Cerus Corporation and 1200 Concord LLC.
10.12(14)	First Amendment to Lease, dated May 11, 2018, between Cerus Corporation and 1200 Concord LLC.
10.13(15)	Second Amendment to Lease, dated August 10, 2018, between Cerus Corporation and 1200 Concord LLC.
10.14(16)	Third Amendment to Lease, dated October 5, 2018, between Cerus Corporation and 1200 Concord LLC.
10.15(16)	Fourth Amendment to Lease, dated November 30, 2018, between Cerus Corporation and 1200 Concord LLC.
	Employment Agreements or Offer Letters
10.16(5)*	Employment Letter, by and between Cerus Corporation and William M. Greenman, dated May 12, 2011.
10.17(8)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.18(14)*	Amendment to Employment Letter, by and between Cerus Corporation and William M. Greenman, dated April 17, 2018.
10.19(4)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.20(14)*	Amendment to Employment Letter, by and between Cerus Corporation and Kevin Green, dated April 17, 2018.
10.21(8)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.22(10)*	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPath, dated May 12, 2015.
10.23(12)*	Employment Letter, by and between Cerus Corporation and Vivek Jayaraman, dated May 31, 2016.
	Stock Plans and Related Forms
10.24(28)*	Amended and Restated 1996 Employee Stock Purchase Plan, effective June 3, 2020.
10.25(24)*	Amended and Restated 2008 Equity Incentive Plan, effective June 7, 2023.
10.26(6)*	Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.
10.27(6)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.

10.28(6)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
10.29(11)*	Cerus Corporation Inducement Plan.
10.30(11)*	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Cerus Corporation Inducement Plan.
10.31(11)*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Cerus Corporation Inducement Plan.
10.32(14)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan, amended as of April 17, 2018.
10.33(14)*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the Amended and Restated 2008 Equity Incentive Plan, amended as of April 17, 2018.
10.34(28)*	Cerus Corporation 2024 Equity Incentive Plan.
10.35(28)*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the 2024 Equity Incentive Plan.
	Other Compensatory Plans or Agreements
10.36(8)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.37(14)*	Cerus Corporation Change of Control Severance Benefit Plan, amended as of April 17, 2018.
10.38(3)*	Form of Severance Benefits Agreement.
10.39(28)*	Amended and Restated Non-Employee Director Compensation Policy, effective June 4, 2024.
10.40(17)*	Nonqualified Plan Service and Expense Agreement, by and between Cerus Corporation and Principal Life Insurance Company, dated May 21, 2020.
10.41(17)*	The Executive Nonqualified Excess Plan Adoption Agreement, dated May 21, 2020.
	Other Material Agreements
10.42(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.43(2)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.44(18)	Controlled Equity Offering[SM] Sales Agreement, dated December 11, 2020, by and among Cerus Corporation, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated.
10.45(23)	Amendment No. 1 to the Controlled Equity Offering[SM] Sales Agreement, dated March 1, 2023, by and among Cerus Corporation, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated.
10.46(25)	Amendment No. 2 to the Controlled Equity Offering[SM] Sales Agreement, dated November 2, 2023, by and among Cerus Corporation, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated.
10.47††	License Agreement, dated as of February 2, 2005, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare S.A. and Baxter Healthcare Corporation).
19.1	Cerus Corporation Insider Trading Policy.

21.1	List of Registrant's subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
31.1	Certification of the Principal Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(29)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Incentive Compensation Recoupment Policy.
101.INS	Inline XBRL Instance Document. – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).
†	Certain portions of this exhibit are subject to a confidential treatment order.
††	Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.
*	Compensatory Plan.
(1)	Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(2)	Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on April 30, 2009.
(3)	Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 1, 2009.
(4)	Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.
(5)	Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2011.
(6)	Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2012.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(21) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

(22) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.

(23) Incorporated by reference to the like-described exhibit to the Registrant's Post-Effective Amendment No. 1 to Registration Statement (File No. 333-251302) on Form S-3, filed with SEC on March 1, 2023.

(24) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023.

(25) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement (File No. 333-275284) on Form S-3, filed with SEC on November 2, 2023.

(26) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on January 5, 2024.

(27) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023.

(28) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.

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

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

None.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerus Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cerus Corporation (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 26, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Revenue Recognition

Description of the Matter	In the year ended December 31, 2024, the Company recognized $180.3 million of product revenue. As discussed in Note 2 to the consolidated financial statements, product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration which the Company expects to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, INTERCEPT Fibrinogen Complex, spare parts and storage solutions are recognized upon the transfer of control of the products to the customer. Auditing the Company's revenue recognition was challenging due to variability in terms and conditions within certain customer contracts, whereby these customer contracts can include multiple products and/or services requiring management to apply judgment to determine whether the products and services are distinct performance obligations or should be accounted for as a combined performance obligation. Customer contracts must be carefully evaluated for terms that might affect the timing or measurement of revenue recognition.
How We Addressed the Matter in Our Audit	We obtained an understanding of, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process, including management's assessment of its performance obligations.

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

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

/s/ Ernst & Young LLP

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

San Mateo, California

February 26, 2025

CERUS CORPORATION

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,266	$ 11,647
Short-term investments	60,186	54,205
Accounts receivable, net	29,777	35,500
Current inventories	38,150	39,868
Prepaid and other current assets	3,643	3,221
Total current assets	152,022	144,441
Non-current assets:		
Property and equipment, net	7,154	8,640
Operating lease right-of-use assets	8,384	10,713
Goodwill	1,316	1,316
Restricted cash	1,095	1,712
Non-current inventories	14,145	19,501
Other assets	16,801	11,425
Total assets	$ 200,917	$ 197,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 21,695	$ 23,842
Accrued liabilities	18,943	19,225
Debt – current	19,297	20,000
Operating lease liabilities – current	2,275	2,452
Deferred revenue	1,398	2,002
Total current liabilities	63,608	67,521
Non-current liabilities:		
Debt – non-current	64,862	59,796
Operating lease liabilities – non-current	11,663	13,751
Other non-current liabilities	3,888	3,236
Total liabilities	144,021	144,304
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized, issuable in series; zero shares issued and outstanding at December 31, 2024 and 2023, respectively		
Common stock, $0.001 par value; 400,000 and 400,000 shares authorized; 185,766 and 181,248 shares issued and outstanding at December 31, 2024 and 2023, respectively	186	181
Additional paid-in capital	1,121,887	1,098,353
Accumulated other comprehensive loss	(400)	(1,274)
Accumulated deficit	(1,065,528)	(1,044,610)
Total Cerus Corporation stockholders' equity	56,145	52,650
Noncontrolling interest	751	794
Total liabilities and stockholders' equity	$ 200,917	$ 197,748

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

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

	Year Ended December 31,		
	2024	2023	2022
Product revenue	$ 180,270	$ 156,367	$ 162,048
Cost of product revenue	80,748	69,967	74,954
Gross profit on product revenue	99,522	86,400	87,094
Government contract revenue	21,051	30,430	26,267
Operating expenses:			
Research and development	58,907	67,639	64,107
Selling, general and administrative	75,891	75,516	83,335
Restructuring	—	3,728	—
Total operating expenses	134,798	146,883	147,442
Loss from operations	(14,225)	(30,053)	(34,081)
Non-operating expense, net:			
Foreign exchange gain (loss)	370	(648)	(690)
Interest expense	(8,877)	(8,386)	(5,831)
Other income (expense), net	1,976	1,765	(1,735)
Total non-operating expense, net	(6,531)	(7,269)	(8,256)
Loss before income taxes	(20,756)	(37,322)	(42,337)
Provision for income taxes	205	325	488
Net loss	(20,961)	(37,647)	(42,825)
Net loss attributable to noncontrolling interest	(43)	(158)	(46)
Net loss attributable to Cerus Corporation	$ (20,918)	$ (37,489)	$ (42,779)
Net loss per share attributable to Cerus Corporation			
Basic and diluted	$ (0.11)	$ (0.21)	$ (0.24)
Weighted average shares outstanding:			
Basic and diluted	184,563	180,270	176,545

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Net loss	$ (20,961)	$ (37,647)	$ (42,825)
Other comprehensive loss			
Foreign currency translation adjustment	(14)	(85)	—
Unrealized gains (losses) on available-for-sale investments, net of taxes	888	1,598	(2,638)
Comprehensive loss	(20,087)	(36,134)	(45,463)
Comprehensive loss attributable to noncontrolling interest	(43)	(158)	(46)
Total comprehensive loss attributable to Cerus Corporation	$ (20,044)	$ (35,976)	$ (45,417)

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income (Loss)	Accumulated	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital		Deficit	Interest	Equity
Balance at December 31, 2021	173,670	$ 174	$ 1,048,936	$ (149)	$ (964,342)	$ 998	$ 85,617
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	3,912	3	3,949	—	—	—	3,952
Stock-based compensation	—	—	24,456	—	—	—	24,456
Other comprehensive loss	—	—	—	(2,638)	—	—	(2,638)
Net loss	—	—	—	—	(42,779)	(46)	(42,825)
Balance at December 31, 2022	177,582	$ 177	$ 1,077,341	$ (2,787)	$ (1,007,121)	$ 952	$ 68,562
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	3,666	4	741	—	—	—	745
Stock-based compensation	—	—	20,271	—	—	—	20,271
Other comprehensive income	—	—	—	1,513	—	—	1,513
Net loss	—	—	—	—	(37,489)	(158)	(37,647)
Balance at December 31, 2023	181,248	$ 181	$ 1,098,353	$ (1,274)	$ (1,044,610)	$ 794	$ 53,444
Issuance of common stock from vesting of restricted stock units and ESPP purchases	4,518	5	667	—	—	—	672
Stock-based compensation	—	—	22,867	—	—	—	22,867
Other comprehensive income	—	—	—	874	—	—	874
Net loss	—	—	—	—	(20,918)	(43)	(20,961)
Balance at December 31, 2024	185,766	$ 186	$ 1,121,887	$ (400)	$ (1,065,528)	$ 751	$ 56,896

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Operating activities			
Net loss	$ (20,961)	$ (37,647)	$ (42,825)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,855	2,599	2,984
Stock-based compensation	22,867	20,271	24,456
Non-cash operating lease cost	2,482	2,308	1,575
Changes in valuation of warrant investment	—	—	2,183
Net loss on sale of available-for-sale securities	7	54	108
Unrealized gain on investments	(135)	(170)	(564)
Loss on disposal of fixed assets	3	65	—
Impairment charges for facilities consolidation	—	1,698	—
Non-cash interest expense	398	374	609
Foreign currency remeasurement (gain) loss	(388)	(685)	1,911
Changes in operating assets and liabilities:			
Accounts receivable	5,504	(1,102)	(9,200)
Inventories	7,030	(14,947)	(1,768)
Prepaid and other assets	(3,025)	(994)	1,168
Accounts payable	(1,477)	(7,335)	(4,905)
Accrued liabilities and other non-current liabilities	(2,198)	(9,070)	(1,263)
Deferred revenue	(603)	1,413	(84)
Net cash provided by (used in) operating activities	11,359	(43,168)	(25,615)
Investing activities			
Capital expenditures	(2,837)	(4,597)	(2,000)
Purchases of investments	(42,975)	(2,486)	(29,640)
Proceeds from maturities and sale of investments	37,682	15,707	40,104
Net cash (used in) provided by investing activities	(8,130)	8,624	8,464
Financing activities			
Net proceeds from equity incentives	804	925	4,084
Net costs from public offerings	(137)	(175)	(104)
Net (payments on) proceeds from revolving line of credit	(703)	5,091	212
Proceeds from loans, net of issuance costs	5,000	4,832	—
Net cash provided by financing activities	4,964	10,673	4,192
Effect of exchange rates on cash, cash equivalents, and restricted cash	(191)	(128)	(727)
Net increase (decrease) in cash, cash equivalents, and restricted cash	8,002	(23,999)	(13,686)
Cash, cash equivalents, and restricted cash, beginning of period	13,359	37,358	51,044
Cash, cash equivalents, and restricted cash, end of period	$ 21,361	$ 13,359	$ 37,358
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 9,295	$ 9,210	$ 5,100
Cash paid for income taxes	356	322	270

See accompanying Notes to Consolidated Financial Statements.

Note 1. Nature of Operations and Basis of Presentation

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

The Company sells its INTERCEPT platelet and plasma systems in North America, Europe, Middle East and Africa, and other regions around the world. Also in the United States ("U.S."), the INTERCEPT Blood System for Cryoprecipitation is approved for the production of INTERCEPT Fibrinogen Complex, a therapeutic product for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. The Company conducts significant research, development, testing and regulatory compliance activities on its product candidates that, together with anticipated selling, general and administrative expenses, are expected to result in substantial additional losses, and the Company may need to adjust its operating plans and programs based on the availability of cash resources.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, the collectability of accounts receivable, inventory classification and related reserves, fair values of investments, the allowance for credit losses, stock-based compensation, goodwill, useful lives of property and equipment, income taxes, and incremental borrowing rate, among others. The Company bases its estimates on historical experience, future projections, and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

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

The Company's main source of revenue is product revenue from sales of the INTERCEPT Blood System for platelets and plasma ("platelet and plasma systems" or "disposable kits"), UVA illumination devices ("illuminators"), INTERCEPT Fibrinogen Complex ("IFC"), spare parts and storage solutions, and maintenance services of illuminators. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. The Company sells its IFC primarily to hospitals and blood banks. The Company uses a binding purchase order or signed sales contract as evidence of a contract and satisfaction of its policy. Generally, the Company's sales contracts for disposable kits and illuminators with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. The contracts with customers can include various combinations of products, and to a lesser extent, services. The Company must determine whether products or services are capable of being distinct and accounted for as separate performance obligations, or are accounted for as a combined performance obligation. The Company must allocate the transaction price to each performance obligation on a relative SSP basis and recognize the product revenue when the performance obligation is satisfied. The Company determines the SSP by using the historical selling price of the products and services. If the amount of consideration in a contract is variable, the Company estimates the amount of variable consideration that should be included in the transaction price using the most likely amount method, to the extent it is probable that a significant future reversal of cumulative product revenue under the contract will not occur. Product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration to which the Company expects to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, IFC, spare parts and storage solutions are recognized upon the transfer of control of the products to the customer. Product revenue from maintenance services are recognized ratably on a straight-line basis over the term of maintenance as customers simultaneously

consume and receive benefits. Freight costs charged to customers are recorded as a component of product revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

The Company receives funding under its U.S. government contracts that support research and development of defined projects. The Biomedical Advanced Research and Development Authority ("BARDA") and the U.S. Food and Drug Administration ("FDA") contracts generally provide for reimbursement of approved costs incurred under the terms of the contracts. Revenue related to the cost reimbursement provisions is recognized as the qualified direct and indirect costs on the projects are incurred. The Department of Defense ("DoD") contract provides for payments upon completion of each milestone. Revenue from the DoD contract is recognized on the application of the cost-to-cost input method, which measures the extent of progress towards completion of its single performance obligation based on the ratio of actual costs incurred to the total estimated costs over the performance period of the agreement. Revenue is recorded as a percentage of the transaction price based on the extent of progress towards completion. The Company invoices under its U.S. government contracts using the provisional rates in the government contracts and thus is subject to future audits at the discretion of the government. The Company believes that government contract revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. However, these audits could result in an adjustment to government contract revenue previously reported, which adjustments could be potentially significant. Costs incurred related to services performed under the contracts are included as a component of research and development or selling, general and administrative expenses in the Company's consolidated statements of operations. The Company's use of estimates in recording accrued liabilities for government contract activities (see "Use of Estimates" above) affects the revenue recorded from development funding and under the government contracts.

Disaggregation of Product Revenue

Product revenue by geographical locations of customers during the years ended December 31, 2024, 2023 and 2022, was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Product revenue:			
North America	$ 121,794	$ 99,187	$ 103,978
Europe, Middle East and Africa	56,327	55,008	56,297
Other	2,149	2,172	1,773
Total product revenue	$ 180,270	$ 156,367	$ 162,048

Contract Balances

The Company invoices its customers based upon the terms in the contracts, which generally require payment 30 to 60 days from the date of invoice. Accounts receivable are recorded when the Company's right to the consideration is estimated to be unconditional. The Company's conditional rights to the consideration are recorded as contract assets. The Company had no contract assets as of December 31, 2024 and December 31, 2023.

Contract liabilities mainly consist of deferred revenue related to maintenance services, unshipped products, and uninstalled illuminators, or receivables from customers that are not yet recognized as revenue. Maintenance services are generally billed upfront at the beginning of each annual service period and recognized ratably over the contractual service period. The Company applies an optional exemption to not disclose the value of unsatisfied performance obligations for contracts that have an original expected duration of one year or less. As of December 31, 2024 and December 31, 2023, the Company had $0.5 million and $1.5 million, respectively, of contract liabilities related to the DoD included within "Deferred revenue" on the Company's consolidated balance sheets.

Research and Development Expenses

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

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

Cash Equivalents

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

Investments

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

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

During the years ended December 31, 2024, 2023 and 2022, the Company recorded zero, zero and $2.2 million, respectively, of impairment of investments in certain preferred stock and warrants in "Other income (expense), net" on the Company's consolidated statements of operations.

Deferred Compensation Plan

The Company's deferred compensation plan, pursuant to which compensation deferrals began in 2020, is a nonqualified deferred compensation plan that allows highly compensated employees to defer up to 80 percent of their base salary and up to 100 percent of their variable compensation each plan year. The Company may make discretionary contributions to each participant in an amount determined each year. To fund the deferred compensation plan's long-term liability, the Company purchases Company-owned life insurance contracts on certain employees. The insurance serves as an investment source for the funds being set aside. Participants in the deferred compensation plan select the mutual funds in which their compensation deferrals are deemed to be invested as a component of the insurance contracts. As of December 31, 2024 and December 31, 2023, $2.8 million and $2.6 million, respectively, were included in "Other assets" on the Company's consolidated balance sheets, which represents the cash surrender value of the associated life insurance policies. As of December 31, 2024 and December 31, 2023, $3.1 million and $2.8 million, respectively, were included in "Other non-current liabilities" on the Company's consolidated balance sheets, which represents the carrying value of the liability for deferred compensation. Gains and losses on the investments related to the nonqualified deferred compensation plan are included in "Other income (expense), net", on the Company's consolidated statements of operations, and corresponding changes in their deferred compensation liability are included in operating expenses.

Restricted Cash

As of December 31, 2024 and December 31, 2023, the Company's restricted cash consisted primarily of a letter of credit relating to an office building lease. As of December 31, 2024 and December 31, 2023, the Company also had certain non-U.S. dollar denominated deposits recorded as restricted cash in compliance with certain foreign contractual requirements.

Concentration of Credit Risk

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

Pursuant to the Company's investment policy, substantially all of the Company's cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company's investments carry high credit quality ratings, which is in accordance with its investment policy. At December 31, 2024, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

On a regular basis, including at the time of sale, the Company performs credit evaluations of its significant customers that it expects to sell to on credit terms. Generally, the Company does not require collateral from its customers to secure accounts receivable. To the extent that the Company determines credit losses may occur, the Company maintains an allowance for estimated credit losses on its consolidated balance sheets and records a charge on its consolidated statements of operations as a component of selling, general and administrative expenses.

The Company had one and three customer(s) that accounted for more than 10% of the Company's outstanding accounts receivables at both December 31, 2024 and December 31, 2023, respectively. These customers cumulatively represented approximately 37% and 51% of the Company's outstanding trade receivables at December 31, 2024 and December 31, 2023, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At December 31, 2024 and December 31, 2023, inventory consisted of raw materials, work-in-process and finished goods. Finished goods include INTERCEPT disposable kits, illuminators, and certain components for the illuminators. Platelet and plasma systems' disposable kits generally expire no later than 24 months from the date of manufacture. However, in the three months ended December 31, 2024, the Company received FDA approval for an 18-month shelf life for our platelet kits. Illuminators and individual components do not have regulated expiration dates. Raw materials and work-in-process includes certain components that are manufactured over a protracted length of time before being ultimately incorporated and assembled by Fresenius, Inc. (with their affiliates, "Fresenius") into the finished INTERCEPT disposable kits. It is not customary for the Company's production cycle for inventory to exceed 12 months, however, in certain circumstances the Company purchases inventory components it expects to consume beyond 12 months. The Company uses its best judgment to factor in lead times for the production of its raw materials, work-in-process and finished units to meet the Company's forecasted demands. Additionally, from time-to-time, the Company may engage in strategic longer-range inventory purchases due to concentration of supplier risk, obsolescence of materials or components, or simply as safety stock to mitigate disruption to supply. Based upon estimated production needs and current inventory levels, the Company determines the amount of inventory necessary for the next 12 months. Any amounts in excess of this 12 month rolling projection are classified as "Non-current inventories" in the consolidated balance sheets. Changes to those estimates could potentially impact amounts recorded as current or non-current assets.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or net realizable value. The Company uses judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded within "Cost of product revenue" on the Company's consolidated statements of operations. At December 31, 2024 and December 31, 2023, the Company had $0.9 million and $0.7 million, respectively, for potential obsolete, expiring or unsalable product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, leasehold improvements, construction-in-progress, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated on a straight-line basis over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements. During the years ended December 31, 2024, 2023 and 2022, the Company had non-cash purchases of capital expenditures of less than $0.1 million, $0.8 million and $0.7 million, respectively.

Goodwill

Goodwill is not amortized, but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Such impairment analysis is performed on August 31 of each year, or more frequently if indicators of impairment exist. The test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative goodwill impairment test. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative impairment test; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The quantitative goodwill impairment test compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates as one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not impaired. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess, limited to the carrying amount of goodwill in the Company's one reporting unit.

During the years ended December 31, 2024, 2023 and 2022, the Company did not dispose of, impair or recognize additional goodwill.

Long-lived Assets

The Company evaluates its long-lived assets for impairment by continually monitoring events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted

expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets.

Foreign Currency

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

The functional currency of the JV (as defined below) is the Chinese Renminbi. Monetary assets and liabilities denominated in foreign currencies are remeasured in Renminbi using the exchange rates at the balance sheet date. The financial statements of JV are translated into U.S. dollar for consolidation. The JV's balance sheet is translated using the month-end exchange rate, and the JV's income statement is translated using the monthly average exchange rate, the difference is recognized as cumulative translation adjustment.

Stock-Based Compensation

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

See Note 12, *Stock-Based Compensation*, for further information regarding the Company's stock-based compensation assumptions and expenses.

Consolidated Variable Interest Entity

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

Operating expenses for the JV were de minimis for all periods presented.

Income Taxes

The provision for income taxes is accounted for using an asset and liability approach, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company does not recognize tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance is not an appropriate substitute for derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's U.S. federal tax returns filed for years 2004 through 2023, and California tax returns filed for years through 2023, remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a valuation allowance on substantially all of its net deferred tax assets.

Net Loss Per Share Attributable to Cerus Corporation

Basic net loss per share attributable to Cerus Corporation is computed by dividing net loss attributable to Cerus Corporation by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to Cerus Corporation gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options, employee stock purchase plan rights and restricted stock units, which are calculated using the treasury stock method. For the years ended December 31, 2024, 2023 and 2022, all potentially dilutive securities outstanding have been excluded from the computation of dilutive weighted average shares outstanding because such securities have an antidilutive impact due to losses reported.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per share for the years ended December 31, 2024, 2023 and 2022 (in thousands, except per share amounts):

	Year Ended December 31,		
	2024	2023	2022
Numerator for Basic and Diluted:			
Net loss attributable to Cerus Corporation	$ (20,918)	$ (37,489)	$ (42,779)
Denominator:			
Basic weighted average number of shares outstanding	184,563	180,270	176,545
Effect of dilutive potential shares	—	—	—
Diluted weighted average number of shares outstanding	184,563	180,270	176,545
Net loss per share attributable to Cerus Corporation:			
Basic and diluted	$ (0.11)	$ (0.21)	$ (0.24)

The table below presents potential shares that were excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the years ended December 31, 2024, 2023 and 2022 (shares in thousands):

	Year Ended December 31,		
	2024	2023	2022
Weighted average number of anti-dilutive potential shares:			
Stock options	12,993	14,896	16,072
Restricted stock units	13,880	10,192	7,966
Employee stock purchase plan rights	349	396	252
Total	27,222	25,484	24,290

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in "Operating lease right-of-use assets", "Operating lease liabilities – current" and "Operating lease liabilities – non-current" in the Company's consolidated balance sheets. As of December 31, 2024 and December 31, 2023, the Company did not have finance leases.

Operating lease right-of-use assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The operating lease right-of-use assets also include any lease payments made and excludes lease incentives. The lease terms may include options to extend or terminate the lease when the options are reasonably certain to be exercised. Operating leases are recognized on a straight-line basis over the lease term.

Guarantee and Indemnification Arrangements

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

The Company generally provides for a one-year warranty on certain of its disposable kits and illuminators covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at December 31, 2024 and December 31, 2023.

Fair Value of Financial Instruments

The Company applies the provisions of fair value relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of its debt approximates their carrying amounts. The Company measures and records certain financial assets and liabilities at fair value on a recurring basis, including its available-for-sale securities. The Company classifies instruments within Level 1 if quoted prices are available in active markets for identical assets, which include the Company's cash accounts and money market funds. The Company

classifies instruments in Level 2 if the instruments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. These instruments include the Company's corporate debt and U.S. government agency securities holdings. The available-for-sale securities are held by a custodian who obtains investment prices from a third-party pricing provider that uses standard inputs (observable in the market) to models which vary by asset class. The Company classifies instruments in Level 3 if one or more significant inputs or significant value drivers are unobservable. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

See Note 3, *Available-for-sale Securities and Fair Value on Financial Instruments*, for further information regarding the Company's valuation of financial instruments.

New Accounting Pronouncements

Recently adopted accounting pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Adoption of the ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is also permitted. The Company adopted ASU 2023-07 effective December 31, 2024, on a retrospective basis. The adoption of 2023-07 did not change the way that the Company identifies its reportable segments and, as a result, did not have a material impact on the Company's segment-related disclosures. Refer to Note 16, *Segment, Customer and Geographic Information*, for further information on the Company's reportable segment.

Recently issued accounting pronouncements not yet adopted

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. The ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. The Company does not expect the adoption of this guidance to have a material impact on the Company's consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. The new disclosure requirements are effective for the Company's annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently in the process of evaluating the impact of this pronouncement on the Company's related disclosures.

The Company continues to monitor new accounting pronouncements issued by the FASB and does not believe any accounting pronouncements issued through the date of this report will have a material impact on the Company's Consolidated Financial Statements.

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

Available-for-sale Securities

The following is a summary of available-for-sale securities at December 31, 2024 (in thousands):

	December 31, 2024				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Allowance for Credit Loss	Fair Value
Money market funds	$ 1,773	$ —	$ —	$ —	$ 1,773
United States government agency securities	24,060	54	(52)	—	24,062
Corporate debt securities	33,357	53	(39)	—	33,371
Mortgage-backed securities	3,070	—	(317)	—	2,753
Total available-for-sale securities	$ 62,260	$ 107	$ (408)	$ —	$ 61,959

The following is a summary of available-for-sale securities at December 31, 2023 (in thousands):

	December 31, 2023				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Allowance for Credit Loss	Fair Value
Money market funds	$ 5,062	$ —	$ —	$ —	$ 5,062
United States government agency securities	19,652	16	(314)	—	19,354
Corporate debt securities	32,395	3	(638)	—	31,760
Mortgage-backed securities	3,347	7	(263)	—	3,091
Total available-for-sale securities	$ 60,456	$ 26	$ (1,215)	$ —	$ 59,267

Available-for-sale securities at December 31, 2024 and December 31, 2023, consisted of the following by contractual maturity (in thousands):

	December 31, 2024		December 31, 2023	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$ 38,174	$ 38,173	$ 42,598	$ 41,789
Greater than one year and less than five years	24,086	23,786	17,858	17,478
Total available-for-sale securities	$ 62,260	$ 61,959	$ 60,456	$ 59,267

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

	December 31, 2024					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 14,002	$ (27)	$ 3,967	$ (12)	$ 17,969	$ (39)
United States government agency securities	8,468	(37)	3,279	(15)	11,747	(52)
Mortgage-backed securities	402	(10)	2,351	(307)	2,753	(317)
Total	$ 22,872	$ (74)	$ 9,597	$ (334)	$ 32,469	$ (408)

	December 31, 2023					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 1,466	$ (12)	$ 29,647	$ (626)	$ 31,113	$ (638)
United States government agency securities	4,855	(25)	10,991	(289)	15,846	(314)
Mortgage-backed securities	242	(1)	2,647	(262)	2,889	(263)
Total	$ 6,563	$ (38)	$ 43,285	$ (1,177)	$ 49,848	$ (1,215)

The Company typically invests in highly-rated securities, and its investment policy limits the amount of credit exposure to any one issuer. The policy generally requires investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for expected credit losses, the Company reviews factors such as the length of time and extent to which fair value has been below its cost basis, the financial condition of the issuer and any changes thereto, changes in market interest rates, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's cost basis. The Company also regularly reviews its investments in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the years ended December 31, 2024, 2023 and 2022, the Company did not recognize any expected credit losses. The Company has no current

requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held.

The Company recorded less than $0.1 million of gross realized gains from the sale or maturity of available-for-sale investments during the year ended December 31, 2024, 2023 and 2022, respectively. The Company recorded less than $0.1 million, $0.1 million and $0.1 million of gross realized losses from the sale or maturity of available-for-sale investments during the year ended December 31, 2024, 2023 and 2022, respectively.

Fair Value Disclosures

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

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

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

To estimate the fair value of Level 2 debt securities as of December 31, 2024, the Company's primary pricing service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2024 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 1,773	$ 1,773	$ —	$ —
United States government agency securities	Short-term investments	24,062	—	24,062	—
Corporate debt securities	Short-term investments	33,371	—	33,371	—
Mortgage-backed securities	Short-term investments	2,753	—	2,753	—
Total short-term investments		$ 61,959	$ 1,773	$ 60,186	$ —

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2023 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 5,062	$ 5,062	$ —	$ —
United States government agency securities	Short-term investments	19,354	—	19,354	—
Corporate debt securities	Short-term investments	31,760	—	31,760	—
Mortgage-backed securities	Short-term investments	3,091	—	3,091	—
Total short-term investments		$ 59,267	$ 5,062	$ 54,205	$ —

The Company did not have any transfers among fair value measurement levels during the years ended December 31, 2024 and December 31, 2023.

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

	Years Ended December 31,		
	2024	2023	2022
Loss from changes in the fair value of level 3 investments	$ —	$ —	$ (570)

Note 4. Inventories

Inventories at December 31, 2024 and December 31, 2023, consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Raw materials	$ 8,641	$ 13,680
Work-in-process	22,522	20,668
Finished goods	21,132	25,021
Total inventories	52,295	59,369
Less: non-current inventories	14,145	19,501
Total current inventories	$ 38,150	$ 39,868

Non-current inventories primarily consists of raw materials and work-in-process.

Note 5. Property and Equipment, net

Property and equipment, net at December 31, 2024 and December 31, 2023, consisted of the following (in thousands):

	December 31,	
	2024	2023
Machinery and equipment	$ 5,949	$ 5,534
Computer equipment and software	3,969	3,949
Furniture and fixtures	2,008	2,008
Leasehold improvements	12,192	12,192
Consigned equipment	1,475	1,429
Total property and equipment, gross	25,593	25,112
Accumulated depreciation and amortization	(18,439)	(16,472)
Total property and equipment, net	$ 7,154	$ 8,640

Depreciation and amortization expense related to property and equipment, net was $2.0 million, $2.4 million and $2.5 million for the years ended December 31, 2024, 2023 and 2022, respectively. As part of the Company's restructuring plan, $0.7 million was recognized as an impairment of long-lived assets for leasehold improvements and furniture and fixtures and was recorded within "Restructuring" on the Company's consolidated statement of operations for the year ended December 31, 2023. No impairment charges were incurred for the year ended December 31, 2024.

Note 6. Accrued Liabilities

Accrued liabilities at December 31, 2024 and December 31, 2023, consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued compensation and related costs	$ 11,939	$ 11,822
Accrued professional services	3,406	3,139
Other accrued expenses	3,598	4,264
Total accrued liabilities	$ 18,943	$ 19,225

Note 7. Restructuring

In June 2023, pursuant to the Board of Directors' approval, the Company began implementing a restructuring plan to pursue greater efficiency and to realign its business and strategic priorities. This included a facilities consolidation strategy to cease use of a part of its

corporate office building under its operating lease (see Note 10, *Commitments and Contingencies*) and reduction in force of its employee base. Affected employees received severance consideration and continuation of benefits, as well as transition assistance. During the twelve months ended December 31, 2023, the Company recognized $3.7 million of restructuring charges related to severance cost and facilities consolidation. The Company substantially implemented the restructuring plan in 2023. The following is a summary of the Company's accrued restructuring costs for one-time termination benefits, recorded within "Accrued liabilities" on the Company's consolidated balance sheets (in thousands):

	Balance at December 31, 2023	Restructuring Charge	Cash Payments	Balance at December 31, 2024
One-time termination benefits	$ 84	$ —	$ (84)	$ —
Other	238	—	(32)	206
Total	$ 322	$ —	$ (116)	$ 206

Note 8. Debt

Debt at December 31, 2024, consisted of the following (in thousands):

	Principal	Unamortized Discount	Net Carrying Value
Term Loan	$ 65,000	$ (138)	$ 64,862
Revolving Loan	19,297	—	19,297
Total debt	84,297	(138)	84,159
Less: current portion	19,297	—	19,297
Non-current portion	$ 65,000	$ (138)	$ 64,862

Debt at December 31, 2023, consisted of the following (in thousands):

	Principal	Unamortized Discount	Net Carrying Value
Term Loan	$ 60,000	$ (204)	$ 59,796
Revolving Loan	20,000	—	20,000
Total debt	80,000	(204)	79,796
Less: current portion	20,000	—	20,000
Non-current portion	$ 60,000	$ (204)	$ 59,796

Principal, interest and fee payments on the Term Loan Credit Agreement (as defined below) at December 31, 2024, are expected to be as follows (in thousands):

Year ended December 31,	Principal	Interest and Fees	Total
2025	$ —	$ 7,581	$ 7,581
2026	24,375	6,630	31,005
2027	32,500	2,998	35,498
2028	8,125	1,459	9,584
2029	—	—	—
Total	$ 65,000	$ 18,668	$ 83,668

Loan Agreements

On March 29, 2019, the Company entered into a Credit, Security and Guaranty Agreement (Term Loan) (the "Prior Term Loan Credit Agreement") with MidCap Financial Trust ("MidCap") to borrow up to $70 million in three tranches (collectively "Prior Term Loan"), with a maturity date of March 1, 2024. The first advance of $40.0 million ("Tranche 1") was drawn by the Company on March 29, 2019, with the proceeds used in part to repay in full the outstanding term loans and fees under a prior loan agreement. The second advance of $15.0 million ("Tranche 2") was drawn by the Company on March 29, 2021. The third advance of $15.0 million ("Tranche 3") expired on December 31, 2021. The borrowings under the Prior Term Loan bear interest at the sum of a fixed percentage spread and the greater of (i) 1.80% or (ii) one month SOFR plus 0.1%.

On March 31, 2023, the Company entered into an Amended and Restated Credit, Security and Guaranty Agreement (Term Loan) (the "Term Loan Credit Agreement") which amended and restated the Prior Term Loan Credit Agreement. The Term Loan Credit Agreement

provides a secured term loan facility in an aggregate principal amount of up to $75.0 million. The Company borrowed the first advance of $40.0 million ("Tranche 1") and the second advance of $15.0 million ("Tranche 2") on the closing date to refinance the term loans under the Prior Term Loan Credit Agreement. Under the terms of the Term Loan Credit Agreement, (i) the third advance of $10.0 million ("Tranche 3") was available to the Company through July 1, 2024, and (ii) the fourth advance of $10.0 million ("Tranche 4"), is available to the Company through July 1, 2025, subject to the Company's satisfaction of certain other conditions described in the Term Loan Credit Agreement.

Tranche 1, Tranche 2, Tranche 3, and Tranche 4, each bear interest at a floating rate equal to the sum of the Term SOFR rate (subject to a floor of 1.00%) plus 6.50%. Interest on each term loan advance is due and payable monthly in arrears. Interest only payments are due for the first 36 months, and the remaining payments are due over the remaining 24 months. The interest only payment period can be extended for 12 months upon achievement of a specified trailing 12 month net revenue target. The interest rate at December 31, 2024 is approximately 11.5%.

On September 1, 2023, the Company entered into Amendment 1 of the Term Loan Credit Agreement. At the close of this amendment, the Company borrowed $5.0 million available under Tranche 3. On January 5, 2024 the Company entered into Amendment 2 of the Term Loan Credit Agreement which was effective December 31, 2023, which removed the minimum revenue condition applicable to the remaining $5.0 million available in Tranche 3, which became eligible to be drawn at any time prior to July 1, 2024. The Company borrowed the remaining $5.0 million available in Tranche 3 on March 27, 2024.

Prepayments of the term loans under the Term Loan Credit Agreement, in whole or in part, will be subject to early termination fees which decline each year through the term of the Term Loan Credit Agreement. The Company also must pay an annual administrative fee equal to a fractional percentage of the amount outstanding pursuant to the Term Loan Credit Agreement, and upon the final payment must also pay an exit fee of a percentage of the amount borrowed pursuant to the Term Loan Credit Agreement (the "Exit Fee"). The Company is required to pay a pro rata portion of the Exit Fee in connection with any prepayment. The Company uses the effective interest method to recognize the Exit Fee over the term of the debt.

The Company also maintained a Credit, Security and Guaranty Agreement (Revolving Loan) (the "Prior Revolving Loan Credit Agreement") with MidCap. The borrowing limit under the Prior Revolving Loan Credit Agreement was $15.0 million which had a maturity date of March 1, 2024. The amount borrowed under the Prior Revolving Loan Credit Agreement could be increased, upon request by the Company, by up to an additional $5.0 million, subject to agent and lender approval and the satisfaction of certain conditions.

On March 31, 2023, the Company entered into Amended and Restated Credit, Security and Guaranty Agreement (Revolving Loan) (the "Revolving Loan Credit Agreement") which amended and restated the Prior Revolving Loan Credit Agreement and has a maturity date of March 1, 2028. The Revolving Loan Credit Agreement provides a secured revolving credit facility in an initial aggregate principal amount of up to $20.0 million. The Company may request an increase in the total commitments under the Revolving Loan Credit Agreement by up to an additional $15.0 million, subject to agent and lender approval and the satisfaction of certain conditions.

Loans under the Revolving Loan Credit Agreement accrue interest at a floating rate equal to the Term SOFR rate (subject to a floor of 1.00%) plus 3.75%. Accrued interest on the revolving loans will be paid monthly and revolving loans may be borrowed, repaid and re-borrowed until March 1, 2028, when all outstanding amounts must be repaid. Termination or permanent reductions of the revolving loan commitment under the Revolving Loan Credit Agreement will be subject to termination fees which decline each year until the fourth anniversary of the Revolving Loan Credit Agreement, at which time there is no early termination fee.

In connection with the Revolving Loan Credit Agreement, the Company is required to pay customary fees, including an origination fee equal to a fractional percentage of the original commitment amount at closing (and an equivalent origination fee with respect to any increased commitments at the time of the applicable increase), a monthly unused line fee based upon the average daily unused allowable borrowing base of the revolving credit facility and a monthly collateral management fee based upon the average daily used portion of the revolving credit facility. The Company is also required to maintain a minimum drawn balance under the revolving line or pay interest on the minimum drawn balance.

As of December 31, 2024 and December 31, 2023, the Company had borrowed $19.3 million and $20.0 million, respectively, under the Revolving Loan Credit Agreement, which is included in "Debt – current" in the Company's consolidated balance sheets.

The Term Loan Credit Agreement and Revolving Loan Credit Agreement contain certain financial and non-financial covenants, with which the Company was in compliance at December 31, 2024. Additionally, the Company's obligations under both agreements are secured by a security interest in substantially all of the Company's assets, with some exclusions.

Note 9. Leases

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment and automobiles under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating

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

The Company reduced its office space and ceased using approximately 15,000 square feet of rentable area of corporate office building during the third quarter of 2023. The Company recognized a loss of $1.7 million related to this facilities consolidation in the twelve months ended December 31, 2023 included in "Restructuring" on the Company's consolidated statement of operations.

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

	Year Ended December 31,		
	2024	2023	2022
Cash payments for operating leases	$ 3,684	$ 4,188	$ 3,345
Right-of-use assets obtained in exchange for operating lease obligations	231	1,476	1,401

	December 31, 2024	December 31, 2023
Weighted-average remaining lease term	4.8 years	5.4 years
Weighted-average discount rate	8.6%	8.5%

Future minimum non-cancelable payments under operating leases as of December 31, 2024, were as follows (in thousands):

	Operating Leases
2025	$ 3,309
2026	3,160
2027	3,454
2028	3,272
2029	3,328
Thereafter	844
Total future lease payments	$ 17,367
Less imputed interest	3,429
Present value of lease liabilities [(1)]	$ 13,938

[(1)] Lease liabilities include those operating leases that we plan to sublease as a part of our facilities consolidation restructuring efforts. See Note 7 for additional information.

During the years ended December 31, 2024, 2023 and 2022, the Company recorded operating lease expenses of $3.9 million, $3.5 million and $3.2 million, respectively. As of December 31, 2024, the Company had no leases that have not yet commenced.

Note 10. Commitments and Contingencies

Purchase Commitments

The Company is party to agreements with certain providers for certain components of the INTERCEPT Blood System. Certain of these agreements require minimum purchase commitments from the Company. As of December 31, 2024, the Company had $31.6 million of short-term purchase commitments and $2.6 million of long-term purchase commitments, which are not recorded in the Company's consolidated balance sheets.

Note 11. Stockholders' Equity

Sales Agreement

On December 11, 2020, the Company entered into the Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated (each a "Sales Agent" and collectively, the "Sales Agents"), under which the Company may issue and sell from time to time up to $100.0 million of the Company's common stock through or to the Sales Agents, as sales agent or principal.

On March 1, 2023, the Company entered into Amendment No.1 to the Sales Agreement (the "Amended Sales Agreement"). Under the Amended Sales Agreement, the Company was able to issue and sell from time to time up to $96.8 million of the Company's common stock through or to the Sales Agents, as sales agent or principal. Under the Amended Sales Agreement, each Sales Agent receives compensation based on an aggregate of 3% of the gross proceeds on the sale price per share of the Company's common stock. The issuance and sale of these shares by the Company pursuant to the Amended Sales Agreement are deemed an "at-the-market" offering and are registered under the Securities Act of 1933, as amended.

During the year ended December 31, 2024, no shares of the Company's common stock were sold under the Amended Sales Agreement. At December 31, 2024, the Company had approximately $96.8 million of common stock available to be sold under the Amended Sales Agreement.

Note 12. Stock-Based Compensation

Employee Stock Plans

Employee Stock Purchase Plan

The Company maintains an Employee Stock Purchase Plan (the "Purchase Plan"), which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. Under the Purchase Plan, eligible employee participants may purchase shares of common stock of the Company at a purchase price equal to 85% of the lower of the fair market value per share on the start date of the offering period or the fair market value per share on the purchase date. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. In June 2020, the Company's stockholders approved an amendment and restatement of the Purchase Plan that increased the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 1.5 million shares. In June 2024, the Company's stockholders approved an amendment and restatement of the Purchase Plan that increased the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 2.0 million shares. At December 31, 2024, the Company had 2.3 million shares available for future issuance.

Equity Incentive Plans

The Company also maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors.

2008 Equity Incentive Plan

Prior to the approval by the Company's stockholders in June 2024 of the 2024 Equity Incentive Plan (the "2024 Plan"), the Company granted equity awards from the 2008 Equity Incentive Plan and its subsequent amendments (collectively, the "Amended 2008 Plan"). The Amended 2008 Plan allowed for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units ("RSUs"), stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. In June 2019, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 11.8 million shares. In June 2020, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 5.0 million shares. In June 2021, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 7.6 million shares. In June 2022, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 12.0 million shares. In June 2023, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of

common stock authorized for issuance by 7.0 million shares. Following the approval by the Company's stockholders in June 2024 of the 2024 Plan, no additional awards will be granted under the Amended 2008 plan. Option awards under the Amended 2008 Plan generally have a maximum term of ten years from the date of the award. The Amended 2008 Plan generally required options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Options granted by the Company to employees generally vest over four years. RSUs are measured based on the fair market value of the underlying stock on the date of grant. RSUs granted by the Company to employees generally vest over three to four years. Performance-based stock awards granted under the Amended 2008 Plan were limited to 500,000 shares of common stock per recipient per calendar year. Performance-based cash awards granted under the Amended 2008 Plan were limited to $1.0 million per recipient per calendar year. At December 31, 2024, 2.6 million shares of performance-based stock awards were outstanding.

2024 Equity Incentive Plan

In June 2024, the Company's stockholders approved the 2024 Plan. The 2024 Plan is intended as the successor to and continuation of the Amended 2008 Plan. No additional awards will be granted under the Amended 2008 Plan. The shares remaining available for grant under the Amended 2008 Plan as of the effective date of the 2024 Plan, plus an additional 5.0 million shares of common stock are available for grant and issuance under the 2024 Plan. In addition, the following shares of common stock subject to any outstanding award granted under either the Amended 2008 Plan or the Cerus Corporation Inducement Plan will become available for grant and issuance under the 2024 Plan: (i) any shares subject to such award that on or following the effective date of the 2024 Plan are not issued because such award expires or otherwise terminates without all of the shares covered by such award having been issued; (ii) any shares subject to such award that on or following the effective date of the 2024 Plan are not issued because such award is settled in cash; and (iii) any shares issued pursuant to such award that on or following the effective date of the 2024 Plan are forfeited back to or repurchased by us because of a failure to vest. Option awards under the 2024 Plan generally have a maximum term of ten years from the date of the award. The 2024 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Options granted by the Company to employees generally vest over four years. RSUs are measured based on the fair market value of the underlying stock on the date of grant. RSUs granted by the Company to employees generally vest over three to four years.

At December 31, 2024, the Company had approximately 26.0 million shares of its common stock subject to a combination of outstanding options and unvested RSUs outstanding under the 2024 Plan, of which approximately 12.3 million shares and 13.7 million shares were subject to outstanding options and unvested RSUs, respectively. Approximately 12.7 million shares were available for future issuance under the 2024 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options or vesting of RSUs.

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

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balance at December 31, 2023	14,515	$ 5.20
Granted	—	—
Exercised	—	—
Forfeited/canceled	(2,218)	5.79
Balance at December 31, 2024	12,297	5.10

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

	Number of RSUs Unvested	Weighted Average Grant Date Fair Value per Share
Balance at December 31, 2023	10,686	$ 3.74
Granted [(1)]	7,729	2.14
Vested [(1)]	(4,029)	4.22
Forfeited [(1)]	(725)	3.02
Balance at December 31, 2024	13,661	2.73

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

The total fair value of RSUs as of their respective vesting dates, for the years ended December 31, 2024, 2023 and 2022, were $8.4 million, $8.7 million and $15.0 million, respectively.

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2024, was as follows (in thousands except weighted average exercise price and contractual term):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2024				
Stock options outstanding	12,297	$ 5.10	3.60	—
Stock options vested and expected to vest	12,295	5.10	3.60	—
Stock options exercisable	11,796	5.06	3.46	—

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

There were no stock options exercised during the years ended December 31, 2024 and December 31, 2023. The total intrinsic value of options exercised for the year ended December 31, 2022 was $1.1 million. The total intrinsic value of exercised stock options is calculated based on the difference between the exercise price and the quoted market price of the Company's common stock as of the close of the exercise date.

Stock-based Compensation Expense

Stock-based compensation expense recognized on the Company's consolidated statements of operations for the years ended December 31, 2024, 2023 and 2022, was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 5,897	$ 5,823	$ 5,635
Selling, general and administrative	16,970	14,448	18,821
Total stock-based compensation expense	$ 22,867	$ 20,271	$ 24,456

Stock-based compensation expense in the above table does not reflect any income taxes as the Company has experienced a history of net losses since its inception and has a nearly full valuation allowance on its deferred tax assets. In addition, there was neither income tax benefits realized related to stock-based compensation expense nor any stock-based compensation costs capitalized as part of an asset during the years ended December 31, 2024, 2023 and 2022.

As of December 31, 2024, the Company expects to recognize the remaining unamortized stock-based compensation expense of $1.4 million related to non-vested stock options and $19.5 million related to RSUs, net of estimated forfeitures, over an estimated remaining weighted average period of 1.0 years and 1.3 years, respectively.

Valuation Assumptions for Stock-based Compensation

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

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

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

The weighted average assumptions used to value the Company's stock-based awards for the years ended December 31, 2024, 2023 and 2022, was as follows:

	Year Ended December 31,		
	2024	2023	2022
Stock Options:			
Expected term (in years)	—	—	6.82
Estimated volatility	—	—	55%
Risk-free interest rate	—	—	1.89%
Expected dividend yield	—	—	0%
Employee Stock Purchase Plan Rights:			
Expected term (in years)	0.75	0.75	0.74
Estimated volatility	79%	70%	56%
Risk-free interest rate	4.66%	5.29%	2.25%
Expected dividend yield	0%	0%	0%

There were no stock options granted during the year ended December 31, 2024 and December 31, 2023. The weighted average grant-date fair value of stock options granted during the year ended December 31, 2022 was $3.12 per share. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2024, 2023 and 2022, was $0.92 per share, $0.88 per share and $1.63 per share, respectively.

Note 13. Retirement Plan

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

Note 14. Development and License Agreements

Agreements with Fresenius

In May 2022, the Company entered into the Second Amended and Restated Supply and Manufacturing Agreement ("2022 Agreement") with Fresenius Kabi AG, Fenwal France SAS, and Fenwal International, Inc. (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 Company is obligated to purchase, finished disposable kits for the platelet and plasma systems. Fresenius sources most of the components used in the production of disposable kits, except for certain other components that the Company sources from other third-parties and provides to Fresenius for inclusion into the finished disposable kits. The 2022 Agreement permits the Company 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. Each party has 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 the Company and subject to an annual adjustment based on variation in a price index.

Government contracts

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

The 2016 BARDA agreement and its subsequent modifications include a base period (the "Base Period") and option periods (each, an "Option Period"). The agreement includes committed funding for clinical development of the INTERCEPT Blood System for red blood cells (the "red blood cell system"). In September 2023, BARDA committed an additional $3.5 million raising the committed funding to up to $185.5 million as of December 31, 2024. However, the potential for the exercise by BARDA of subsequent Option Periods that, if exercised by BARDA and completed, was reduced by $8.8 million and would bring the total funding opportunity to $270.2 million through September 2026. If exercised by BARDA, subsequent Option Periods would fund activities related to broader implementation

of the platelet and plasma system or the red blood cell system in areas of emerging pathogens, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. The Company could be responsible for up to $1.4 million of co-investment if certain Option Periods are exercised. BARDA will make periodic assessments of the Company's progress and the continuation of the agreement is based on the Company's success in completing the required tasks under the Base Period and each exercised Option Period. BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate the agreement for convenience at any time. As of December 31, 2024 and December 31, 2023, $2.4 million and $5.6 million, respectively, of billed and unbilled amounts were included in "Accounts receivable, net" on the Company's consolidated balance sheets related to the 2016 BARDA agreement.

In September 2024, the Company entered into a new agreement with BARDA ("2024 BARDA Agreement"). The 2024 BARDA agreement builds on the 2016 BARDA agreement and aims to further advance the development of the red blood cell system. The 2024 BARDA agreement includes access to funding that is intended to support a planned FDA modular premarket approval application and potential post-approval studies, accelerate development of an improved version of the red blood cell system, and scale up chemistry, manufacturing, and controls activities to enable a broad product launch, if approved. The six-year agreement with BARDA includes a base period (the "2024 Base Period") with committed funding of up to $32.1 million, and subsequent option periods (each, a "2024 Option Period") that, if exercised by BARDA and completed, would bring the total funding opportunity to $188.4 million as of December 31, 2024. The Company could be responsible for cost sharing of up to $60.1 million. BARDA will make periodic assessments of the Company's progress, and the continuation of the agreement is based on the Company's success in completing the required tasks under the 2024 Base Period and each 2024 Option Period (if and to the extent any 2024 Option Periods are exercised by BARDA). BARDA has rights under certain contract clauses to terminate the 2024 BARDA agreement, including the ability to terminate for convenience at any time. Under the contract, the Company will be reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. As of December 31, 2024, $0.1 million of billed amount was included in "Accounts receivable, net" on the Company's consolidated balance sheets related to the 2024 BARDA agreement.

In September 2020, the Company entered into a five-year agreement with the FDA for the development of next-generation compounds to optimize pathogen reduction treatment of whole blood to reduce the risk of transfusion-transmitted infections. The total contract value is $11.1 million. As of December 31, 2024 and December 31, 2023, $0.5 million and $0.5 million, respectively, of billed and unbilled amounts were included in "Accounts receivable, net" on the Company's consolidated balance sheets related to FDA.

In September 2022, the Company entered into an agreement with the U.S. Department of Defense, or DoD, Industrial Base Analysis and Sustainment program for the development of pathogen reduced, lyophilized cryoprecipitate to treat bleeding due to trauma. In May 2023, the Company and the DoD entered into an amendment to the agreement to extend the agreement to February 2027 and increased the total contract value from $9.1 million to $17.8 million. The revenue associated with the DoD contract is recognized on the application of the cost-to-cost input method, which measures the extent of progress towards completion of the single performance obligation based on the ratio of actual costs incurred to the total estimated costs over the performance period of the agreement. Revenue is recorded as a percentage of the transaction price based on the extent of progress towards completion. The estimate of the Company's measure of progress, which can include additional services, if any, and the estimate of any additional consideration for those additional services, if any, are included in the transaction price which is updated at each reporting date, and revenue is recognized on a cumulative catch-up basis. As such, management applies a certain amount of judgment in estimating both the services and the corresponding timeline through to completion of the performance obligation, which are key inputs when using the cost-to-cost input method. Given that the estimate of the Company's measure of progress is updated at each reporting date, and revenue is recognized on a cumulative catch-up basis, a significant change in the remaining estimated costs to complete the services (including revisions to transaction price) could have a significant impact on revenues previously recognized under this arrangement (including reversal of previously recognized revenue) at each reporting date.

As of December 31, 2024 and December 31, 2023, $1.0 million and $3.7 million, respectively, of billed amount was included in "Accounts receivable, net" on the Company's consolidated balance sheets related to DoD. As of December 31, 2024 and December 31, 2023, $0.5 million and $1.5 million, respectively, were included in "Deferred revenue" as contract liabilities on the Company's consolidated balance sheets related to the DoD contract.

Note 15. Income Taxes

U.S and foreign components of consolidated loss before income taxes for the years ended December 31, 2024, 2023 and 2022, was as follows (in thousands):

	2024	2023	2022
Loss before income taxes:			
U.S.	$ (21,318)	$ (38,281)	$ (43,096)
Foreign	562	959	759
Loss before income taxes	$ (20,756)	$ (37,322)	$ (42,337)

The provision for income taxes for the years ended December 31, 2024, 2023 and 2022, was as follows (in thousands):

	2024	2023	2022
Provision for income taxes:			
Current:			
Foreign	$ 130	$ 285	$ 520
Federal	—	—	—
State	70	36	5
Total current	200	321	525
Deferred:			
Foreign	—	—	—
Federal	3	2	(18)
State	2	2	(19)
Total deferred	5	4	(37)
Provision for income taxes	$ 205	$ 325	$ 488

The difference between the provision for income taxes and the amount computed by applying the federal statutory income tax rate to loss before taxes for the years ended December 31, 2024, 2023 and 2022, was as follows (in thousands):

	2024	2023	2022
Federal statutory tax	$ (4,359)	$ (7,838)	$ (8,891)
Federal research credits	(853)	(1,065)	(1,874)
State research credits	(767)	(642)	(822)
Expiration of federal carryovers	5,206	7,284	4,858
Change in valuation allowance	(2,357)	1,361	6,379
Compensation related items	4,015	3,257	1,794
State taxes	(259)	(1,710)	(1,127)
Revision to prior year items	(676)	(664)	—
Other	255	342	171
Provision for income taxes	$ 205	$ 325	$ 488

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. The significant components of the Company's deferred tax assets and liabilities at December 31, 2024, 2023 and 2022, were as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 127,184	$ 133,476
Research and development credit carryforwards	29,739	28,567
Capitalized research and development	35,861	33,571
Compensation related items	9,437	10,306
Operating leases	3,005	3,462
Other	10,928	9,823
Total deferred tax assets	216,154	219,205
Valuation allowance	(214,321)	(216,888)
Net deferred tax assets	$ 1,833	$ 2,317
Deferred tax liabilities:		
Right-of-use assets	$ 1,676	$ 2,173
Other	226	209
Total deferred tax liabilities	$ 1,902	$ 2,382

The valuation allowance decreased by $2.6 million for the year ended December 31, 2024, compared to the increase of $1.0 million and $6.4 million for the years ended December 31, 2023 and 2022, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization and expected near-term future losses. The Company expects to maintain a valuation allowance until circumstances change.

For the year ended December 31, 2024, the Company reported pretax net losses on its consolidated statement of operations and calculated taxable losses for federal purposes and varying taxable income and losses for state purposes based on individual jurisdictions. The differences between reported net loss and taxable income or loss are due to differences between book accounting and the respective tax laws. The most notable differences are the treatment of research and development expenses and compensation related items

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

	Total	Expires 2025-2027	Expires 2028-2034	Expires 2035-2044	No Expiration
Federal losses carryovers	$ 559,551	$ 58,345	$ 193,684	$ 116,604	$ 190,918
California loss carryovers	108,685	—	67,796	40,889	—
Other state loss carryovers	45,090	128	2,762	30,630	11,570
Federal research credits	17,074	1,279	1,927	13,868	—
California research credits	16,011	—	—	—	16,011
Federal foreign tax credits	610	610	—	—	—

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

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

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

	December 31, 2024	December 31, 2023
Unrecognized tax benefits at beginning of period	$ 7,924	$ 8,652
Decreases related to expired carryforwards	(344)	(1,126)
Decreases related to administrative proceedings	(127)	—
Increases related to prior year tax positions	94	100
Increases related to current year tax positions	290	298
Unrecognized tax benefits at end of period	$ 7,837	$ 7,924

The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense.

Note 16. Segment, Customer and Geographic Information

The Company manages its business activities on a consolidated basis and operates in one reportable segment. The Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM makes decisions on resource allocation, assesses performance of the business, and monitors budget versus actual results using loss from operations.

Significant expenses within loss from operations include cost of product revenue, research and development, and selling, general and administrative expenses, which are each separately presented on the Company's Consolidated Statements of Operations.

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

The Company had the following significant customers that accounted for more than 10% of the Company's total product revenue, during the years ended December 31, 2024, 2023 and 2022 (in percentages):

	Year Ended December 31,		
	2024	2023	2022
American Red Cross	35%	35%	35%
Établissement Français du Sang	11%	12%	12%

Revenues by geographical location were based on the location of the customer during the years ended December 31, 2024, 2023 and 2022, and was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Product revenue:			
United States	$ 111,073	$ 93,232	$ 101,391
France	19,692	18,490	19,327
Other countries	49,505	44,645	41,330
Total product revenue	180,270	156,367	162,048
Government contract revenue:			
United States	21,051	30,430	26,267
Total government contract revenue	21,051	30,430	26,267
Total revenue	$ 201,321	$ 186,797	$ 188,315

Long-lived assets by geographical location at December 31, 2024 and December 31, 2023, were as follows (in thousands):

	December 31,	
	2024	2023
United States	$ 6,807	$ 8,444
Europe & other	347	196
Total long-lived assets	$ 7,154	$ 8,640

SIGNATURES

Pursuant to the requirement of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 26th day of February, 2025.

CERUS CORPORATION

By: /s/ WILLIAM M. GREENMAN
William M. Greenman
President and Chief Executive Officer

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

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

Signature	Title	Date
/s/ WILLIAM M. GREENMAN **William M. Greenman**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2025
/s/ KEVIN D. GREEN **Kevin D. Green**	Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 26, 2025
/s/ DANIEL N. SWISHER, JR. **Daniel N. Swisher, Jr.**	Director and Chair of the Board of Directors	February 26, 2025
/s/ ERIC H. BJERKHOLT **Eric H. Bjerkholt**	Director	February 26, 2025
/s/ DEAN A. GREGORY **Dean A. Gregory**	Director	February 26, 2025
/s/ ANN LUCENA **Ann Lucena**	Director	February 26, 2025
/s/ TIMOTHY L. MOORE **Timothy L. Moore**	Director	February 26, 2025
/s/ JAMI NACHTSHEIM **Jami Nachtsheim**	Director	February 26, 2025
/s/ GAIL SCHULZE **Gail Schulze**	Director	February 26, 2025
/s/ HUA SHAN, MD, PH.D. **Hua Shan, MD, Ph.D.**	Director	February 26, 2025
/s/ FRANK WITNEY, PH.D. **Frank Witney, Ph.D.**	Director	February 26, 2025

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 10.3

SECOND AMENDED AND RESTATED

SUPPLY AND MANUFACTURING AGREEMENT

THIS SECOND AMENDED AND RESTATED SUPPLY AND MANUFACTURING AGREEMENT (THE "***Supply Agreement***" or "***Agreement***") is made effective as of the 1st day of January, 2025 (the "Effective Date") by and between Cerus Corporation ("***Cerus***"), a Delaware corporation, having its principal place of business at 1220 Concord Ave, Concord, CA 94520, and Porex Corporation ("***Porex***"), a Delaware corporation, having its principal place of business at 500 Bohannon Road, Fairburn, GA 30213. (Cerus and Porex are each individually referred to in this Supply Agreement as a "Party" and, collectively, as the "***Parties***").

WITNESSETH

WHEREAS, the Parties desire to set forth the terms under which Cerus may purchase from Porex [*] porous plastic [*] wafers designed for the pathogen inactivation system for platelets **(**the **"*Platelet Wafers*")** and [*] porous plastic [*] disks designed for the pathogen inactivation system for plasma **(**the "***Plasma Disks***") (collectively, the "***Components***") made to Cerus specifications as further detailed in **EXHIBIT A** and **EXHIBIT B** attached hereto, respectively **(**the "***Specifications***"); and

WHEREAS, the Platelet Wafers and Plasma Disks will be used in the manufacture of disposable products forming part of the INTERCEPT Blood System for platelets and the INTERCEPT Blood System for plasma, respectively, for sale by Cerus and its affiliates, and disposable products forming part of similar systems for sale by a third party (collectively, the "***Products***").

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth herein, Cerus and Porex agree as follows:

1 PURCHASES

1.1 Purchase and Sale

1.1.1 During the term of this Supply Agreement, Porex shall sell to Cerus Components ordered pursuant to Section 1.3 of this Supply Agreement.

1.1.2 By written notice to Porex, Cerus may designate, from time to time, one or more third parties (hereinafter referred to as "***Designee***") provided such Designee is not a Porex competitor as defined in Section 13.3 below, that is authorized to:

(a) issue purchase orders for Components pursuant to Section 1.3; and

(b) receive, inspect and test shipments from Porex for such ordered Components pursuant to Section 1.4.

Designees are not authorized to act for Cerus in any other capacity or to bind Cerus in any other respect whatsoever. Notwithstanding anything contained herein to the contrary, Cerus shall be legally responsible for any act, omission or obligation of Designee pertaining to this Agreement. Porex acknowledges that Fresenius-Kabi Deutschland GmbH and its affiliates, including Fenwal Inc. (collectively, "***Fenwal***") are not as of the Effective Date Porex Competitors.

1.1.3Purchase Commitment: Subject to the terms and conditions of this Supply Agreement, Cerus shall purchase no less than [*] exclusively from Porex; provided, however, that the foregoing obligation of Cerus shall apply solely with respect to Components used in the manufacture of Products that are [*]; and provided, further, that notwithstanding such exclusivity Cerus may purchase Components from a third party to the extent that [*]. The foregoing exclusivity shall not apply from and after [*]. Provided that Porex is not in breach of any of the material provisions of the Agreement, Cerus shall [*] (such [*], the "**[*]**")."

1.2Raw Materials

1.2.1 Cerus shall arrange, at its own expense, for the supply and delivery to Porex of [*] (in conformance with the specifications set forth on **EXHIBITS A-1** and **B-1**), [*] for production of Plasma Disks (collectively, the "***Raw Materials***") as set forth in the Porex Raw Material Projections (as hereinafter defined). Porex shall timely inspect all Raw Materials. If such Raw Materials fail to meet the specifications for such Raw Materials set forth in **EXHIBITS A-3, A-4, A-5 AND B-2**, Porex shall have the right to reject such Raw Materials. If Porex does not deliver such written notice to Cerus within the [*] business day period from inspection of such Raw Materials, Porex shall be deemed to have accepted the Raw Materials. During quarterly business review (QBR) meetings, Porex and Cerus shall meet in person or virtually to discuss Porex's anticipated: (i) requirements for Raw Materials needed to manufacture the quantity of Components forecasted by Cerus for the upcoming Purchase Order Period (as defined in Section 1.3); and (ii) the required delivery dates of such Raw Materials needed to meet Cerus' projected delivery schedule for the upcoming Purchase Order Period.

1.2.2 Porex shall be solely responsible for obtaining the [*] (in conformance with the specifications set forth on **EXHIBIT B-2**) used for production of the Plasma Disks (the "[*]"). Porex shall also be responsible for ordering and purchasing packaging material for all Components meeting the Specifications. In the event Porex experiences an increase in the [*] costs equal to or greater than [*] that is [*] , Porex may reopen price negotiations solely with respect to the affected Component by providing Cerus with written notice quantifying the impact of the Raw Material cost increase (the "***RM Increase Notice***"). The parties agree to enter into good faith negotiations related to the allocation of additional costs for the Component that is impacted by the Raw Material cost increase(s) in a manner that is proportional to the actual increase. In the event Porex and Cerus cannot agree on new pricing for the Component impacted by the Raw Material cost increase(s) pricing within [*] of the RM Increase Notice, [*] the price increase in Raw Material cost on the affected Component, based on [*] such increase in Raw Material cost for such Component, in all cases, as supported by Porex documentation. Porex may [*] such documentation. For illustrative purposes:

[*]

In the event Raw Materials are supplied to Porex in excess of the Raw Materials consumed in the manufacture of Product, Porex shall notify Cerus and use such Raw Materials in fulfillment of the subsequent order. In the event Porex requires Raw Materials in excess of Raw Materials specified in the Porex Raw Material Projections as a result of Porex's failure to comply with the procedures applicable to the production of Components, Porex shall bear all additional costs for obtaining such additional materials from Cerus or its designated supplier at a price equal to Cerus' cost.

1.2.3 Cerus and Porex will work together towards a goal of a production loss % of ≤ [*]. Table 1 of Exhibit F sets forth the calculations of yield based on such production loss % of ≤ [*] (the "**Target Rates**"). Table 2 of Exhibit F sets forth the current Raw Material yield rates for each Component produced by Porex hereunder (the "**Current Rates**"). Porex shall provide monthly inventory reports of, and shall track the Raw Material usage for, each lot of Raw Material supplied by Cerus. Such Raw Material reports shall contain the quantity of wafers or disks manufactured for lots of [*] supplied by Cerus. Porex will also notify Cerus when [*]. The Parties shall collectively review and discuss the root cause, financial responsibility, and what actions, if any, shall be taken to [*]. Notwithstanding the foregoing, [*] will not exceed [*] without the prior written consent of Cerus, which consent will be conditioned upon a discussion regarding the root cause, disposition and the financial responsibility for scrap rates in excess of [*]. Further, notwithstanding the goal of the Target Rates as set out in Exhibit F, the Parties recognize [*] the Target Rates and such failure to achieve the Target Rates shall [*].

1.2.4 Porex agrees to [*] subject to mutual agreement on scope, which [*] will be [*]. Additionally, Porex will [*], as agreed to with Cerus' development and quality teams. The parties agree to work together in good faith to finalize project and implementation of [*] with a target date of [*].

1.3Forecasts/Purchase Orders

In order to assist Porex in its production planning of Components, Cerus will provide to Porex during the Term of this Supply Agreement a rolling 12-month forecast by Component product code, which forecast shall include monthly delivery dates (the "***Forecast***") and the first [*] months ("***Purchase Order Period***") of which will constitute a firm purchase order (such portion, a 'Purchase Order Period") for such Purchase Order Period. Within [*] after receipt of each Forecast, Porex shall provide to Cerus: (a) written confirmation of its ability to meet the monthly requirements in the Forecast; (b) a good faith estimate of the additional Raw Materials (as defined below), if any, needed by Porex to manufacture the forecasted quantity of Components; and (c) the latest date by which such Raw Materials must be received by Porex to meet Cerus' projected delivery schedule (subclauses "(b)" and "(c)", the "***Raw Material Projections***"). Porex shall not unreasonably reject Cerus' monthly requirements in the Forecast. In no event shall any Purchase Order without written approval from Porex: require delivery exceeding the quantity specified in the "Porex Capacity Limitations" section below in any single month.

1.4Delivery

1.4.1 Porex shall ship the Components to destinations specified by Cerus (directly or through its Designee) in the Purchase Order, by mutually agreed upon carriers, [*]. Cerus shall pay

all shipping and applicable insurance charges. Porex shall provide to Cerus or Designee (as the case may be) all documentation as described in the Specifications.

1.4.2 All Components shipped hereunder shall be received subject to inspection and testing by Cerus (directly or through its Designee) for compliance with the Specifications, which testing shall be completed within sixty (60) days from the receipt of said shipment. Cerus (directly or through its Designee) shall also, within that same period, notify Porex in writing of the acceptance or rejection of a shipment for failure to meet Specifications and if rejected, specifying in detail the reasons for rejection. If the shipment is rejected, Cerus (directly or through its Designee) shall promptly make such Components available to Porex for examination and testing and Porex shall either (i) credit Cerus for the amount of such non-conforming Components for which Cerus has previously paid Porex, or (ii) provide replacement for Components that fail to meet the Specifications as soon as such replacement can be completed within Porex's normal schedules and operating capacity without adversely affecting Porex' current production. If Cerus or its Designee does not deliver such written notice to Porex within the sixty (60) day period from the receipt of shipment, Cerus shall be deemed to have accepted the shipment.

1.4.3Raw Material Replacement Costs. With respect to: (a) any quantities of Components that are [*], and (b) all [*] that are [*], [*]the cost to replace the Raw Materials provided by Cerus for such [*]. [*] the cost to replace Raw Materials [*].

1.4.4Supply Failure. In the event that Porex, for any reason other than [*], has been or will be unable to timely supply Components meeting the Specifications and warranties contained in Section 7.1 in the following quantities: (a) at least [*]; or (b) at least [*], Porex shall be deemed to have suffered a "***Supply Failure***", and upon Cerus notifying Porex of such Supply Failure, Porex shall provide to Cerus (a) a written action plan detailing the steps Porex will undertake to remedy the Supply Failure; (b) the timeline over which such action plan will occur; and (c) the target date to which Porex believes, in good faith, it will resolve the Supply Failure and/or resume its production of Components (such target date, the "***Committed SF Date***") (the foregoing subsections (a) through (c) shall be the "***SF Report***"). If (1) Porex does not timely provide to Cerus the SF Report, (2) the Committed SF Date is more than [*] following the [*], or (3) Porex fails to [*] within [*] following [*], and such inability is [*], then [*]. In all cases, Porex shall exercise its best efforts to resume production as quickly as possible and shall keep Cerus informed in writing of its progress toward that end. In the event that Cerus has [*] and Porex resolves the Supply Failure prior to [*], then [*].

1.4.5Last Time Buy. For purposes of this Supply Agreement, the following shall each be deemed a "***Last Time Buy Trigger***": (a) during the [*] immediately prior to the expiration of this Supply Agreement, (b) in the event that the Parties mutually agree to terminate the Agreement, or (c) in the event of any discontinuance of Porex supplied raw material, reagent, component or other ingredient of the Components. In the event of a Last Time Buy Trigger, Cerus may, in its sole discretion, submit orders for Components or place orders for Components through its Designee, which orders shall be deemed accepted by Porex to the extent the number of units of Components so ordered does not exceed the then-current Porex Capacity Limitation. Porex shall satisfy any such order as soon as reasonably practicable, and in any event Porex shall deliver [*] of the number of units of Components ordered pursuant to this Section 1.4.5 no later than [*] months after the date of such order and shall deliver all remaining Components ordered pursuant to this Section 1.4.5 over a period no longer than [*] after the date of such order.

1.5 Price; Payment Terms

1.5.1 Prices to be paid by Cerus (the "***Prices***") are set forth in **EXHIBIT C**. Subject to any cost adjustment in Section 1.2.2., Pricing will be held firm through December 31, 2026 and then shall be set in accordance with the volume pricing tier table in Exhibit C, starting from January 1, 2027.

1.5.2 Porex will invoice Cerus monthly for Components shipped pursuant to Purchase Orders placed for that month. Cerus will pay the amount of the invoice within [*] days following (i) receipt of the invoice by Cerus, or (ii) delivery of such Components covered by such invoice, whichever later occurs. Past due payments will bear interest at [*] per month from the due date.

2 MANUFACTURING FACILITY

2.1 Capacity

Porex represents that as of the Effective Date, its annual capacity for the production of Components is consistent with the Porex Capacity Limitations, as outlined in the table below (expressed as annual delivery quantities). Porex agrees not to reduce the foregoing capacity during the Term. Further, in the event that additional capacity in excess of the Porex Capacity Limitations is required to meet Cerus' production demands for Components, and as agreed to in advance by Porex (which agreement shall not be unreasonably withheld, delayed or conditions) following a review of the business case for such expansion, Porex shall undertake any equipment and/or facility improvements and associated validation activities, subject to a cost sharing plan agreed to by the Parties, necessary to meet Cerus' increased demand forecasts on the timelines required.

[*]

2.2 Disk Minimum Lot Sizes. Porex will make reasonable commercial efforts to provide a minimum wafer and disk lot size of [*] units, pending the parties' mutual agreement on [*]. Notwithstanding the foregoing and except in the case of force majeure, Porex will not ship any lot with less than [*].

2.3 Dedicated Space. Porex shall reserve the space identified in **EXHIBIT D** (the "***Cerus Dedicated Space***") solely for the manufacture and production of the Products under this Supply Agreement. No other activities other than those agreed upon in advance in writing by Cerus may be performed in the Cerus Dedicated Space. Cerus shall have unrestricted access, subject to providing reasonable advance notice to Porex, to the Cerus Dedicated Space during the Term of this Supply Agreement to ensure that the products are being manufactured and produced in compliance with the terms of this Supply Agreement and the terms of the Quality Agreement (as hereinafter defined). In [*] the provisions of this Section 2.3, [*]. In the event that Porex is unable to produce the quantity of Product set forth in a Purchase Order(s) due to regulatory or compliance issues, or facility driven production downtime, [*]. For illustrative purposes only, if Cerus delivers a Purchase Order for a total of [*] units during a Purchase Order Period, but Porex is only able to produce and ship [*] units due to facilities closures in that year, Cerus shall [*].

2.4Tooling Fee. Porex shall be responsible for procuring any tooling necessary to manufacture Components hereunder, at its sole cost and expense, provided, however, that on an annual basis, Cerus agrees to fund such costs for an aggregate fee of $[*] (the "***Tooling Fee***"), which Tooling Fee will be amortized into the price per unit of the first [*]t purchased in each calendar year, by including a surcharge of $[*] per [*], as reflected in Exhibit C. In the event that Cerus falls short of ordering [*] in any calendar year such that the annual Tooling Fee is not fully amortized, Cerus shall pay Porex the balance of the Tooling Fee that was not covered by amortization. Such balance shall be paid on or prior to [*] of the following calendar year.

2.5Ownership of Equipment

[*] ownership of all stations, tooling and additional equipment set forth on **EXHIBIT E,** which items were funded in whole or in part by [*] and [*] (collectively, the "***Equipment***"). The Equipment will be considered [*]. [*] shall be responsible for maintaining, servicing and insuring the Equipment, and keeping appropriate records regarding such use, maintenance and service during the term of this Supply Agreement. The Equipment shall be used by Porex during the term of this Supply Agreement solely for production of Components for Cerus under this Supply Agreement. Upon termination or expiration of this Supply Agreement, Porex will remove and destroy any Tooling set forth on Exhibit E embodying Cerus' proprietary specifications or design).

2.6Ownership of Facility Improvements

[*] shall own all facility improvements set forth on **EXHIBIT E** which improvements were funded in whole or in part by [*] (the "***Facility Improvements***").

3 COMPONENT CHANGES

During the term of the Supply Agreement, Cerus may propose modifications to the Components; provided, however, that any proposed modifications and any work related thereto shall be subject to mutual agreement by the Parties, which agreement by Porex shall not be unreasonably withheld or delayed. In approving any modification contemplated by this Section 3, the Parties shall work in good faith to mutually agree upon defining the scope of the change, including the respective roles and responsibilities of the Parties with respect thereto, as well as the allocation of any cost or expense related to such modification, which scope shall be set forth in writing and executed by each of the Parties. Any changes to the raw material, product or process Specifications, or required manufacturing environment (i.e., classification of a clean room) must be done pursuant to change control projects mutually agreed upon by the Parties in writing. Further, to the extent such modification was requested by Cerus and such modification results in an increase in the cost to manufacture the Products, the Parties shall mutually agree on revisions, if any, to the pricing set forth on **EXHIBIT C**.

4 QUALITY OBLIGATIONS

The Parties have concurrently entered into the Amended and Restated Quality Agreement attached hereto as **EXHIBIT F** (the "***Quality Agreement***"). The Parties shall review and, if necessary, update the Quality Agreement on or prior to each anniversary of the date hereof (or sooner if circumstances so dictate). Further, Porex shall provide, at its sole cost, at least one

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experienced, management-level quality manager to oversee the production and supply of Product under this Supply Agreement. The Parties hereto acknowledge that the provisions of this Section 4 are an essential and material component of this Supply Agreement.

5 REGULATORY RESPONSIBILITY

Cerus is solely responsible for all regulatory compliance and requirements relating to the Products and use of Components in the Products and Porex will provide its full cooperation and attention in assisting Cerus fulfill the foregoing responsibilities, as required by Cerus' authorized regulatory bodies. This will include providing any required records or information related to the Components and their manufacture by Porex as the contract manufacturer thereof either directly to Cerus or to the requesting regulatory body (with a copy to Cerus so long as such records or information contain information to which Cerus is otherwise entitled to access, otherwise, Porex shall provide redacted versions of such records or information).

6 FORCE MAJEURE

Porex shall not be liable for delays in performance or for non-performance of its obligations hereunder if prevented by causes outside of its reasonable control. Without limiting the foregoing, such causes shall include, but not be limited to, acts of God or the public enemy, fires, floods, earthquake, riots, boycotts, strikes, lock-outs, and delays in transportation or shortage of supplies necessary for production, in each case where delays could not reasonably have been prevented. Upon discovering that timely performance will be delayed, Porex will promptly notify Cerus of the nature of the delay and Porex's disaster recovery plan along with timing expectations.

7 WARRANTIES; INDEMNIFICATIONS

7.1 Porex Warranties

7.1.1 The warranties set forth herein are made solely for the benefit of Cerus and its affiliates. All claims hereunder shall be made by Cerus and may not be made by Cerus customers or any third parties. The term "affiliate", as used in this Supply Agreement, means with respect to a Party any entity that, directly or indirectly, controls, or is controlled by, or is under common control with, such Party. The term "controls", "controlled by", or "under common control with", means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether by contract or through the ownership of voting securities, including the ownership of more than fifty percent (50%) of the equity, partnership, membership or similar interest in such entity.

7.1.2 Porex shall not be responsible for any Components that do not meet the Specifications if such failure is caused by the Raw Materials supplied by Cerus under this Supply Agreement, subject to Porex's inspection obligations as provided under Section 1.2.1, and the Porex warranties in Section 7.1 do not extend to such failure to meet the Specifications if caused by the Raw Materials or any specifications or processes provided by Cerus for the Raw Materials if such Raw Materials supplied by Cerus did not pass the inspection provided for in Section 1.2.1.

7.1.3 In no event shall Porex be responsible for any damage, change or effect to the Components or Products resulting from or related to any acts or omissions of Cerus or its Designees or their respective affiliates, agents, distributors, vendors or customers or any intermediary or end user of any product manufactured, distributed or sold by Cerus or its Designee, including, but not limited to, improper storage, handling, installation, modifications, abuse or misuse.

7.1.4 Porex warrants and represents that:

7.1.4.1it will comply with all laws, decrees, rules, regulations, codes, orders, ordinances, actions and requests of all federal, state and local governmental bodies and courts applicable to Porex's obligations under this Agreement and that the Products manufactured hereunder will be manufactured in compliance with the foregoing, as well as current Good Manufacturing Practices;

7.1.4.2 Porex's technology, processes, know-how, trade secrets and other intellectual property used by Porex to manufacture the Components will not infringe upon the intellectual property rights of any third party, and Porex has the right to use such technology, processes, know-how and other intellectual property; and

7.1.4.3 Porex's performance of its obligations under this Agreement will not result in the breach of any covenant, undertaking or obligation of Porex to any third party.

7.1.5EXCEPT AS PROVIDED IN SECTION 7.1.3, POREX WARRANTS THAT THE COMPONENTS SHALL CONFORM TO THE SPECIFICATIONS, AND POREX WARRANTS THAT POREX TRANSFERS GOOD AND MARKETABLE TITLE TO THE COMPONENTS SOLD TO CERUS UNDER THIS SUPPLY AGREEMENT AS OF THE TIME THAT POREX SHIPS SUCH COMPONENTS AND RECEIVES PAYMENT. THE WARRANTIES IN SECTION 7.1.4 AND THIS SECTION 7.1.5ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY POREX, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, ANY OTHER WARRANTY OF TITLE, REGULATORY COMPLIANCE, OR ANY WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE. THE SOLE AND EXCLUSIVE REMEDY FOR BREACH OF ANY AND ALL WARRANTIES SHALL BE LIMITED TO THE REPLACEMENT OR EXCHANGE OF THE DEFECTIVE COMPONENTS.

7.2Indemnification

7.2.1 Cerus will indemnify, defend and hold harmless Porex, its affiliates, and their respective officers, directors, agents, and employees (each a **"Porex Indemnified Party"**) from and against any and all third party claims, actions, causes of action, liabilities, losses, costs, damages or expenses (including reasonable attorney's fees) to the extent arising out of or in consequence of (i) the possession or use of any Products including, but not limited to, those containing the Components; (ii) the death of or bodily injury to any person on account of the use of any Cerus Product containing the Components or use of any Components; (iii) any claim that the Products or Components violate a patent or trademark or the intellectual property rights of any third party; or, (iv) Cerus' failure to obtain any clearance, approval or license for the Products or the Components that is actually required

by applicable law (collectively, "**Claims**"), except to the extent arising under Porex's indemnity obligation in Section 7.2.2. However, subject to the combined aggregate limitation set forth in Section 7.2.3 hereof, Cerus shall not be obligated to indemnify a Porex Indemnified Party from any liability to the extent caused by a Porex Indemnified Party's negligence or misconduct, as finally determined by a court of competent jurisdiction.

7.2.2 Porex will indemnify, defend and hold harmless Cerus and its respective officers, directors, agents, employees and affiliates (each a **"Cerus Indemnified Party"**) from and against any and all third party claims, actions, causes of action, liabilities, losses, costs, damages or expenses (including reasonable attorney's fees) to the extent arising out of or in consequence of any claim of patent, trademark or trade secrets infringement which relates to Porex's proprietary manufacturing process(es) for [*] porous plastic [*].

7.2.3 Notwithstanding anything contained herein to the contrary, the combined aggregate amount by which (x) Cerus' indemnification obligations pursuant to Section 7.2.1 may be reduced pursuant to the last sentence of Section 7.2.1 and (y) Porex may be liable for recalls under Section 9 of this Agreement, shall not exceed a combined aggregate limit of [*] during the term of this Agreement.

7.2.4 Each indemnified party agrees to give the indemnifying party prompt written notice of any claims, including any claims asserted or made by any governmental authority, for which the other might be liable under the foregoing indemnification, together with the opportunity to defend, negotiate and settle such claims. Such notice shall be given to the indemnifying party promptly after receipt of such claim. Failure to provide or promptly provide such notice shall not release the indemnifying party from any of its obligations hereunder except to the extent that the indemnifying party is materially prejudiced by such failure. Each indemnified party will cooperate fully with the indemnifying party in defending or otherwise resolving any such action, and each indemnified party in any such action may at its option and expense be represented in such action. No party shall be responsible or bound by any compromise made by any other party without its prior written consent, provided that such any such party requested to give consent shall not unreasonably withhold its consent to any such settlement.

7.3LIMITATION OF LIABILITY

IN NO EVENT, OTHER THAN FOR PAYMENT OF DEFENSE AND INDEMNITY UNDER SECTION 7.2, SHALL CERUS BE LIABLE TO POREX, FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, LOST USE, OR THE LIKE) ARISING OUT OF OR IN CONNECTION WITH THIS SUPPLY AGREEMENT OR THE MANUFACTURE, USE OR PERFORMANCE OF THE COMPONENTS OR PRODUCTS, EVEN IF SUCH PARTY IS ADVISED OF THE POSSIBLITY OF SUCH DAMAGES. IN NO EVENT SHALL POREX BE LIABLE TO CERUS UNDER ANY THEORY OF LAW OR EQUITY, WHETHER IN CONTRACT, TORT OR OTHERWISE, FOR ANY DAMAGES INCLUDING, BUT NOT LIMITED TO, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY OR COSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, LOST USE, OR THE LIKE), ARISING OUT OF THIS SUPPLY AGREEMENT OR THE MANUFACTURE, USE, OR PERFORMANCE OF THE COMPONENTS OR

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PRODUCTS, IN AN AGGREGATE AMOUNT IN EXCESS OF [*]. DURING THE TERM OF THIS AGREEMENT, EXCEPT AS PROVIDED IN SECTIONS 1.2.3, 2.3, 2.4, 7.2, 8.2, 9, 10, 11 AND 13.3 OF THIS SUPPLY AGREEMENT, IN WHICH CASE SUCH LIABILITY SHALL BE CAPPED AT [*]. THE PARTIES AGREE THAT THE FOREGOING LIMITATIONS OF LIABILITY ARE A REASONABLE AND NEGOTIATED ALLOCATION OF RISK BETWEEN THE PARTIES AND THAT THEY WOULD NOT ENTER INTO THIS SUPPLY AGREEMENT ABSENT SUCH TERMS. EACH PARTY AGREES THAT IT SHALL NOT CLAIM THAT THESE LIMITATIONS ARE UNREASONABLE, AGAINST PUBLIC POLICY, OR CAUSE ANY REMEDY TO FAIL OF ITS ESSENTIAL PURPOSE; THESE LIMITATIONS SHALL BE ENFORCED DESPITE ANY SUCH CLAIM.

7.4Insurance

During the term of this Supply Agreement and for [*] thereafter, Cerus shall at all times keep and maintain the following insurance coverage and limits of liability:

(a) General Commercial Liability for death or personal injury and damage to property (including, but not limited to, coverage for products liability and completed operations, advertising injury and independent contractors coverage) with limits of not less than $[*] per occurrence and $[*] in the aggregate. Such insurance to provide for broad form contractual liability coverage, including coverage for the liabilities assumed in this Supply Agreement.

(b) Umbrella/Excess Insurance follow form over (a) above with a limit of $[*].

(c) Statutory Workers' Compensation in accordance with the laws of California and Employers Liability Insurance with a limit of not less than $[*].

Policies of insurance set forth in Section 7.4(a) and 7.4(b) above shall provide for the following:

i.) Name Porex and its officers, directors, employees, subsidiaries, parent company, if any, and agents as additional insureds.

ii.) Be primary and non-contributory with respect to all obligations of Cerus under this Supply Agreement. Any insurance carried by Porex shall not contribute to, or be excess of insurance maintained by Cerus, nor in any way provide benefit to Cerus, its affiliates, officers, directors, employees, subsidiaries, parent company, if any, or agents.

iii.) Have reasonable and customary deductible amounts, provided that in no event shall such deductible amounts exceed $[*] per occurrence. Any deductibles that exceed $[*] must be pre-approved in writing by Porex.

iv.) Be issued by insurance carriers licensed to do business under the laws of the country, state, commonwealth, province or territory in which Cerus'

obligations are provided, and with a rating of not less than A VII, as rated in the most currently available "Best's Insurance Guide."

v.) Provide a waiver of subrogation in favor of Porex and its officers, directors, employees, subsidiaries, parent company, if any, and agents.

vi.) Include a separation of insurance clause and cross-liability coverage where Porex is an additional insured.

Upon execution of this Supply Agreement, Cerus shall cause certificates to be issued evidencing that the coverages and policy endorsements required under this Supply Agreement are maintained in force and effect and providing for not less than 30 days, 10 days in the case of nonpayment, written notice to Porex prior to any material modification, cancellation or non-renewal of the policies. Certificates shall expressly confirm the above limits and obligations. The certificate of insurance shall be delivered to Porex's address as set forth in the Notices provision of this Supply Agreement. The receipt of any certificate does not constitute acceptance by Porex that the insurance requirements have been met.

If Cerus fails to procure and maintain the insurance coverage types or limits, or any portion thereof, as specified herein, Porex, in its sole discretion, may procure and maintain the required insurance for and in the name of Cerus and Cerus shall pay the cost thereof or such cost shall be deducted from monies due to Cerus by Porex. Cerus shall furnish to Porex all information necessary to acquire and maintain such insurance. Cerus shall not violate or knowingly permit any violation of any conditions or terms of the policies of insurance described herein.

8 INTELLECTUAL PROPERTY

8.1 Cerus understands and agrees that nothing in this Supply Agreement is intended to grant Cerus any right, title, interest, or license to use or disclose Porex's Confidential Information, intellectual property (both as further defined in the Confidentiality Agreement referenced in Section 10 below), or manufacturing processes, including, but not limited to, Porex products, designs and specifications.

8.2 Porex understands and agrees that this Supply Agreement is not intended to grant Porex any right, title, interest or license to use or disclose Cerus' Confidential Information, intellectual property (both as further defined in the Confidentiality Agreement referenced in Section 10 below), including, but not limited to Products designs and Specifications.

8.3 Neither this Supply Agreement nor one Party's disclosure of Confidential Information or intellectual property shall be deemed, by implication or otherwise to vest in any other Party any rights in any patents, trade secrets, trademarks, trade names, designs, copyrights, or other property of the disclosing Party; provided, however, that Porex is granted a limited license to use the intellectual property of Cerus to the extent required for Porex to perform its obligations under this Supply Agreement.

9 FIELD ACTION

Any removal, correction, or other similar action involving Products shall be made solely by Cerus at Cerus' sole discretion and expense. However, if in the event of a recall due solely to a failure of the Components to meet the Specifications (other than as a result of the Raw Materials), Porex shall, subject to [*] set forth in Section 7.2.3 of this Agreement, reimburse Cerus for actual, reasonable direct costs and expenses actually incurred by Cerus in connection with all such recalls including, but not limited to, direct costs of (i) administration of the recalls, (ii) retrieving Products already delivered to customers, and (iii) notification, shipping and handling charges. The Parties will cooperate fully with each other in effecting any actions under this Section. Cerus will be responsible for communications to its customers and users of the Products.

10 DISCLOSURE AND USE OF INFORMATION

The Agreement Regarding the Exchange of Confidential Information between Porex and Cerus, effective February 22, 2007, (the **"Confidentiality Agreement")** is attached hereto as **Exhibit G** and hereby incorporated by reference in their entirety herein and any exchange of information between Porex and Cerus pursuant hereto and this Supply Agreement shall be subject to the terms of such Confidentiality Agreement. Section 13 of the Confidentiality Agreement is hereby amended to provide that the end date of the period which covers the provision of Confidential Information by the parties has been extended to five (5) years following the termination of this Agreement. Cerus will insure that any and all Designees agree in writing to be bound by the Confidentiality Agreement and Cerus will be responsible for any and all breaches of the Confidentiality Agreement by Designees.

11 [OMITTED]

12 TERM; TERMINATION

12.1 This Supply Agreement will have a term (the "***Initial Term***") which commences on the Effective Date and continue through December 31, 2027. After the Initial Term, this Supply Agreement will automatically renew for an additional period of one (1) year (the "***Renewal Term***" and, together with the Initial Term, the "***Term***"), unless terminated in accordance with Section 12.2, 12.3, 12.4, or 12.5.

12.2 Cerus may terminate this Supply Agreement in its sole discretion at any time by giving Porex at least twelve (12) months' prior written notice of its intent to terminate this Supply Agreement.

12.3 In the event that Cerus' aggregate billable units fall below [*] units in any calendar year during the Term (unless such shortfall is due to regulatory or compliance issues or facility-driven production downtime), Porex may terminate this Supply Agreement in its sole discretion by giving Cerus at least twelve (12) months' prior written notice of its intent to terminate this Supply Agreement.

12.4 If a Party materially breaches this Supply Agreement and such breach remains uncured for a period of ninety (90) days after written notice containing details of the breach is

delivered to the breaching Party, then the non-breaching Party may terminate this Supply Agreement as to the breaching Party by further notice delivered no later than thirty (30) days after the expiration of the initial ninety (90) day cure period.

12.5 Each Party may terminate this Supply Agreement effective immediately with written notice in the event the other Party ("***Insolvent Party***") files for bankruptcy, is adjudicated bankrupt, takes advantage of applicable insolvency laws, makes an assignment for the benefit of creditors, is dissolved or has a receiver appointed for its property (which in the case of a receiver is not removed within thirty (30) days after notice to the Insolvent Party). Such termination is only effective as to the Insolvent Party.

12.6 The provisions of Sections 2.3, 2.4, 12.6, 4, 5 and 7 through 10 and 13 of this Supply Agreement shall survive termination of the Supply Agreement and remain in effect in accordance with their terms.

13 MISCELLANEOUS

13.1Entire Agreement

This Supply Agreement and the Confidentiality Agreement contain the entire agreement between the Parties relating to the Components and supersede all prior agreements and negotiations between Cerus and Porex. None of the terms of this Supply Agreement shall be deemed to be waived or amended by any Party unless such a waiver or amendment specifically references this Supply Agreement and is in writing signed by the Party to be bound.

13.2Notices

All notices and demands required or permitted to be given or made pursuant to this Supply Agreement shall be in writing and effective when personally given or when placed in an envelope and deposited in the United States mail postage prepaid and return receipt requested, or delivered by a recognized commercial courier service, addressed as follows:

If to Cerus:
Chief Executive Officer
Cerus Corporation
1220 Concord Ave
Concord, CA 94520
cc: Chief Legal Officer

If to Porex:
President
Porex Corporation
500 Bohannon Road
Fairburn, Georgia

Or to such other address as to which any Party may notify the other Parties.

13.3Assignment

This Supply Agreement shall be binding upon and inure to the benefit of the Parties, their successors and assigns. This Supply Agreement shall be assignable: (i) by either Party to an affiliate of the Party, in whole or in part, without the consent of the other Party, provided such affiliate is not a competitor of the other Party; (ii) by either Party with the written consent of the other Party, which consent shall not be unreasonably withheld or delayed (it being understood that withholding such consent on the basis of the assignee's financial and/or competitive status shall not be deemed to be unreasonable); or (iii) by any Party without the consent of the other Party to the purchaser of substantially all the assets of its business to which this Supply Agreement relates or to any corporate successor to a Party by merger, consolidation or otherwise. Any change of control of ownership of fifty (50) percent or more of any Party will be deemed an assignment under (iii) immediately above. For the purpose of this Section and Section 1.1.2, a "Porex competitor" shall mean those persons, entities or companies who sell competitive products that directly compete with Porex's products and a "Cerus competitor" shall mean those companies who sell competitive products to Products in the field of blood pathogen inactivation. Any attempted assignment that does not comply with the terms of this Section shall be void. Each Party shall cause this Supply Agreement to be assigned in whole to any business organization that purchases its operations supporting this Supply Agreement or to any corporate successor to a Party by merger, consolidation or otherwise. Despite any assignment under this Section, the Party making the assignment shall remain liable for its obligations as a Party to this Supply Agreement.

13.4Governing Law

This Supply Agreement is deemed to have been executed in and shall be governed by and construed in accordance with the Uniform Commercial Code as enacted in the State of New York and other applicable laws of the State of New York. The Parties hereby submit to the jurisdiction of the courts of that State for purposes of resolving any dispute. If particular portions of this Supply Agreement are ruled unenforceable, such portions shall be deleted and all other terms and conditions of this Supply Agreement shall remain in full force and effect. Except where a remedy is expressly stated to be the exclusive remedy, the rights and remedies of the Parties under this Agreement shall be cumulative and in addition to any other rights or remedies provided by law or equity.

13.5Independent Contractors; Relationship of Parties; Waiver; Proceedings

13.5.1 The relationship of the Parties under this Supply Agreement shall be and at all times one of independent contractors. No Party is an employee, agent or legal representative of any other Party or shall have any authority to assume or create obligations on any other Party's behalf.

13.5.2 Cerus shall have the right to revoke any designation as a Designee made pursuant to Section 1.1.2 of this Supply Agreement, by providing thirty (30) days prior written notice of such to Porex, and thereafter said Designee will no longer be authorized to purchase Components on Cerus's behalf or perform any other of the tasks described in Section 1.1.2.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

13.5.3 Nothing herein shall be construed as giving any third party, including Designee, any rights, interest or claims hereunder or be entitled to any benefits under or on account of this Supply Agreement as a third-party beneficiary or otherwise and the sole and intended beneficiaries of this Supply Agreement are Cerus and Porex.

13.5.4 Failure of any Party at any time to require performance by any other Party of its obligations under this Supply Agreement shall in no way affect the right to require such performance at any time thereafter. The waiver by any Party of a breach of any provision of this Supply Agreement shall not constitute a waiver of any succeeding breach of the same or any other provision.

13.5.5 If any Party files any action or brings any proceeding against the other Party arising out of this Supply Agreement, the prevailing Party in such action or proceeding shall be entitled to recover reasonable attorneys' fees to be fixed by the court sitting without a jury.

IN WITNESS WHEREOF, the Parties have executed this Supply Agreement in counterparts, effective as of the day and year first written above.

CERUS CORPORATION

By: /s/ Kevin D. Green

Name: Kevin D. Green
Title: Chief Financial Officer

POREX CORPORATION

By: /s/ Richard Walder

Name: Richard Walker

Title: VP Porex Americas

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Exhibit G

Confidentiality Agreement

AGREEMENT REGARDING THE EXCHANGE OF CONFIDENTIAL INFORMATION

In connection with the possible development, manufacture and sale of certain parts by POREX CORPORATION ("Porex") to CERUS CORPORATION ("Cerus") and, collectively with Porex, the "Parties" and each of Porex and Cerus may be referred to individually as a "Party"), Parties have determined that it is necessary and useful for the Parties to exchange Confidential Information belonging to each Party. Except as set forth below, Confidential Information of a Party shall include all information relating to such Party's (or an affiliate of such Party's) data, books, records, specifications, trade secrets, know-how, formulas, processes, manufacturing methods, techniques, raw materials, sources of supply, applications for particular technologies, vendor lists, customer lists, employee lists, management systems, financial information, pricing, sales and marketing plans, research and development, inventions, and such other documents and materials that are delivered or otherwise disclosed (including, without limitation, through facility tours) by such Party to the other Party, whether orally or in writing, and whether or not identified as confidential. Notwithstanding anything to the contrary herein, Confidential Information shall not include information (i) which is developed or discovered by a Party independent of and without the use of the Confidential Information, (ii) in the possession of both Parties prior to the date of this Agreement and there is competent evidence to establish such fact, (iii) established at any time to be in the public domain otherwise than by breach of this Agreement, or (iv) is required to be disclosed in compliance with any law, governmental regulation, or court order, provided the receiving Party shall notify the disclosing Party in advance of any such disclosure, if feasible, and will assist the disclosing Party in pursuing such non-disclosure or protective orders as may be available. For and in consideration of the mutual promises herein contained, the Parties agree as follows effective the 22 day of February 2007 (the "Effective Date"):

1. The receiving Party shall keep the Confidential Information secret and confidential and will not, without the prior written consent of the disclosing Party, use or disclose the Confidential Information for the term of this Agreement plus five (5) years, except that the confidentiality obligations with respect to any Confidential Information that constitutes a trade secret shall continue in effect for so long as the information remains a trade secret. The term "trade secret" as used in this Agreement shall mean Confidential Information that: (i) derives economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain secrecy. Without limiting any of the other provisions hereof, each Party agrees to use at least the same degree of care to avoid and prevent disclosure of the other Party's Confidential Information as it uses to prevent disclosure of its own Confidential Information, and in no event less than a reasonable standard of care.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

2. A receiving Party will restrict transmission of Confidential Information to those of its directors, officers, employees, agents and affiliates who are consulted concerning the discussions with the disclosing Party and who need to know Confidential Information for the purpose of facilitating those discussions, provided such individuals shall have been advised of the confidential nature of the Confidential Information and the obligations imposed under this Agreement. The receiving Party shall be responsible to the disclosing Party for any improper disclosure or use of the Confidential Information by such persons.

3. No right of title or interest in or to the Confidential Information or license, either expressed or implied, under any patent, trade secret or otherwise is granted hereunder.

4. All Confidential Information in tangible form received or delivered hereunder shall be returned within thirty (30) days after the request of the Party submitting it.

5. The Parties agree that they shall not assume or incur any financial liability merely by receipt of Confidential Information, and any financial, supply or other agreement between the Parties will be covered by subsequent agreement(s).

6. Each Party acknowledges and agrees that the misappropriation, unauthorized use or disclosure of the Confidential Information of the other Party or its affiliate would cause irreparable harm to the other Party. In the event of a breach of any part of this Agreement, the Party which has been damaged by the breach or such affiliate shall be entitled to relief by appropriate legal or equitable means, including but not limited to a temporary restraining order, temporary injunction and/or permanent injunctive relief, restraining and prohibiting the Party in breach from breaching or continuing to breach the terms of this Agreement. In addition, the Party damaged by the breach or such affiliate shall be entitled to the recovery of any and all damages incurred as a result of such breach, including cost of enforcement, reasonable attorney's fees and court costs.

7. This Agreement shall be binding upon and shall inure to the benefit of the Parties, their successors, assigns and affiliates, except that no assignment of any right to access the Confidential Information may be made by the receiving Party without the prior written consent of the disclosing Party. The waiver of any provision in any instance shall not be construed as a waiver in other instances.

8. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and with respect to the matters contained herein and supersedes all prior agreements or understandings. This Agreement shall not be modified except in writing signed by both Parties. Notwithstanding anything to the contrary herein, this Agreement shall not release either Party from any obligation to the other Party of confidentiality or non-use created pursuant to any prior agreement or understanding between the Parties, and each such obligation shall remain in full force and effect.

9. The Parties agree that this Agreement is for the purposes of protecting proprietary information only. This Agreement is not a joint venture or other such business arrangement; and any agreement between the Parties as to joint business activities will be set forth in subsequent written agreements.

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10. The Parties acknowledge that each of them (or an affiliate thereof) may be engaged now or in the future in a business similar to or competitive with that of the other, and that the terms of this agreement shall in no way restrict either Party from engaging in such business activities, except that each Party shall be bound by its agreements herein as they relate to Confidential Information.

11. Neither Party under this Agreement shall publicly announce or disclose the existence of this Agreement, or its contents, or any discussions relating thereto, without the prior consent of the other Party or except as may be required by law, in which case the Party required to make disclosure shall give the other Party the maximum feasible prior notice of such disclosure.

12. This Agreement shall be governed by the laws of the State of Georgia, which relate to contracts negotiated, executed and performed within such state, without regard to the conflict of laws provisions thereof, and only the courts sitting in such state shall have exclusive jurisdiction of the Parties for the purposes of adjudicating any disputes under this Agreement. The Parties hereby consent to personal jurisdiction and venue in the courts of the State of Georgia and hereby waive any claim or defense that the party lacks minimum contacts with the forum, that the courts of .the State of Georgia lack personal jurisdiction of the Parties, or that the courts of the State of Georgia are an improper or inconvenient venue. The Parties further agree that service of process may be accomplished by certified mail, return receipt.

13. This Agreement shall remain in force until the earlier of (i) five (5) years from the Effective Date and (ii) the cancellation of this Agreement by either Party by written notification to the other Party. No expiration, cancellation or termination of this Agreement for any reason will affect the validity and enforceability of the Confidentiality, non-disclosure and non-use provisions contained in Paragraphs 1 and 2 hereof.

The completed signatures of the Parties attest to their mutual agreement to the conditions of this Agreement.

CERUS CORPORATION
2411 Stanwell Drive
Concord, California 94520

By: /s/ Howard G. Ervin

Print Name: Howard G. Ervin

Title: Vice President, Legal Affairs

Date: February 22, 2007

POREX CORPORATION
500 Bohannon Road
Fairburn, Georgia 30213-2828

By: /s/ Victor L. Marrero

Print Name: Victor L. Marrero

Title: Executive Vice President & Chief Financial Officer

Date: February 22, 2007

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Exhibit 10.47

LICENSE AGREEMENT

This **LICENSE AGREEMENT** ("Agreement"), dated as of February 2, 2005 ("Effective Date"), is entered into by and between Baxter Healthcare S.A., a corporation organized under the laws of Switzerland ("BHSA"), Baxter Healthcare Corporation, a company organized under the laws of Delaware ("BHC") (BHSA and BHC are collectively referred to as "Baxter") and Cerus Corporation, a company organized under the laws of Delaware ("Cerus"). Baxter and Cerus, as corporations, are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, Baxter and Cerus have developed technology for the inactivation of pathogens in blood and blood components (the "INTERCEPT Blood System").

WHEREAS, BHC and Cerus are parties to a Development, Manufacturing and Marketing Agreement, dated as of December 10, 1993, as amended to the date hereof (the "Platelet Agreement") relating to products referred to herein as the "Platelet System", and to a Development, Manufacturing and Marketing Agreement, dated April 1, 1996, as amended and restated June 30, 1998, as further amended to the date hereof, (the "RBC/FFP Agreement") relating to products referred to herein as the "Plasma System" and the "RBC System";

WHEREAS, Baxter, owns or has rights in certain proprietary Licensed Materials, Licensed Patents and Licensed Know-How (all as hereafter defined) relating to the INTERCEPT Blood System.

WHEREAS, contemporaneously with the effectiveness of this License Agreement, the Parties are entering into a Restructuring Agreement (the "Restructuring Agreement") and other "Concurrent Agreements" (as defined therein) including a Manufacturing and Supply Agreement (the "Manufacturing and Supply Agreement") whereby Baxter will manufacture and supply finished goods, sub-assemblies, components and raw materials for the production of the INTERCEPT Blood System and related products on the terms and conditions set forth in that agreement.

WHEREAS, the Parties have previously entered into a Commercialization Agreement and related agreements with BioOne Corporation ("BioOne") whereby rights and obligations to commercialize the INTERCEPT Blood System for Platelets and the Intersol Solution (as defined herein) in certain countries of Asia were transferred to BioOne, on the terms and conditions set forth in those agreements.

NOW, THEREFORE, in consideration of the premises and the covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows.

Article 1

Definitions

In this Agreement, the following terms have the meanings specified or referred to in this Article 1 and shall be equally applicable to both the singular and plural forms. The words “including”, “includes” and “include” shall be deemed to be followed by the phrase “without limitation”, unless the context clearly dictates otherwise. Any agreement, schedule, attachment or exhibit referred to herein shall mean such agreement, schedule, attachment or exhibit as amended, restated, supplemented or modified from time to time to the extent permitted by the applicable provisions of this Agreement. Reference to any statute or regulation means such statute or regulation as amended at the time and from time to time and includes any successor statute or regulation. The definitions of Conversion Kit, INTERCEPT Illuminator, Intersol Solution, Plasma Sets, Plasma Systems, Platelet Sets, Platelet Systems, RBC Equipment, RBC Sets, RBC Systems, Residual Products, Storage Solution Containers and Systems include all improvements and modifications to current and future products developed, produced, marketed or sold to accomplish a similar purpose to the defined items. Unless otherwise stated, references to recitals, articles, sections, paragraphs, schedules and exhibits shall be references to recitals, articles, sections, paragraphs, schedules and exhibits of this Agreement.

“Affiliate” means, with respect to any Person, at the time in question, any other Person controlling, controlled by or under common control with such Person. For purposes of this definition, “control” shall mean (a) in the case of corporate entities, direct or indirect ownership of any of the stock or shares having the right to vote for the election of a majority of directors, (b) in the case of non-corporate entities, direct or indirect ownership of any of the equity interest with the power to direct the management and policies of such non-corporate entities.

“Assigned Patents” means those Patents assigned to Cerus under a Patent Assignment entered into between the Parties pursuant to Section 2.6 of this Agreement.

“BioOne Territory” means the following countries: Japan, China (including all Special Administrative Regions), Taiwan, South Korea, Thailand, Vietnam and Singapore, except as rights to any such countries shall revert to Baxter and Cerus from BioOne Corporation.

“Commercialization Rights” means, as to a particular country or region, (a) as to Baxter, the right and responsibility to market, distribute and sell the Platelet System pursuant to the Platelet Agreement, and the Plasma System pursuant to the RBC/FFP Agreement (and as further provided under the Restructuring Agreement), in that country or region; or (b) as to Cerus, all rights of Cerus under the Restructuring Agreement and Concurrent Agreements upon termination of Baxter’s Commercialization rights in that country or region. For the purposes of this agreement, references to termination of Baxter Commercialization Rights, or to Cerus gaining Commercialization Rights, in a particular country or region means that licenses and related rights have been released and relinquished to Cerus pursuant to Section 4 of the Restructuring Agreement, under the Platelet Agreement or the RBC/FFP Agreement as the case may be.

"Conversion Kit" means a disposable set having Intersol Solution which permits the preparation of single donor platelets collected on a non-Baxter apheresis collection platform to interface with the Platelet System.

"ESOL Solution" means a proprietary red blood cell storage solution, also known as erythrosol in all formulations thereof.

"Field of Use" means (a) the inactivation or reduction of pathogens for the decontamination of all blood cells and blood components, including inactivation of pathogens in whole blood, and (b) the inactivation of leukocytes or reduction of leukocyte activity through nucleic acid binding.

"INTERCEPT Illuminator" means a proprietary illumination device, including operating software and data management system including source code for each, developed for use with Platelet Sets and Plasma Sets.

"Intersol Solution" means a proprietary platelet storage solution currently sold under the trademark "Intersol" in all formulations thereof.

"Licensed Know-How" means all information necessary to manufacture and packaging of the Products.

"Licensed Materials" means all designs, specifications, know-how, regulatory data, software used in connection with the Products, including the data management system (IDMS) and source code of such software (including source code used to maintain and upgrade the software), owned by or licensed to Baxter that are required to manufacture, obtain regulatory approval, market and sell the Products, including all Product Specifications, all advertising, educational and promotional materials for the INTERCEPT Blood System, in each case as the same may be updated or otherwise amended from time to time.

"Licensed Patents" means all Patents owned or licensed by Baxter during the Term, including any patents acquired after the Effective Date, that absent a license would prohibit a Person from making, having made, assembling, packaging, using, selling, offering for sale, distributing, importing and exporting the Products in the Territory, including expressly, but without limitation, the Patents set forth in Exhibit A. With respect to Patents jointly owned by Baxter and Cerus, "Licensed Patents" refers to Baxter's interest in such Patents. Without limiting the foregoing, "Licensed Patents" includes all Patents on inventions embodied in or useful to manufacture Products, or constituting methods of use relating to Products, as the Products, prototypes and designs have been developed by the Parties pursuant to the Platelet Agreement and the RBC/FFP Agreement, and as they may be further developed or modified during the Term, not limited to development under such agreements. Notwithstanding the foregoing, Licensed Patents excludes the rights and licenses expressly excluded in Section 2.4 hereof.

"Net Sales" means the gross amount invoiced by Cerus, Affiliates or sublicensees (if applicable to a sublicense pursuant to Section 5.1(b), 5.2(b), 5.3(b) or 5.4(b)) upon the first sale of a Royalty- Bearing Product under the Licensed Patents to a third party who is not Cerus' Affiliate, less the following to the extent not already reflected in the invoice price: (i) actual credits from customers and/or resellers for damaged, out-dated, rejected or returned Product; (b) actual freight and insurance costs incurred in transporting Products to customers; and, (c) actual sales taxes and taxes or governmental charges incurred in connection with the exportation or importation of the

Products. If Cerus has reduced the price of the Products as a result of other consideration paid by the purchaser of the Products, then Net Sales shall be increased to reflect the amount that Cerus would have received for the sale for such Products absent such consideration.

"Patent" means any patent or patent application issued or filed in the Territory, including any continuation, continuation-in-part, re-examination, patent by addition, inventor's certification, Supplemental Protection Certificate, patent term extension, division, provisional, renewal, reissue, patent disclosure, substitution, and any related improvement.

"Person" means an individual, corporation, limited liability company, partnership, sole proprietorship, joint venture, or other form of organization or governmental agency or authority.

"Plasma Products" means Plasma Systems.

"Plasma Sets" means disposable processing sets, including without limitation, single unit and jumbo configurations, for inactivation of pathogens in plasma components of blood, containing the raw material amotosalen ("S-59") or other psoralen compounds.

"Plasma System" means Plasma Sets and INTERCEPT Illuminators.

"Plasma Territory" means those countries or regions in which Cerus gains Commercialization Rights for the Plasma System pursuant to the Restructuring Agreement.

"Platelet Product" means Platelet Systems, Conversion Kits and Storage Solution Containers.

"Platelet Sets" means disposable processing sets for the inactivation of pathogens in platelet components of blood, containing the raw material amotosalen ("S-59") or other psoralen compounds.

"Platelet Systems" means the Platelet Sets and INTERCEPT Illuminators.

"Platelet Territory" means those countries or regions in which Cerus gains Commercialization Rights for the Platelet System pursuant to the Restructuring Agreement.

"Products" means Platelet Products, Plasma Products, RBC Products and Residual Products.

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"Product Specifications" has the meaning set forth in the Manufacturing and Supply Agreement, as may be revised by Baxter and Cerus thereunder, from time to time.

"RBC Equipment" means dosing and mixing devices and incubator and compound removal devices for use in connection with RBC Sets.

"RBC Products" means RBC Systems, ESOL Solution and Storage Solution Containers.

"RBC Sets" means disposable processing sets for inactivation of pathogens in the red blood cell components of blood, containing the raw material S-303 or other nucleic acid-binding compound.

"RBC System" means RBC Sets and RBC Equipment.

"RBC Territory" means all parts of the world.

"Residual Products" means any products within the Field of Use that are not included within the definition of Platelet Products, the Plasma Products or RBC Products.

"Residual Product Territory" means all parts of the world.

"Royalty-Bearing Products" means Products covered by the Licensed Patents or the Assigned Patents, without which Cerus would be prohibited from making, having made, assembling, using, selling, offering for sale, distributing, importing and exporting the Products in the Territory.

"Royalty Period" for each Product is defined in Section 6.3 hereof.

"Storage Solution Containers" means containers for blood component storage solution and methods and devices for connecting or integrating such containers into blood component pooling sets and blood component collection kits or other components for interface with a System.

"Systems" means the Platelet Systems, the Plasma Systems and the RBC Systems.

"Territory" means (a) as to Platelet Products, the Platelet Territory, (b) as to Plasma Products, the Plasma Territory, (c) as to RBC Products, the RBC Territory and (d) as to Residual Products, the Residual Territory, in each case as such Territory shall accrete from time to time as to particular Products pursuant to the Restructuring Agreement.

"Transition Services Agreement" means the Transition Services Agreement entered into concurrently with this Agreement whereby Baxter will provide certain transition services to Cerus following Termination, as such term is defined in the Restructuring Agreement.

Article 2

License Grant; Process for Assigned Patents

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE CERUS CORPORATION HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO CERUS CORPORATION IF PUBLICLY DISCLOSED.

2.1 License Grant. Subject to the terms and conditions of this Agreement, Baxter hereby grants to Cerus and its Affiliates, solely in the Field of Use:

(a) an exclusive (even as to Baxter) royalty-bearing right and license under the Licensed Patents and Licensed Know-How to make, have made, assemble, use, sell, offer for sale, distribute, import and export:

(i) Platelet Products solely for sale in the Platelet Territory;

(ii) Plasma Products solely for sale in the Plasma Territory;

(iii) RBC Products solely for sale in the RBC Territory; and

(iv) Residual Products solely for sale in the Residual Territory; and

(b) a nonexclusive, royalty-bearing right and license to use, reproduce, display, translate, distribute copies of, and to modify and create derivative works of the Licensed Materials within the respective parts of the Territory set forth in Clause 2.1(a).

This license will be registered with authorities in the Territory, to the extent such registrations are permitted. Cerus shall bear the costs and responsibility of registering the license. From time to time during the term of this Agreement, Baxter agrees to execute and deliver to Cerus such documents as requested by Cerus or any authority in the Territory in order to effectively register the grant of the rights hereunder to Cerus.

2.2 Right to Sublicense. Pursuant to the license rights granted to Cerus in Article 2, Baxter also grants to Cerus the right to sublicense its rights under Section 2.1 to third parties, solely to make, have made, assemble, use, sell, offer for sale, distribute, import and export the Products, and to use, reproduce, display, translate, distribute copies of, and to modify and create derivative works of the Licensed Materials, in the respective parts of the Territory set forth in clause 2.1(a) under the Licensed Patents, Licensed Know-How and Licensed Materials as necessary to allow the sublicensee to exercise the sublicense granted herein. Any sublicense shall be at least as protective of Baxter and its intellectual property, including the Licensed Patents, Licensed Know-How and the Licensed Materials, as the terms and conditions of this Agreement.

2.3 Reservation of Rights. Notwithstanding anything to the contrary set forth herein, Baxter shall retain all the rights necessary for Baxter to perform its obligations under (a) the Manufacturing and Supply Agreement, including the rights to manufacture, sell and supply the Manufactured Products (as defined therein) to Cerus under the terms and conditions of that agreement and (b) the Manufacturing and Supply Agreement with BioOne, dated as of June 28, 2004 (the “BioOne Manufacturing Agreement”), including the rights to manufacture, sell and supply the Manufactured Products (as defined therein) to BioOne under the terms and conditions of that agreement. All rights in and to the Licensed Materials and the Licensed Patents not specifically granted herein are reserved by Baxter. The license granted to Licensed Materials does not restrict any rights previously

granted by Baxter to **[*]** under the **[*]** entered into as of **[*]**, as amended effective **[*]**, to **[*]** under the Supply Agreement entered into as of **[*]**, and to **[*]**. under the Supply Agreement entered into as of **[*]**. Baxter has provided Cerus with true and correct copies of each such agreement and all amendments, modifications thereto to the date of this Agreement. Nothing herein shall restrict or prohibit Baxter from manufacturing, having manufactured, assembling, using, selling, offering for sale or distributing the Products or otherwise utilizing the Licensed Patents and Licensed Materials with respect to particular Products outside of the Territory that relates to such Products. Baxter retains the exclusive right to manufacture its platelet collection disposable kits with INTERSOL solution containers for sale in the Territory.

2.4 Exclusion of Rights. Baxter does not grant to Cerus and its Affiliates the right or license to make or have made (a) Baxter's proprietary **[*]**, (b) Baxter's proprietary technology relating to **[*]**, (c) Baxter's **[*]**. The availability and access of these items to and by Cerus as well as other sub-assemblies, components, and raw materials of the Products are provided for in the Manufacturing and Supply Agreement. It is understood that, as to amotosalen ("S-59") and S-303, Cerus is the owner of the proprietary rights in such compounds and, pursuant to the Restructuring Agreement, Baxter has relinquished its license in such compounds in the Territory. Accordingly, no license to those compounds is granted under this Agreement. The license hereunder shall not cover any Patent rights to make, have made, assemble, use, sell, offer for sale, distribute, import or export **[*]**, except as provided below, it being understood and agreed that, as co-owner of the Patents respecting **[*]**, Cerus has the right independently to exercise such rights, and grant licenses thereto, without accounting to Baxter otherwise than as provided herein. Cerus, however, agrees not to provide **[*]** to customers, or license it to any Person for use by customers, unless Baxter at any time ceases to make available to customers generally, or fails to provide reasonable assurances to Cerus of its commitment to continue to make available to customers generally, **[*]**. In such event, as to **[*]**, Cerus' shall gain the license rights stated in Section 2.1(a) as if Intersol Solution were expressly referenced in such Section. Baxter agrees not to license Patent Rights or Know-How relating to the **[*]** to any third Persons without Cerus' prior written consent. As to the compound adsorption devices (CADs) employed in the Systems, Cerus acknowledges that the proprietary rights in certain elements of the CADs, such as the beads and matrix, are owned by third Persons. Accordingly, no license to those elements is granted under this Agreement. The license under this Agreement does, however, cover any elements of the CADs that are proprietary to Baxter, including the plastic housing of the CAD for the Plasma System. Cerus and its Affiliates shall have the right to contract directly with Baxter's suppliers in the event Baxter cannot supply all requirements of Cerus, its Affiliates and sublicensees for CADs or other components, or in the event that Cerus elects to have such CADs or other components manufactured directly for Cerus by the third-party supplier in order to achieve a lower cost or superior quality that can be obtained through Baxter.

2.5 Process for Assigned Patents. It is understood that Baxter has concluded that the Licensed Patents potential have applications outside the Field of Use, and accordingly is licensing, rather

than assigning, those patents to Cerus. Should Baxter subsequently determine that any of such patents have application solely within the Field of Use, Baxter may elect to assign such patents to Cerus, subject to Cerus' acceptance of such assignment, which will not be unreasonably withheld. Any patents so assigned are referred to in this Agreement as "Assigned Patents." Any such assignment will be made pursuant to a mutually agreed upon patent assignment agreement, referred to in this Agreement as a "Patent Assignment."

Article 3

Delivery of Licensed Materials; Licensed Patents Prosecution and Maintenance

3.1 Delivery. Within **[*]** days of the execution of this Agreement, Baxter shall deliver to Cerus a current copy of the Licensed Patents. Within **[*]** days of the execution of this Agreement, Baxter shall deliver to Cerus a current copy of the Licensed Materials in such form and format as the Parties may agree. Baxter will provide Cerus with any updates and other amendments of the Licensed Materials promptly, and in no event later than **[*]** days, after their creation. Within **[*]** days of the execution of this Agreement, Baxter shall deliver to Cerus all prototypes, models, mock-ups of the RBC Equipment and RBC Sets, and single unit CAD for the Plasma System, in all configurations in Baxter's possession and component lists therefor.

3.2 Obtaining Issued Licensed Patents. Baxter shall continue to prosecute and pay all fees, expenses and taxes necessary to obtain issued Licensed Patents for those that are pending or may be filed in the future but have yet to issue in the Territory. Exhibit A shall be updated by Baxter from time to time to indicate the status of such filings. Baxter will provide Cerus with documentation covering prosecution decisions relating to pending applications for Licensed Patents prior to submission with appropriate patent office or examiner. Cerus may comment on such decisions within **[*]** days of receipt of such documentation. Baxter will take Cerus' comments into consideration, but Cerus' approval of such decision is not required for Baxter to continue with the prosecution of the subject pending application.

3.3 Maintaining Licensed Patents. Baxter shall maintain at its expense issued Licensed Patents in the Territory. Baxter shall provide Cerus all documentation relating to the prosecution and maintenance of all Licensed Patents. If a Licensed Patent becomes an Assigned Patent, Baxter will cease to have any obligation to maintain such patent.

3.4 Ownership.

(a) Baxter shall own all right, title and interest, or joint title and interest together with Cerus, as applicable, in and to: (i) the Licensed Materials and the Licensed Patents, and all future inventions and discoveries that are discovered, made, conceived or reduced to practice solely by Baxter (and joint rights to any of the same it jointly makes, conceives or reduces to practice), and

any derivative works of Baxter thereof; and (ii) all of its Confidential Information (as defined in Section 4.1).

(b) Cerus shall own all right, title and interest in and to, (i) all future inventions and discoveries that are discovered, made, conceived or reduced to practice solely by Cerus, including those which are improvements of the Licensed Patents and works which are derivative works of the Licensed Materials (and joint rights to any of the same it jointly makes, conceives or reduces to practice); and (ii) all of its Confidential Information (as defined in Section 4.1).

3.5 Cooperation. Each Party shall execute any documents of registration of proprietary or other rights reasonably requested by another Party and shall perform any and all further acts deemed necessary or desirable by a Party in order to confirm, exploit or enforce the provisions of this Article. If a Party fails to do so within **[*]** days of another Party's reasonable request, and the Party failing to execute such document does not promptly object (within such time period) to the execution of other documentation, such Party hereby authorizes the other Party and its agents and/or representatives to execute all such documents in such Party's name and on such Party's behalf, including filing and/or recording such documents in appropriate governmental or administrative offices anywhere throughout the Territory.

Article 4

Confidentiality

4.1 Confidential Information. All information and materials containing information provided by any Party to another relating to this Agreement, including but not limited to customer requirements, lists, preferences and methods of operation, the technology, any know-how, data, process, or technique of any Party relating to such Party's products, and any research project, work in process, future development, scientific, engineering, or manufacturing information, know-how, designs, drawings, management information reports and other computer-generated reports, financial information, pricing policies and details, details of contracts, operational methods, plans or strategies, business acquisition plans, and the business affairs of such Party, whether in oral, graphic or written form, as the case may be, are and shall be treated as confidential, provided such information and materials are clearly marked as "confidential" and, if verbal, are specified as "confidential" at the time of disclosure and reduced to writing and marked "confidential" within [*] days after disclosure ("Confidential Information"). Among other things, Confidential Information shall include confidential or proprietary information or materials of third Persons and the Parties' respective Affiliates, that are in the possession of one of the Parties and provided pursuant to this Agreement. It is understood and agreed that the Systems have been co-developed by Cerus, which may disclose or use information concerning the Systems as it deems appropriate in the exercise of its rights under this Agreement; provided that information concerning Baxter's proprietary plastics formulations and radio frequency heat sealing processes shall remain the Confidential Information of Baxter.

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4.2 Obligations. Except as expressly authorized by prior written consent of the disclosing Party, the receiving Party shall:

(a) limit access to any Confidential Information of the disclosing Party received by it to its Affiliates', sublicensees' and distributors' employees, agents, representatives, and consultants who have a need-to-know in connection with this Agreement and the rights and obligations of the Parties hereunder, and who are under appropriate non-use and non-disclosure restrictions which are at least as restrictive as those set forth herein;

(b) safeguard all Confidential Information of the disclosing Party received using a reasonable degree of care, but not less than that degree of care used by the receiving Party in safeguarding its own similar information or material; and

(c) use the Confidential Information of the disclosing Party only for the purposes and in connection with the performance of such Party's obligations set forth in this Agreement.

4.3 Exceptions to Confidentiality. Notwithstanding Section 4.2, the Parties' obligations of confidentiality and non-use shall not apply to any particular information or materials that the receiving Party can demonstrate:

(a) was, at the time of disclosure to it, in the public domain;

(b) after disclosure to it, is published or otherwise becomes part of the public domain through no fault of the receiving Party;

(c) was received after disclosure to it from a third party who had a lawful right to disclose such information or materials to it;

(d) was required to be disclosed to any regulatory body having jurisdiction over the receiving Party or any of its respective Affiliates, sublicensees or customers;

(e) that disclosure is necessary by reason of applicable legal, accounting or regulatory requirements beyond the reasonable control of the receiving Party; or

(f) is subsequently developed by the receiving Party independently of the information received from the disclosing Party.

In the case of any disclosure pursuant to Sections 4.3(d) or 4.3(e), to the extent practical, the receiving Party shall notify the disclosing Party in advance of the required disclosure and shall use commercially reasonable efforts to assist the disclosing Party in obtaining a protective order, if available, covering such disclosure. If such a protective order is obtained, such information and materials shall continue to be deemed to be Confidential Information.

Notwithstanding Section 4.2, Cerus shall have the right to disclose Confidential Information of a disclosing Party to its attorneys, accountants, actual or potential sources of financing, and actual

or potential investors, acquirers or collaborators under appropriate non-use and non-disclosure restrictions which are at least as restrictive as those set forth herein.

4.4 Use of Certain Information. Except as otherwise set forth in this Agreement or the Manufacturing and Supply Agreement, no Party shall, without the appropriate Party's prior written consent, use the names, service marks or trademarks of another Party as trademarks or to suggest any affiliation, sponsorship, endorsement or recommendation. All employees, agents, representatives and consultants of each Party and Licensee's Affiliates and sublicensees shall be required to comply with the terms of this Section 5, and each Party, as applicable, shall be responsible for any breach thereof and the performance or non-performance of each such Person.

4.5 No Publicity. Except as required by law, no Party shall originate any news release or other public announcement relating to this Agreement or the terms hereof without the prior written approval of the other Parties; provided, however that any party to this Agreement may provide public information concerning this transaction to the extent necessary or appropriate to comply with applicable securities laws and/or customary corporate communications processes.

4.6 Equitable Remedies. Each Party acknowledges that if it, its Affiliates or its respective employees, agents, representatives, or consultants breach (or attempt to breach) the obligations set forth in this Section 4, the other Parties will suffer immediate and irreparable harm, it being acknowledged that legal remedies are inadequate. Accordingly, if a court of competent jurisdiction should find that any such Party or Person has breached (or attempted to breach) any such obligations, such Party or Person shall not oppose the entry of an appropriate order compelling performance by such Party or Person and restraining it from any further breaches (or attempted breaches).

Article 5

Royalties

5.1 Royalties for Platelet Products.

(a) For all Platelet Products sold by Cerus or Cerus' Affiliates, Cerus shall pay to Baxter ten percent (10%) of Net Sales of such Platelet Products.

(b) For all Platelet Products sold by a Cerus sublicensee (other than a Cerus Affiliate), Cerus shall pay to Baxter **[*]** percent (**[*]**%) of the **[*]** received by Cerus from the sublicensee. Such payment shall be in lieu of the royalty payable under Section 5.1(a).

5.2 Royalties for Plasma Products.

(a) For all Plasma Products sold by Cerus or Cerus' Affiliates, Cerus shall pay to Baxter three percent (3%) of Net Sales of such Plasma Products.

(b) For all Plasma Products sold by a Cerus sublicensee (other than a Cerus Affiliate), Cerus shall pay to Baxter **[*]** percent (**[*]**%) of the **[*]** received by Cerus from the sublicensee. Such payment shall be in lieu of the royalty payable under Section 5.2(a).

5.3 Royalties for RBC products.

(a) For all RBC Products sold by Cerus or Cerus' Affiliates, Cerus shall pay to Baxter five percent (5%) of the Net Sales of such RBC Products.

(b) For all RBC Products sold by a Cerus sublicensee (other than a Cerus Affiliate), Cerus shall pay to Baxter **[*]** percent (**[*]**%) of the **[*]** received by Cerus from the sublicensee. Such payment shall be in lieu of the royalty payable under Section 5.3(a).

5.4 Royalties for Residual Products.

(a) For all Residual Products sold by Cerus, Cerus' Affiliates or sublicensees, Cerus shall pay to Baxter (i) **[*]** percent (**[*]**%) of the **[*]** of any Residual Products that are systems for inactivation of pathogens in whole blood, and (ii) **[*]** percent (**[*]**%) of the **[*]** of any other Residual Products.

(b) For all Residual Products sold by a Cerus sublicensee (other than a Cerus Affiliate), Cerus shall pay to Baxter (i) **[*]** percent (**[*]**%) of the **[*]** received by Cerus from the sublicensee on sales of systems for inactivation of pathogens in whole blood, and (ii) **[*]** percent (**[*]**%) of the **[*]** received by Cerus from the sublicensee on sales of other Residual Products. Such payment shall be in lieu of the royalty payable under Section 5.3(a).

(c) For the purpose of clarity, a system for the inactivation of pathogens in whole blood will bear only the royalty set forth in this Section 5.4, and not any royalty under Sections 5.1 through 5.3 above.

5.5 Country Restrictions.

(a) The Parties recognize that in certain countries Cerus may have the royalty rate or Cerus' ability to withdraw currency from the country limited by the government in the context of a foreign exchange registration or other agreement with the government. If such restrictions prohibit Cerus from paying the above-described royalties, then the Parties will discuss other terms and conditions to reach an agreement that fairly provides compensation to Baxter, and to the extent permitted and financially practical, such as payment in local currency.

(b) The Parties also recognize that in certain countries within the Territory Cerus may take an ownership position in an entity, e.g. Cerus' Affiliate, in order to make, sell or distribute the Products in the country and in compliance with such country's regulations. If Cerus receives compensation or equity in the entity in place of royalty payments, then the Parties will discuss

other terms and conditions to reach an agreement that fairly provides compensation to Baxter and Cerus in an amount equivalent to the above-described royalties.

5.6 Up-Front and Milestone Payments. For the avoidance of doubt, in the event that Cerus receives any up-front, milestone, license fee or similar payments (collectively "Lump Sum Payments") from any sublicensee, collaborator or partner in connection with the granting of any development, marketing, distribution or other rights under this Agreement, Cerus **[*]**. Notwithstanding the foregoing, in the event that (a) rights revert from BioOne to Baxter and Cerus in Japan and/or China as to the Platelet System, and (b) within **[*]** months of the date of such reversion, Cerus enters into a license agreement with a third party for commercialization of the Platelet System in Japan or China, as the case may be, then Cerus shall pay to Baxter **[*]** of any lump sum Payments that are received by Cerus from the third party for such license and that relate to such countries. Lump sum payments shall not be considered to include any funds paid to Cerus specifically for development or support activities relating to commercialization of the Platelet System or any equity investment in Cerus.

5.7 Waiver of Royalties During Term of Transition Services Agreement. Notwithstanding the other provisions of Article 5, Baxter waives any royalties that would otherwise be payable by Cerus with respect to Products that are covered by the Transition Services Agreement during the term of that agreement.

5.8 Concerning Platelet System and Plasma System Sublicenses. In the event that Cerus intends to sublicense rights to both the Platelet System and the Plasma System to a third party, Cerus will not enter into a sublicense agreement that provides for **[*]**, unless Baxter consents in writing to such **[*]**, such consent not to be unreasonably withheld.

5.9 Concerning Certain Transactions. In the event that Cerus enters into a transaction with a third party that provides for **[*]**, and the same transaction **[*]**, or **[*]** the **[*]** for **[*]** at a **[*]** (and **[*]**), Baxter and Cerus will negotiate a **[*]** between Cerus and Baxter that is **[*]** they would have received if the third party agreement had provided for **[*]**, all such calculations to take into account appropriate discount rates to adjust for risk and the time value of money. In no event, however, will Baxter's **[*]**stated in Sections 5.1(b), 5.2(b), 5.3(b) or 5.4(b), relative to the respective Products described in such Sections. If the Parties cannot agree upon appropriate sharing in any such instance, the matter will be resolved pursuant to Section 10.12 hereof.

5.10 Royalty-Bearing Products. Notwithstanding Sections 5.1 through Section 5.4, the royalties upon Platelet Products, Plasma Products, RBC Products and Residual Products shall be applicable to such Products solely to the extent that they are Royalty-Bearing Products.

Article 6

Royalty Reports and Payments

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE CERUS CORPORATION HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO CERUS CORPORATION IF PUBLICLY DISCLOSED.

6.1 Reports. Within **[*]** days after the end of each calendar quarter, Cerus agrees to make written reports to Baxter identifying Cerus' actual Net Sales of Products during such calendar quarter and the amount of royalties due to Baxter. In each such report sales will be broken down in terms of Platelet Products, Plasma Products, RBC Products, and Residual Products.

6.2 Payment of Royalties. Within **[*]** days after calendar quarter end, Cerus shall pay to Baxter the royalties due for the Net Sales of the Products in U.S. dollars. Only one royalty payment is due and payable to Baxter by Cerus as described herein with regard to each Product sold regardless of the number of Licensed Patents covering such Product.

6.3 Expiration of Royalty Payment Obligation. Determined for each individual country within the Territory, the period of time over which Cerus shall report and pay royalties is **[*]** years from the date **[*]** in the relevant country or until **[*]** in the relevant country whichever period is longer (the "Royalty Period"). For any Products manufactured by Cerus prior to the expiration of the applicable Royalty Period and sold by Cerus within **[*]** months after the expiration of such Royalty Period, Cerus shall pay to Baxter the applicable royalty amount set forth in Article 5 and subject to Section 5.5.

6.4 Currency. All payments due hereunder shall be made in U.S. Dollars as described above. Pricing for the Products will be presented in local currency and converted into U.S. dollars during the Royalty Period being reported subject to Section 6.3 hereof. The conversion rate to U.S. dollars shall be the average conversion rate over all days of the Royalty Period reported, as quoted in the Wall Street Journal.

6.5 Late Payment. Failure by Cerus, Cerus' Affiliates or sublicensees to pay any undisputed amounts when due shall result in the accrual of interest on the remaining unpaid balance at a rate equal to the lesser of **[*]** percent (**[*]**%) per month or the **[*]**.

6.6 Withholding Taxes. Where required to do so by applicable law, Cerus shall withhold taxes required to be paid to a taxing authority on account of any payments to Baxter hereunder, and Cerus shall furnish Baxter with satisfactory evidence of such withholding and payment in order to permit Baxter to obtain a tax credit or other relief as may be available under the applicable law. Cerus shall be responsible for penalties and interest accessed for late payment or failure to withhold.

6.7 Audit. For a period of **[*]** years after sales of any Products by Cerus in the Territory (the "Audit Period"), Cerus agrees to keep records of all such sales of such Product in sufficient detail to enable the royalties payable hereunder to be determined. From time to time during such Audit Period, Baxter may at its own expense cause an independent third party auditor reasonably acceptable to Cerus to audit Cerus' relevant books and records for the purpose of determining compliance with this Agreement.

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In the event that an audit is proposed with respect to Cerus' proprietary information ("Restricted Information"), then on the written demand of Cerus the individuals conducting the audit with respect to the Restricted Information will be limited to Baxter's independent auditors. Such independent auditors shall enter into an agreement with Cerus, under which such independent auditors shall agree to maintain the confidentiality of the information obtained during the course of such audit and establishing what information such auditors will be permitted to disclose in reporting the results of any audit of Restricted Information.

Any such audit shall be conducted during regular business hours in a manner that does not interfere unreasonably with the operations of Cerus. The aggregate number of audits of Cerus' books and records conducted under this Section 6.7 shall not exceed **[*]** financial audit in any **[*]** month period. Subject to the foregoing limitations, any such audit shall be conducted when requested by notice given not less than **[*]** days prior to the commencement of the audit.

Any overpayment or underpayment of royalties determined by this Section 6.7 shall be due and payable to the other party by the party owing such amount within **[*]** days after notice of such audit finding. In the event that any audit performed hereunder results in an increase of **[*]** percent (**[*]**%) or more in any payment due Baxter hereunder, Cerus shall be obligated to pay any reasonable expenses incurred by Baxter with respect to such audit.

Article 7

Enforcement of Intellectual Property Rights; Insurance

7.1 Enforcement of Intellectual Property Rights. Each Party shall promptly, but in no event later than **[*]** days after receipt of notice thereof, notify the other Parties (i) of any Patent nullity actions, oppositions, reexaminations, declaratory judgment actions of which it is aware alleging the invalidity or unenforceability of any Patents included in the Licensed Patents or any alleged or threatened infringement of any Patents included in the Licensed Patents or the misappropriation or violation of any intellectual property rights relating to the Licensed Materials or the Licensed Patents; or (ii) if it reasonably believes that the Licensed Materials or Licensed Patents are being infringed, misappropriated or violated by a third party.

Each Party shall cooperate with the other Parties, at its own reasonable expense, in any action taken by a third party involving a nullity action, opposition, reexamination or any other action taken by such third party alleging the invalidity or unenforceability of any Licensed Materials or Licensed Patents.

Cerus, at its expense, shall have the right to respond to, defend or prosecute, and pursue, as appropriate and as determined by Cerus in its commercially reasonable discretion, any actions taken to defend any alleged or threatened infringements, misappropriations or any other violation by a third party of the Licensed Materials and/or Licensed Patents in the Territory provided such violations are not caused by Baxter, or Baxter's Affiliates or sublicensees. In addition, Cerus, at its

expense, shall have the right to pursue, as determined by Cerus in its commercially reasonable discretion, all necessary actions against any third party that Cerus reasonably believes is infringing, misappropriating or violating any of the Licensed Materials and/or Licensed Patents in the Territory. Cerus shall: (i) have the sole ability to direct the conduct of such response or defense; (ii) bear all legal fees and other costs and expenses associated with such response or defense, including those incurred by Baxter at Cerus' request; and (iii) after payment of all expenses (including prosecution and maintenance of the Licensed Patents, litigation associated expenses including attorney fees, travel expenses), pay royalties to Baxter on all amounts recovered from third parties in connection with such response or defense, treating such recoveries as Net Sales allocable to the particular Product as to which the infringement occurred. Baxter shall cooperate with Cerus and its legal counsel, join in suits or actions that may be brought by Cerus, at Cerus' reasonable request, allow itself to be named as a party, at Cerus' reasonable request, and be available at Cerus' reasonable request to be an expert witness or otherwise to assist in such proceedings.

In the event Cerus decides not to respond to, defend or prosecute, and pursue any actions taken to defend any alleged or threatened infringements, misappropriations or any other violations by a third party of the Licensed Materials and/or Licensed Patents in the Territory then Cerus will notify Baxter of such decision within **[*]** days of the notification of infringement. In view of such a decision by Cerus, Baxter may take such actions under its own name.

7.2 Baxter Insurance. Baxter shall carry, through self-insurance or a combination of self-insurance and commercially placed insurance, appropriate levels of insurance coverage consistent with its commercially reasonable business practices.

7.3 Cerus Insurance. Cerus shall carry appropriate levels of insurance coverage consistent with its commercially reasonable business practices.

Article 8

Representations and Warranties; Covenants; Warranty Disclaimer

8.1 General. Each Party represents and warrants to the other that: (a) all corporate action necessary for the authorization, execution and delivery of this Agreement by such Party and the performance of its obligations hereunder has been taken; (b) the execution, delivery and anticipated performance of this Agreement do not violate or conflict with any law applicable to it, any provision of its charter or bylaws, any order or judgment of any court or other agency of government applicable to it or any of its assets or any contractual restriction or provision or agreement or instrument binding on or affecting it or any of its assets; and (c) its obligations hereunder constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms (subject to applicable bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditors' rights generally and subject, as to enforceability, to equitable

principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law)).

8.2 Baxter's Additional Representations and Warranties; Covenants. Baxter represents and warrants to Cerus as of the Execution Date, and covenants to Cerus, that:

(a) Baxter is the sole owner, or joint owner with Cerus, of all right, title and interest in and to the Licensed Patents and Licensed Materials;

(b) with regard to the Licensed Patents and the Licensed Materials, Baxter has all sufficient rights necessary to grant the license to Cerus in accordance with the terms of this Agreement;

(c) Baxter is not in default or breach of any agreement or license under which it has acquired any rights to license the rights licensed to Cerus hereunder;

(d) the information and materials set forth in the Licensed Materials, and the rights licensed hereunder, are all that is reasonably necessary for Cerus to manufacture the Products and Baxter has been successfully manufacturing the current configuration of the Platelet System marketed in Europe with only such information, materials and rights;

(e) Baxter has not granted to any other Person any rights, licenses or privileges in the Licensed Patents in the Territory and is not a party to any agreements, regulations or covenants which would require third party consents, waivers and authorizations (including any government consents, waivers or authorizations) necessary or appropriate for consummation of the transactions contemplated by this Agreement;

(f) Baxter shall not impair or otherwise adversely affect the rights of Cerus in any of the Licensed Patents or Licensed Materials through any action or omission that Baxter knows, or should know, would impair or otherwise adversely affect such rights;

(g) Baxter has taken and will take all actions reasonably necessary to protect the Licensed Patents (including registering the same in jurisdictions determined by Baxter in its reasonable discretion, and all such registered Licensed Patents have not been canceled or abandoned or permitted to lapse);

(h) the Licensed Patents and the Licensed Materials are not subject to any lien or other encumbrance; and

(i) Baxter has not received any notice indicating that sale, offer for sale, import and manufacture of the Products, and use of such Products by customers of Cerus and Cerus' use of the Licensed Materials, would infringe, misappropriate or violate any issued Patent that has not been declared invalid or unenforceable by a final, non-appealable court order, or any copyright,

trademark, trade secret, confidential information or other intellectual property right of any third Person.

8.3 Disclaimer of Warranty. EXCEPT AS PROVIDED HEREIN, BAXTER MAKES NO OTHER WARRANTIES UNDER THIS AGREEMENT, EXPRESS OR IMPLIED, INCLUDING, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR NONINFRINGEMENT.

8.4 Disclaimer of Damages; Limitation of Liability. In no event shall any Party be liable for incidental or consequential damages regardless of whether such Party shall be advised, shall have other reason to know, or in fact shall know of the foregoing, in excess of **[*]** U.S. dollars (U.S. $**[*]**) in the aggregate under this Agreement.

Article 9

Termination

9.1 Term of Agreement. The term of this Agreement (the "Term") shall commence on the Effective Date of this Agreement, and continue until terminated as provided herein.

9.2 Termination. This Agreement may be terminated as follows:

(a) by Baxter and Cerus upon their mutual agreement;

(b) by Baxter upon a Fundamental Breach; as used herein a "Fundamental Breach" is:

(i) failure by Cerus to perform its obligations under Section 7.3 of this Agreement that is not cured within **[*]** days after notice from Baxter or Cerus to Cerus of such failure; *provided, however, that* this Section 9.2(b)(i) shall apply only if the amount unpaid exceeds **[*]** U.S. dollars (U.S.$**[*]**);

(ii) failure by Cerus to make any payment to Baxter under this Agreement (other than a de minimis payment) following repeated previous payment failures or delays, evidencing a conscious disregard by Cerus of its payment obligations to Baxter, and following a written notice to Cerus from Baxter that further payment failures will or could result in termination;

(c) by Cerus upon a material breach of this Agreement by Baxter, provided, however, the breaching party shall be entitled to written notice of such breach and **[*]** days to cure such breach before the Agreement may be terminated.

9.3 Measures In Lieu of Termination. It is understood by the Parties that, inasmuch as Cerus is making significant concessions and will pay significant royalties under the Restructuring Agreement and this Agreement, Cerus would be forced not to terminate this Agreement even though Cerus shall be entitled to terminate this Agreement for cause attributable to Baxter pursuant to Section 9.2(c) hereof. Consequently, Cerus shall be entitled, in lieu of termination of this Agreement for the cause attributable to Baxter pursuant to Section 9.2(c) hereof, to reduce the

royalties payable under this Agreement and to relax other requirements so as to be equitable to the Parties in view of such cause attributable to Baxter, as the case may be.

9.4 Effect of Termination. If this Agreement shall be terminated pursuant to Section 9.2, except as may otherwise be agreed in writing by the Parties, all further obligations of the Parties under this Agreement shall terminate without further liability of any Party to another; provided that the obligations of the Parties contained in the following provisions of this Agreement shall survive any expiration or earlier termination of this Agreement: Articles 1, 4, 7, 8 and 10 and Sections 3.4, 6.7 and 9.4.

Article 10

Miscellaneous

10.1 Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Illinois.

10.2 Assignments and Delegation.

(a) No Party may assign any of its rights under this Agreement other than assignments to a Permitted Assignee, except with the prior written consent of the other Parties. The Parties shall not unreasonably withhold its consent to assignments. Permitted Assignees include Affiliates of the relevant Party and third parties to whom the relevant Party transfers substantially all of the products, business and services to which this Agreement relates. In the case of an assignment by Baxter, assignees must also receive an assignment of all of Baxter's rights in all intellectual property licensed to Cerus hereunder, subject to the licenses granted in this Agreement. It shall be a condition of any such assignment that the assignee shall assume all obligations of the assigning party under this Agreement

(b) No party may delegate any performance under this Agreement.

(c) Any purported assignment of rights or delegation of performance in violation of this Section is void.

10.3 Successors and Assigns. This Agreement inures to the benefit of, and is binding upon, the successors and assigns of the Parties hereto.

10.4 Entire Agreement; Amendments. This Agreement, the Restructuring Agreement and the Manufacturing and Supply Agreement and the other Concurrent Agreements (as defined in the Restructuring Agreement) contain the entire understanding of the Parties with regard to the subject matter contained herein and therein, and supersede all prior agreements or understandings of the Parties with respect to the subject matter of this Agreement, and such other agreements. This Agreement may not be amended, modified or supplemented except by a written instrument signed by an authorized representative of each of the Parties.

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10.5 Force Majeure. No Party will be deemed in default if delayed or prevented from performing its obligations under this Agreement, in whole or in part, due to an act of God, fire, flood, explosion, civil disorder, strike, lockout or other labor trouble, material shortages of utilities, equipment, materials or facilities, delay in transportation, breakdown or accident, riot, war, terrorist attack or other cause beyond its control (a "Force Majeure Event"); provided that it shall notify the other Party promptly of such event and resume full performance of this Agreement as soon as practicable following the conclusion of the Force Majeure Event.

10.6 Interpretation; No Strict Construction. Article titles and headings to Sections herein are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. The language used in this Agreement shall be deemed to be the language chosen by the Parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any Party hereto.

10.7 Partial Invalidity. If any provision of this Agreement, or the application thereof, is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the provisions of this Agreement will in no way be effected, impaired or invalidated, and to the extent permitted by applicable law, any such provision will be restricted in applicability or reformed to the minimum extent required for such provision to be enforceable.

10.8 No Third Party Beneficiary. This Agreement will not confer any rights or remedies on any person other than the Parties hereto and their respective successors and Permitted Assigns.

10.9 Counterparts. This Agreement may be executed in one or more counterparts (and by facsimile), all of which shall be considered one and the same agreement, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other parties.

10.10 Notices. Wherever under this Agreement one Party is required or permitted to give written notice to the other, such notice will be deemed given if made in writing and delivered either by hand, by a recognized overnight delivery service (with delivery charges prepaid), by first class, registered or certified United States mail (postage prepaid), or by facsimile transmission (provided that in the case of facsimile transmission, a confirmation copy of the notice shall be delivered by hand, by a recognized overnight delivery service (with charges prepaid), or by first class, registered or certified United States mail (postage prepaid) within two (2) days of facsimile transmission), addressed to each party as follows:

If to Cerus, such notices shall be delivered to:

Cerus Corporation

2411 Stanwell Drive

Concord, CA 94520

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Attn: Vice President, Legal Affairs

Fax: 925.288.6278

If to Baxter, such notices shall be delivered to:

Baxter Healthcare Corporation

Route 120 & Wilson Road

Round Lake, IL 60073

Attn: President, Transfusion Therapies

Fax: 847.270.3855

Or such other address as any such Party may designate in writing, and delivered to the other Parties hereto pursuant to this Section 10.10.

10.11 Nonwaiver. No alleged waiver, modification or amendment to this Agreement shall be effective against either Party hereto, unless in writing, signed by the Party against which such waiver, modification or amendment is asserted, and referring specifically to the provision hereof alleged to be waived, modified or amended. The failure or delay of either Party to insist upon the other Party's strict performance of the provisions in this Agreement or to exercise in any respect any right, power, privilege, or remedy provided for under this Agreement shall not operate as a waiver or relinquishment thereof, nor shall any single or partial exercise of any right, power, privilege or remedy preclude other or further exercise thereof, or the exercise of any other right, power, privilege, or remedy; provided, however, that the obligations and duties of either Party with respect to the performance of any term or condition in this Agreement shall continue in full force and effect.

10.12 Alternative Dispute Resolution. The Parties will attempt to settle any claim or controversy arising out of this Agreement through good faith negotiations and in the spirit of mutual cooperation. Any issues that cannot be resolved will be referred to a senior management representative from each of the Parties who has the authority to resolve the dispute. In the event such senior management representatives cannot resolve the dispute, the dispute will be submitted to binding arbitration for resolution. Any such proceedings shall be conducted at the place of the principal office of the respondent in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA"). Any such dispute or controversy shall be arbitrated before a single arbitrator selected in accordance with the rules of the AAA. The arbitrator's decision shall be final and binding upon the parties. The parties shall be entitled to full discovery in any such arbitration. Each party shall bear one half of the cost of such arbitration, unless the arbitrator otherwise allocates such costs. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Nothing in this Section will prevent either Party from

resorting to judicial process if injunctive relief from a court is necessary to prevent serious and irreparable injury to one Party or to others.

10.13 Joint and Several Liability. BHSA and BHC's obligations and liability under this Agreement shall be joint and several and each of BHSA and BHC shall be individually responsible for performing the obligations assigned to Baxter hereunder.

10.14 Rights Cumulative. The rights, remedies and powers of each of the Parties contained in this Agreement, the Restructuring Agreement and the Manufacturing and Supply Agreement are cumulative and not exclusive of any rights, remedies or powers provided to the parties by law, this Agreement or otherwise. No single or partial exercise by any of the Parties of any right, remedy or power under this Agreement shall preclude any other or further exercise thereof or the exercise of any other right, remedy or power.

10.15 U.S. Bankruptcy Law. The Parties agree that all intellectual property licensed herein is "intellectual property" as defined in 11 U.S.C. Section 101 (35A) and that Cerus shall be able to rely on all of the protections of 11 U.S.C. Section 365(n) in order to protect its interests in all licenses granted to Cerus herein the event of a rejection of this Agreement in connection with Baxter's bankruptcy, insolvency or related event in any U.S. court.

10.16 Security Interest. As security for the performance of all of Baxter's obligations hereunder and under the Manufacturing and Supply Agreement and any damages owed by Baxter to Cerus in the event of Baxter's breach or default of this Agreement or the Manufacturing and Supply Agreement, Baxter hereby grants to Cerus, a security interest in its respective interest in the Licensed Patents issued or applied for in any country of the Territory, excluding Licensed Patents issued in the United States, and all proceeds thereof, and the granting party shall cooperate with Cerus with respect to all filings and other actions necessary to perfect such security interest.

{Signature Page to Follow}

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IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date first set forth above.

BAXTER HEALTHCARE S. A.	**CERUS CORPORATION**
By: /s/ U. Eisenring	By: /s/ Claes Glassell

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Name: U. Eisenring

Title: Corporate Counsel, Baxter Healthcare SA

Name: Claes Glassell

Title: President and Chief Executive Officer

By: /s/ B. Lenzlinger

Name: B. Lenzlinger

Title: Finance Director

BAXTER HEALTHCARE CORPORATION

By: /s/ John Greisch

Name: John Greisch

Title: Corporate Vice President and CFO

Exhibit A

Licensed Patents

BAXTER DOCKET NO.	**COUNTRY**	**APPLICATION/ PATENT NO.**	**FILING DATE**	**ISSUE DATE/ EXP. DATE PRODUCT**
[*]	**[*]**	**[*]**	**[*]**	**[*]**
[*]	**[*]**	**[*]**	**[*]**	**[*]**

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Exhibit A

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE CERUS CORPORATION HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO CERUS CORPORATION IF PUBLICLY DISCLOSED.

Licensed Patents

BAXTER DOCKET NO.	COUNTRY	APPLICATION/ PATENT NO.	FILING DATE	ISSUE DATE/ EXP. DATE PRODUCT
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
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EXHIBIT 19.1

CERUS CORPORATION
INSIDER TRADING POLICY
(ADOPTED MARCH 29, 2024)

INTRODUCTION

During the course of your relationship with Cerus Corporation ("***Cerus***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about Cerus or other publicly traded companies. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in Cerus's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Cerus securities and in the securities of other applicable publicly traded companies, in each case by our directors, officers and other employees and the other persons or entities subject to this policy as described below.

STATEMENT OF POLICY

It is the policy of Cerus that a director, officer or other employee of Cerus (or any other person or entity subject to this policy) who is aware of material nonpublic information relating to Cerus **may not**, directly or indirectly:

1. engage in any transactions in Cerus securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any Cerus securities;
3. disclose material nonpublic information to persons within Cerus whose jobs do not require them to have that information, or outside of Cerus to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with Cerus's policies regarding the protection or authorized external disclosure of information regarding Cerus; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to Cerus at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Cerus's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the

insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of Cerus that no director, officer or other employee of Cerus (or any other person or entity subject to this policy) may either (a) recommend to another person or entity that they buy, hold or sell Cerus's securities **at any time** or (b) disclose material nonpublic information to persons within Cerus whose jobs do not require them to have that information, or outside of Cerus to other persons (unless the disclosure is made in accordance with Cerus's policies regarding the protection or authorized external disclosure of information regarding Cerus).

In addition, it is the policy of Cerus that no person subject to this policy who, in the course of his or her relationship with Cerus, learns of any confidential information that is material to another publicly traded company, including a customer or supplier of Cerus, may trade in that other company's securities until the information becomes public or is no longer material to that other company.

There are no exceptions to this policy, except as specifically noted above or below.

TRANSACTIONS SUBJECT TO THIS POLICY

This policy applies to all transactions in securities issued by Cerus, as well as derivative securities that are not issued by Cerus, such as exchange-traded put or call options or swaps relating to Cerus's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of Cerus's common stock in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

PERSONS SUBJECT TO THIS POLICY

This policy applies to you and all other directors, officers and other employees of Cerus and its subsidiaries. This policy also applies to members of your family who reside with you, any other persons with whom you share a household, any family members who do not live in your household but whose transactions in Cerus's securities are directed or controlled by you and any other individuals or entities whose transactions in securities you direct or control. The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

MATERIAL NONPUBLIC INFORMATION

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types

of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- status of product, product candidate or process development or regulatory approvals;
- clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;
- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for Cerus's securities;
- gain or loss of a significant, customer, licensor, licensee or supplier;
- major contract awards or cancellations;
- notice of issuance or denial of patents;
- regulatory developments;
- top management or control changes;
- employee layoffs;
- a disruption in Cerus's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- significant write-offs;
- accounting restatements;
- significant litigation or settlements;
- pricing changes or discount policies;
- corporate partner relationships; and
- impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy on the third business day after the information was publicly disclosed. Depending on the particular circumstances, Cerus may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

QUARTERLY TRADING BLACKOUTS

Because the Company's Section 16 reporting officers ("executive officers"), directors, members of the finance group, and members of the marketing group having access to sales data, who we refer to as our "***Covered Insiders****",* are most likely to have regular access to material nonpublic information about Cerus, we require them to do more than refrain from insider trading. To minimize even the appearance of insider trading among our Covered Insiders, we have established "quarterly trading blackout periods" during which our Covered Insiders and their Related Persons—regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Cerus securities. That means that, except as described in this policy, Covered Insiders and their Related Persons will be able to trade in Cerus securities only during limited open trading window periods that generally will begin on the third business day after the

public dissemination of Cerus's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Cerus securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "***quarterly trading blackout period***" will generally begin at the end of the fifteenth calendar day of the month in which each fiscal quarter ends and end on the third business day after the public dissemination of Cerus's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the President, Chief Financial Officer or Chief Legal Officer, there exists undisclosed information that would make trades by Covered Insiders inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Covered Insider who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the Chief Legal Officer. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Chief Legal Officer concludes that the person is not in fact aware of any material nonpublic information relating to Cerus or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

EVENT-SPECIFIC TRADING BLACKOUTS

From time to time, an event may occur that is material to Cerus and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the President, Chief Financial Officer or Chief Legal Officer may not trade in Cerus's securities. In that situation, Cerus will notify the designated individuals that neither they nor their Related Persons may trade in Cerus's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout.

The quarterly and event-driven trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

EXCEPTIONS TO THIS POLICY

This policy does not apply in the case of the following transactions, except as specifically noted:

1.*Option Exercises*. This policy does not apply to the exercise of options granted under Cerus's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company or by delivery to Cerus of already-owned Cerus stock. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2.*Tax Withholding Transactions*. This policy does not apply to the surrender of shares directly to Cerus to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under Cerus's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains

subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

3.*ESPP*. This policy does not apply to the purchase of stock by employees under Cerus's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.

4.*10b5-1 Automatic Trading Programs*. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), directors, officers and other employees may establish a trading plan under which a broker is instructed to buy and sell Cerus securities based on pre-determined criteria (a "***10b5-1 Trading Plan***"). So long as a 10b5-1 Trading Plan is properly established, purchases and sales of Cerus securities pursuant to that Trading Plan are not subject to this policy. To be properly established, a director's, officer's or other employee's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Cerus at a time when Cerus was not in a trading blackout period and they were not otherwise aware of any material nonpublic information relating to Cerus or the securities subject to the Trading Plan. Moreover, all 10b5-1 Trading Plans must be reviewed and approved by Cerus's Chief Financial Officer or Chief Legal Officer (each, a "***Compliance Officer***") before being established to confirm that the 10b5-1 Trading Plan complies with all pertinent company policies and applicable securities laws.

SPECIAL AND PROHIBITED TRANSACTIONS

1.***Inherently Speculative Transactions.*** No Cerus director, officer or other employee may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to Cerus's stock.

2.***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Cerus director, officer or other employee to continue to own Cerus's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Cerus director, officer or other employee may no longer have the same objectives as Cerus's other stockholders. Therefore, Cerus directors, officers and other employees are prohibited from engaging in any such transactions.

3.***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Cerus's securities, Cerus directors, officers and other employees are prohibited from holding Cerus's securities in a margin account or otherwise pledging Cerus's securities as collateral for a loan.

4.***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Cerus director, officer or other employee is in possession of material nonpublic information. Cerus therefore discourages placing standing or limit orders on Cerus's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on

their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements above, directors, officers and other employees face a further restriction: Even during an open trading window, they may not engage in any transaction in, or enter into, modify or terminate any contract, instruction or written plan or arrangement in, Cerus's securities without first obtaining pre-clearance from a Compliance Officer in advance. The Compliance Officer will then determine whether the Covered Insider may proceed. Pre-cleared transactions not completed within three business days (or such other time as the Compliance Officer may designate) will require new pre-clearance.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Compliance Officer.

To the extent possible, officers and directors subject to the reporting obligations under Section 16 of the Exchange Act will give advance notice to a Compliance Officer of upcoming transactions effected pursuant to an established 10b5-1 Trading Plan.

Upon the completion of any transaction by an officer or director subject to the reporting obligations under Section 16 of the Exchange Act, the individual must immediately notify the appropriate persons, as required by the Company's Section 16 Compliance Program, so that the Company may assist in the Section 16 reporting obligations.

SHORT-SWING TRADING, CONTROL STOCK AND SECTION 16 REPORTS

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5) and any notices of sale required by Rule 144.

PROHIBITION OF TRADING DURING PENSION PLAN BLACKOUTS

No director or executive officer of Cerus may, directly or indirectly, purchase, sell or otherwise transfer any equity security of Cerus (other than an exempt security) during any "blackout period'' (as defined in Regulation BTR under the Exchange Act) if a director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a director or executive officer. This prohibition does not apply to any transactions that are specifically exempted, including but not limited to, purchases or sales of Cerus's securities made pursuant to, and in compliance with, a Trading Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and directors to receive automatic grants or awards and specifies the terms of the grants and awards; or acquisitions or dispositions of equity securities involving a *bona fide* gift or by will or the laws of descent or pursuant to a domestic relations order. Cerus will notify each director and executive officer of any blackout periods in accordance with the provisions of Regulation BTR. Because Regulation BTR is very complex, no director or executive officer of Cerus should engage in any transactions in Cerus's securities, even if believed to be exempt from Regulation BTR, without first consulting with the Chief Legal Officer.

POLICY'S DURATION

This policy continues to apply to your transactions in Cerus's securities and the securities of other applicable public companies as more specifically set forth in this policy, even after your relationship with Cerus has ended. If you are aware of material nonpublic information when your relationship with Cerus ends, you may not trade Cerus's securities or the securities of other applicable publicly traded companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave Cerus during a trading blackout period, then you may not trade Cerus's securities or the securities of other applicable companies until the trading blackout period has ended.

INDIVIDUAL RESPONSIBILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about Cerus and to not engage in transactions in Cerus's securities or the securities of other applicable public companies while aware of material nonpublic information, as more specifically set forth in this policy. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of Cerus or any employee or director of Cerus pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by Cerus for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Cerus, including termination of employment. Anyone who has questions about this policy should contact their own attorney or Cerus's Chief Legal Officer.

AMENDMENTS

Cerus is committed to continuously reviewing and updating its policies and procedures. Cerus therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of Cerus's policies regarding insider trading may be obtained by contacting the Chief Legal Officer.

Exhibit 21.1

Cerus Corporation
Subsidiaries of the Registrant

Legal Name	Jurisdiction of Formation
Cerus Europe B.V	Netherlands

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

1. Registration Statements (Form S-3 Nos. 333-275284, 333-93481, 333-47224, 333-61460, and 333-61910) of Cerus Corporation and in the related Prospectuses,
2. Registration Statement (Form S-8 No. 333-27097) pertaining to the 1996 Equity Incentive Plan and the Employee Stock Purchase Plan,
3. Registration Statement (Form S-8 No. 333-74991) pertaining to the 1998 Non-Officer Stock Option Plan,
4. Registration Statements (Form S-8 Nos. 333-84497, 333-63132, 333-92254, 333-136452 and 333-145007) pertaining to the 1999 Equity Incentive Plan,
5. Registration Statement (Form S-8 No. 333-42588) pertaining to the 1998 Non-Officer Stock Option Plan and the 1999 Equity Incentive Plan,
6. Registration Statements (Form S-8 Nos. 333-109170 and 333-127541) pertaining to the Employee Stock Purchase Plan and the 1999 Equity Incentive Plan,
7. Registration Statement (Form S-8 No. 333-125043) pertaining to the 1996 Equity Incentive Plan, Employee Stock Purchase Plan, 1998 Non-Officer Stock Option Plan and the 1999 Equity Incentive Plan,
8. Registration Statement (Form S-8 No. 333-152680) pertaining to the 1998 Non-Officer Stock Option Plan, 1999 Equity Incentive Plan and the 2008 Equity Incentive Plan,
9. Registration Statements (Form S-8 Nos. 333-177751 and 333-192061) pertaining to the 2008 Equity Incentive Plan,
10. Registration Statement (Form S-8 No. 333-183232) pertaining to the 1996 Employee Stock Purchase Plan and the 2008 Equity Incentive Plan,
11. Registration Statement (Form S-8 No. 333-240491) pertaining to the 1996 Employee Stock Purchase Plan and the Amended and Restated 2008 Equity Incentive Plan,
12. Registration Statement (Form S-8 No. 333-206231) pertaining to the Amended and Restated 1996 Employee Stock Purchase Plan and the Amended and Restated 2008 Equity Incentive Plan,
13. Registration Statement (Form S-8 No. 333-213411) pertaining to the Cerus Corporation Inducement Plan, and
14. Registration Statements (Form S-8 Nos. 333-219730, 333-232960, 333-258425, 333-266546, and 333-275285) pertaining to the Amended and Restated 2008 Equity Incentive Plan;

of our reports dated February 26, 2025, with respect to the consolidated financial statements of Cerus Corporation and the effectiveness of internal control over financial reporting of Cerus Corporation included in this Annual Report (Form 10-K) of Cerus Corporation for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Mateo, California

February 26, 2025

Exhibit 31.1

CERTIFICATION

I, William M. Greenman, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: February 26, 2025

/s/ WILLIAM M. GREENMAN

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

Exhibit 31.2

CERTIFICATION

I, Kevin D. Green, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: February 26, 2025

/s/ KEVIN D. GREEN

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 26th day of February, 2025.

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

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

EXHIBIT 97.1

CERUS CORPORATION

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the "***Board***") of Cerus Corporation, a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any

action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.