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, 2025

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 30, 2025, 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 $230 million. [(1)]

As of February 5, 2026, there were 192,171,776 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 2026 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, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

[(1)] Based on a closing sale price of $1.41 per share on June 30, 2025. Excludes 28.4 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, 2025.

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For the Fiscal Year Ended December 31, 2025

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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 existing tariffs and potential new or increased tariffs and the ongoing conflict between Ukraine and Russia as well as the risk of a global conflict 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 existing clinical data will be sufficient in order to obtain a CE Certificate of Conformity and affix a CE Mark to the red blood cell system 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, and the U.S. Department of Defense, or DoD, due to executive orders impacting government contract funding and personnel, previous and potential future U.S. government shutdown or otherwise;***
- ***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 and the DoD, 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.
- An inability to successfully transition from a direct selling model to a kit model, as well as an 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 additional activities or 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.
- We may not be able to achieve, or sustain, profitability.
- 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 as well as tariffs and escalating international trade tensions 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 value.
- 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 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 and has not been commercialized anywhere in the world. 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 application for conformity assessment under the MDR to obtain a CE Certificate of Conformity and affix the CE Mark, or 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 successful completion of the conformity assessment or issuance of a CE Certificate of Conformity. In collaboration with TÜV-SÜD, our Notified Body for the red blood cell system, we developed a plan for resubmission of our application and identified a new Competent Authority. We revised our MDR application to address the questions raised by CBG and submitted a new MDR application for the red blood cell system to TÜV-SÜD. In July 2025, we announced that TÜV-SÜD completed their clinical assessment of our new MDR application and transferred information regarding the active substances, or API, to the identified competent authority, the State Institute for Drug Control, or SÚKL. After discussions with TÜV-SÜD, we decided to transfer the review of the API from SÚKL to the French National Agency for Medicines and Health Products Safety, or ANSM. We cannot predict if or when a decision concerning certification would occur. In addition, as a result of the failure to obtain a CE Certificate of Conformity following 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.

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 selling, general and administrative expenses, may result in operating losses. While our goal is to achieve and maintain a profitable level of operations, we may be unable to do so.

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 and CE Marked under MDR in 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 and CE Marked under MDR in 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, completed enrollment in 2025 • 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 • Application for a conformity assessment to obtain a CE Certificate of Conformity and affix the CE Mark for the EEA was resubmitted in 2025
INTERCEPT Blood System—Cryoprecipitation	• Received FDA approval of the premarket approval supplement with respect to IFC in 2020 • U.S. agreement with certain blood center manufacturing partners
INTERCEPT Illuminator—LED-based	• Commercialized in a number of countries in Europe and selected countries in other regions around the world • Received CE Certificate of Conformity and CE Marked under MDR in 2025

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 in accordance with the MDR 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 in accordance with the 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 2026 will be focused on increasing market adoption of INTERCEPT products by enabling blood center customers to increase the number of platelet and plasma units produced and made available to patients. For IFC, we are shifting

our focus from selling finished therapeutic doses to hospitals to selling kits to blood centers. We plan to continue to develop and raise awareness of INTERCEPT's product profile relative to other products, including conventional, un-treated components. To distribute blood products, including IFC, to hospitals through interstate commerce, U.S.-based blood centers will need to complete process validations and obtain site-specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, before those blood products can be made available to hospital customers outside of the state of IFC production. In addition, 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 pooled 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 this configuration. 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 will also need to obtain new PMAs for our INTERCEPT platelet and plasma systems for use with our new LED-based illuminator. We plan to submit our PMA application for our new LED-based illuminator in mid-2026. 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 MDR application. We initially filed an application for conformity assessment to obtain 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 submitted an MDR application. In October 2024, we announced that TÜV-SÜD, in consultation with CBG, 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 successful completion of the conformity assessment and issuance of a CE Certificate of Conformity. In collaboration with TÜV-SÜD, we developed a plan for resubmission of our application and identified a new Competent Authority. We revised our MDR application to address the questions raised by CBG and submitted a new MDR application for the red blood cell system to TÜV-SÜD. In July 2025, we announced that TÜV-SÜD completed their clinical assessment of our new MDR application and transferred information regarding the API to the identified competent authority, SÚKL. After discussions with TÜV-SÜD, we decided to transfer the review of the API from SÚKL to ANSM. We cannot predict if or when a decision concerning certification would occur. In addition, as a result of the resubmission 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 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 are conducting the Phase 3 RedeS study, a double-blind, controlled, parallel group study randomized to receive either 28 days, or 28 days plus 6 months of transfusion support with INTERCEPT-treated RBCs or conventional RBCs (test or control with 1:1 ratio), with a primary endpoint of hemoglobin increment following transfusion. The study completed enrollment during the fourth quarter of 2025 of 689 patients including 130 transfused patients for the 6-month chronic phase for subjects requiring simple repeat transfusions and 25 transfused patients with Sickle Cell Disease requiring red cell exchange. Subjects that qualified for inclusion into the chronic phase were those with conditions such as Sickle Cell Disease, Thalassemia, or Myelodysplasia. If treatment emergent antibody reactions associated with hemolysis are observed, 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. The preliminary results from the RedeS study are expected in late 2026, and 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.

We are also planning a prospective, open-label, controlled Phase 2 study designed to determine whether INTERCEPT RBC transfusions into patients with pre-existing antibodies to INTERCEPT RBCs will result in increased antibody titer indicative of a secondary immune response. Subjects will have samples drawn pre-transfusion and over 90-days post transfusion to detect responses to INTERCEPT RBC. Clinical evidence of hemolysis will be evaluated using routine laboratory testing. If treatment emergent antibody reactions associated with hemolysis are observed, 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.

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 MDR application 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 2026, 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 first generation of the illuminator and maintain an inventory of those final devices. We submitted an MDR application for a new illuminator and received a CE Certificate of Conformity in 2025. 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, 2027 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, UVA illuminators, and the new LED 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. 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 both expired in October 2025, though we have extended terms to continue the supply while a new agreement is negotiated. We also have an agreement with EFS for maintenance services for illuminators that also expired in October 2025, though we have extended this agreement, pending negotiation of a new contract. 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 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 and will have to generate data from Chinese sites and donors using the products. We cannot provide assurance the JV will be successful in generating sufficient data 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 non-exclusive arrangements or 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 three contracts with U.S. Federal Agencies, two with BARDA and one with the DoD. Revenue from the cost reimbursement provisions under our BARDA 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 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, 2025, 2024 and 2023. 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 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, or IFC, 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, or may perceive the cost of adopting IFC as prohibitive relative to its advantages or compared to competitive products.

In Europe, several companies, including Grifols, Octapharma AG, MacoPharma International and Kedrion Biopharma, have developed in the past and are developing or selling commercial pathogen reduction products, systems, or services for 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 is seeking a CE Certificate of Conformity under the MDR 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. Terumo BCT has also received a Class III CE Certificate of Conformity for a pathogen reduction system for whole blood. 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's Octaplas, a solvent detergent treated pooled plasma product approved in the U.S. for certain indications. 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, or JRC. Terumo Corporation is a large Japan-based, multinational corporation with established products and longstanding relationships. 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 rely on a local partner in the territory. Additionally, in July 2025, we understand that the JRC adopted a bacterial detection system for platelets, which may impact its interest in alternative solutions, including pathogen reduction.

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, 2025, we owned 21 issued or allowed U.S. patents and approximately 154 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2027 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 18 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 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 completion of 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. 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, 2025, 2024 and 2023.

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 MDR application for the red blood cell system under the MDR in June 2021. In October 2024, we announced that TÜV-SÜD, in consultation with CBG, 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 successful completion of the conformity assessment and issuance of a CE Certificate of Conformity. In collaboration with TÜV-SÜD, we developed a plan for resubmission of our application and identified a new Competent Authority. We revised our MDR application to address the questions raised by CBG and submitted a new MDR application for the red blood cell system to TÜV-SÜD. In July 2025, we announced that TÜV-SÜD completed their clinical assessment of our new MDR application and transferred information regarding the API to the identified competent authority, SÚKL. After discussions with TÜV-SÜD, we decided to transfer the review of the API from SÚKL to ANSM. We cannot predict if or

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 were 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, state, or foreign 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 us 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 that purchase INTERCEPT-treated blood products 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 they can sell finished IFC to hospital customers outside of the states producing IFC. While all of the blood centers that were manufacturing partners for us have received a BLA from CBER, we plan to continue working with additional U.S.-based blood centers that are onboarding and producing IFC to support their licensure applications and any delay in obtaining these licenses would adversely impact the nationwide availability of 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 may be negatively impacted. In addition, we have entered into certain agreements with blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation kits which will allow those blood centers and blood center affiliate organizations to produce finished IFC for their own sales efforts to hospitals. We have experienced an acceleration in IFC kit sales to blood centers and a shift away from direct sales to hospitals. We expect this trend to continue and our IFC sales will predominately be kit sales to blood centers.

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 MDR application. Should we be required to generate data for these ancillary solutions, an eventual issuance of a CE Certificate of Conformity to permit the affixing of the CE Mark 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 are and may become 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, personal data collected as part of any clinical trials, other testing, or other business activities, is and may become subject to additional regulatory obligations. This includes, for example, 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. 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.

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 July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

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. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Recent actions, for example, include directing agencies to reduce agency workforce and cut programs. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan" to lower government subsidies to private insurance companies and increase healthcare price transparency, among other things. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. We expect that additional state, federal, and foreign healthcare reform measures will be adopted in the future.

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, 2025, we had 275 employees company-wide.

Below is demographic information about our current employee base as of December 31, 2025.

Cerus Employees	**2025**
Salaried workforce	260
Managers and above	71
Part-time employees	14
Average age	46.5 years
Average length of service in years	7.4 years
Employee turnover rate December 31, 2024 to 2025 (voluntary)	5.89%

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. We have 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.

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 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, tightening of credit markets on our business and existing and potential new or increased tariffs;
- 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 quantities 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;
- 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 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.

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 and may not be cost effective. 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 extensions 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 a significant amount of time 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. 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. As such, we have begun to 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 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 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, 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 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 blood centers producing IFC, there may not be production capacity to supply demand, especially in states outside of the home states of blood centers producing IFC. If blood centers that adopt IFC experience delays in obtaining BLAs or are never issued BLAs, our operating results may be negatively impacted. 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 or be required to offset the economic impact to blood centers, 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.

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 and Trima in PAS, we cannot provide assurance 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. Moreover, if we are unable to generate the additional 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. 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 CBG 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 successful completion of the conformity assessment and issuance of a CE Certificate of Conformity. In collaboration with TÜV-SÜD, our Notified Body for the red blood cell system, we developed a plan for resubmission of our application and identified a new Competent Authority. We revised our MDR application to address the questions raised by CBG and submitted a new MDR application for the red blood cell system to TÜV-SÜD. In July 2025, we announced that TÜV-SÜD completed their clinical assessment of our new MDR application and transferred information regarding the API to SÚKL. After discussions with TÜV-SÜD, we decided to transfer the review of the API from SÚKL to ANSM. We cannot predict if or when a decision concerning certification would occur. In addition, as a result of the resubmission of our MDR application, our product development costs will be ongoing. 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 provide assurance 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 provide assurance 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 provide assurance 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. 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. 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, we anticipate that additional clinical trial data will be required to supplement our two Phase 3 clinical trials, ReCePI and RedeS. Enrollment of the RedeS clinical trial was completed in 2025 and we anticipate completion of the trial in the second half of 2026. Discussion of the planned PMA module submissions with the FDA will not occur prior to the completion of the RedeS trial. 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 provide assurance 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 generate the additional 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. 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 are also planning a prospective, open-label, controlled Phase 2 study designed to determine whether INTERCEPT RBC transfusions into patients with pre-existing antibodies to INTERCEPT RBCs will result in increased antibody titer indicative of a secondary immune response. Subjects will have samples drawn pre-transfusion and over 90-days post transfusion to detect responses to INTERCEPT RBC. Clinical evidence of hemolysis will be evaluated using routine laboratory testing. If treatment emergent antibody reactions associated with hemolysis are observed, 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.

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 successful completion of the conformity assessment and issuance of a CE Certificate of Conformity. In collaboration with TÜV-SÜD, we developed a plan for resubmission of our application and identified a new Competent Authority. We revised our MDR application to address the questions raised by CBG and submitted a new MDR application for the red blood cell system to TÜV-SÜD. In July 2025, we announced that TÜV-SÜD completed their clinical assessment of our new MDR application and transferred information regarding the API to the identified competent authority, SÚKL. After discussions with TÜV-SÜD, we decided to transfer the review of the API from SÚKL to ANSM. We cannot predict if or when a decision concerning certification would occur. In addition, as a result of the resubmission of our MDR application, our product development costs will be ongoing. In any event, we do not know when, if ever, we will receive a CE Certificate of Conformity to affix the CE Mark to the red blood cell system. In addition, we do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to support the new MDR application, 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-SÜD 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 a CE Certificate of Conformity following successful completion 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 contracts with BARDA contemplate development of a more operationally scalable version. If we are unable to access funds contemplated under our BARDA contracts 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 a CE Certificate of Conformity based on the MDR for the INTERCEPT Blood System for platelets and plasma permitting the affixing of the CE mark. 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 MDR and 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 and certain other in-country approvals 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, of which we have a limited number of devices available 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 anticipate that 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. Similar requirements and considerations apply outside the U.S.

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, and comparable foreign 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 and comparable foreign 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 have redesigned the illuminators used in the platelet and plasma systems and may need to further redesign the illuminator. We will need to obtain regulatory approval of any future redesign of the illuminator before it can be commercialized.

We understand that we will be required to obtain new PMAs and certain other in-country approval 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 (and the third parties with whom we work) collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) 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 under various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations, that affect, for example, our sales, marketing and other promotional activities.

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, the U.S. Department of Health and Human Services ("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 investigations are 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 ("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 Marking or 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.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). Many states have enacted laws regulating the 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.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. For example, 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. The CCPA also prohibits discrimination against individuals who exercise their privacy rights, provides for civil penalties for violations and creates a private right of action for certain data breaches. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. 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, impose detailed requirements, for example, 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 by law to represent their interests.

In the ordinary course of business, we 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. 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.

Regulators in the United States are also increasingly scrutinizing certain data transfers and have and may further impose data localization requirements or restrictions on cross-border data transfers. For example, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted and impacts our ability to transfer data in connection with certain transactions or agreements

The CCPA 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, 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 such laws, 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. In addition to data privacy and security laws, we have contractual obligations related to privacy and security.

Complying with our obligations under applicable privacy or security laws, regulations, amendments to or re-interpretations of existing laws and regulations, contracts, and other requirements has in the past and may in the future 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 perceived 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 with whom we work 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), private litigation, fines, audits, inspections, and other penalties (both civil and criminal), as well as 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) have in the past and may in the future increase our costs of doing business. Our personnel use generative artificial intelligence ("AI") and related technologies to perform their work, and the disclosure and use of personal data in connection with AI technologies is or may become subject to various privacy laws and other obligations. Governments have passed and are likely to pass additional laws and regulations relating to AI technologies. Use of such technologies by us (and by the third parties with whom we work) could result in additional compliance costs, regulatory investigations/actions, and lawsuits. If we are unable to use AI technologies, it could make our business less efficient and result in competitive disadvantages.

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. Certain measures also involve increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, continues to significantly impact the health care industry.

There have been amendments and executive, judicial and Congressional challenges to numerous provisions of the ACA. On July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among

other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Further, there has been heightened governmental scrutiny in the U.S. to control the rising cost of healthcare. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Recent actions, for example, include directing agencies to reduce agency workforce and cut programs. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan" to lower government subsidies to private insurance companies and increase healthcare price transparency, among other things. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations.

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. Fulfillment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfill these obligations, or our Notified Body, 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.

In addition, in July 2024, Regulation (EU) 2024/1860 entered into application. The Regulation imposes new manufacturer obligations, including mandatory pre-notification of supply interruptions starting January 10, 2025. In addition, the Regulation introduces the gradual rollout of EUDAMED, the EU's central database for medical devices and diagnostics. Starting from May 28, 2026, the use of the first four modules will become mandatory - actor registration, UDI/Devices registration, notified bodies and certificates, and Market Surveillance. The evolving nature of the EU regulatory environment, including the introduction of these EUDAMED obligations, creates uncertainty for our business, and additional amendments or guidance could further increase compliance burden and may require us to invest in additional systems, process or personnel, which will increase our costs of doing business.

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. On January 12, 2025, Regulation No 2021/2282 entered into application through a phased implementation. Select high-risk medical devices came into scope in 2026. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, and establishes the framework for EU level joint clinical assessments and increased cooperation among Member States on clinical aspects of health technology evaluation. Individual EEA countries will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. 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 additional activities or 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 add options and reimbursement to cover new activities or 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. BARDA is also not obligated to fund any additional activities that may be required to meet licensure requirements. 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, nor are we certain how future U.S. government shutdowns 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, or that we will be able to successfully add new options and reimbursement for incremental activities necessary to meet licensure requirements, or that any such extensions, additions, or changes 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 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 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 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 under the current approved configuration before a redesigned and approved illuminator is available in the U.S. 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 were at one time 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. To provide the best chance of regulatory approval and ultimate market adoption, the JV has decided to generate a body of data using the illuminator and platelet system from Chinese native donors using Chinese collection practices. In order to obtain that regulatory approval, the JV may need to run additional clinical or in vitro studies in China. We cannot provide assurance that the JV will be successful in completing such studies, meeting study endpoints, or be successful in meeting any other requirements or that it will ever receive regulatory approval. If the JV is unable to obtain regulatory approval to sell INTERCEPT in China, our ability to grow our business and achieve significant revenues in China will be negatively impacted. We may be unable to realize a return on any investment in the JV or we may not be able to monetize any profit or otherwise generate meaningful value from our ownership of the JV.

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, or do not renew their supplier agreement, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected. 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. In certain instances, Fresenius has experienced delays and may continue experiencing further delays in the qualification and licensure for its new production facilities, which may adversely impact our ability to continue to grow the platelet and plasma business. Furthermore, continued delays may not result in a favorable return on invested capital, may result in higher costs for both Fresenius and us and may precipitate discussions about the long-term viability of our relationship with Fresenius. 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 first generation illuminator due to obsolescence of certain components. As a result, we will not be able to continue manufacturing the first generation illuminator. We have developed a new illuminator which, though we have received a CE Certificate of Conformity under the MDR and affixed the CE Mark, may take an extended period of time to obtain wide-spread regulatory approval in regions that do not recognize the CE Mark. Novel product launches are susceptible to unknown risks and failures identified after they are commercially launched. Should we be unable to timely, cost effectively or sufficiently resolve any known or to be identified issues with new products, including the new LED-based illuminator, our market uptake may be impaired and we would need to service accounts with the first generation illuminator. Until such time as we obtain wide-spread 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, software bugs or performance issues, 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 received a CE Certificate of Conformity under the MDR and affixed the CE Mark to the new LED-based illuminator, until we obtain additional regulatory approvals, sales of illuminators will be limited to the quantity of the current model illuminator that we have on hand in regions that do not recognize the CE Mark. 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 new LED-based 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, 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 provide assurance 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 and tariffs, 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.

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 any such conflict 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.

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 qualify a new plastic before running out of the existing material or if the existing material is defective or otherwise encounters quality issues, we may not be able to fulfill customer orders. 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 to obtain CE Certificates of Conformity and affix the CE Mark 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 new MDR application and would also increase if existing clinical data is insufficient for us to potentially obtain approval of 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 at times had been able to generate a sufficient amount of revenue and generate positive net cash flows from operations, we may be unable to achieve those results in the future. If we are unable 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 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 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 may 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 tariffs and the threat of potential new or increased 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 prior stimulus programs, the U.S. and many countries have experienced 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. Furthermore, certain components and values of our products are subject to import tariffs which raises our overall cost of goods sold. We may not be able to offset price increases from vendors or the impact of tariffs 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 to obtain 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 a CE Certificate of Conformity following successful completion of our MDR application and our 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 potentially obtain approval of 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, 2025, our total indebtedness under our Term Loan Credit Agreement and Revolving Loan Credit Agreement was approximately $83.9 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 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 provide assurance 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, import tariffs, 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 larger regional conflict may affect our business. We understand that certain of our products were at one time prohibited to be sold under U.S. sanctions against Russia. While a license exception now permits the continued sale of our products ensuring that Russian and Belarusian patients can receive INTERCEPT products, we cannot provide assurance that the license exception will continue to be effective for an extended period of time, if at all. Additionally, 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 Trump administration has imposed tariffs on imports, and other countries have responded with retaliatory tariffs on certain U.S. exports. Given the volatility and uncertainty regarding the scope and duration of import tariffs and other aspects of U.S. and foreign government trade policies, we cannot predict what effects these tariffs and potential additional tariffs will ultimately have

on our business. However, we expect that these tariffs and other trade restrictions will increase our operating costs, reduce our gross margins or cause us to use more cash than we have contemplated. While we have currently chosen to pass on most tariff costs to our customers, the economic value proposition that customers consider when using INTERCEPT may be adversely impacted and our ability to retain and expand customer use of INTERCEPT may be adversely impacted. See "Risks associated with our operations outside of the United States could adversely affect our business."

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 U.S. and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariff and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods, including biomedical products and their components. In particular, we rely on suppliers in the EU for our commercial INTERCEPT kits and

components of our INTERCEPT kits. We conduct our business globally and our operations, including third-party suppliers, span multiple countries outside the U.S. The ongoing trade tensions between the U.S. and other jurisdictions have resulted in multiple rounds of tariffs and anticipated tariffs affecting manufacturing equipment and related supplies. Should such tariffs persist or increase, they would result in additional costs to our business including costs with respect to the raw materials on which our business depends, and will generally increase our manufacturing costs. In addition, such tariffs would increase our supply chain complexity and could also potentially disrupt our existing supply chain. Other governments have imposed and may continue to impose retaliatory tariffs, trade restrictions, or trade barriers on our products, which could impose additional costs and complexity on our business.

We anticipate that our margins may continue to be adversely affected, depending on the ultimate scope and duration of the tariffs imposed. While we have sought to increase prices for many of our products as a result of such tariffs, such price adjustments could reduce the competitiveness of our products. Additionally, such tariffs could affect imports of our products and raw materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by other countries, including restricted access to raw materials used in our products, further disrupting our supply chain and increasing our costs. Given the nature of our products, relocating our manufacturing supply in response to tariffs and other trade restrictions would be a complex, costly and time-consuming process, making it difficult for us to react quickly to a rapidly changing environment. In this regard, it would take a significant amount of time and expense to implement and execute the necessary technology transfer to, and to qualify, new suppliers for our products. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet the FDA's or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, which could negatively impact our anticipated revenues.

Given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results in uncertain and could be significant. In any event, further trade restrictions and export regulations, or new or increased tariffs, including retaliatory measures, could increase our supply chain complexity and our manufacturing costs, decrease our margins, reduce the competitiveness of our products, or restrict our ability to sell our products or purchase necessary equipment and supplies. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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.

Disruptions or other compromises of information technology systems or actual or perceived breaches of data security could adversely affect our business.

In the ordinary course of business, we (and the third parties with whom we work) process personal data and other sensitive information. 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 information technology, systems and networks (and those of the third parties with whom we work) are potentially vulnerable to a variety of evolving threats, including but not limited to breakdown (e.g., as a result of software or hardware failures), ransomware attacks (which have become increasingly prevalent and severe), supply chain attacks, malicious intrusion and computer viruses and other sources of compromise (including those related to natural disasters), which may result in the impairment of production and key business processes or loss or other compromise of data or information. We and our suppliers are also potentially vulnerable to data security breaches, for example, by intentional or accidental actions or inactions or personnel or others. These threats may come from a wide variety of actors, such as traditional hackers, internal and external personnel, and state-sponsored actors. 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. Such breaches and other compromises could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal data (including sensitive personal data) of our employees, clinical trial patients, distributors, customers and others. Remote work has also increased risks to relevant information technology systems and data.

We are and may become subject to contractual, regulatory, and other legal requirements that obligate us to use industry-standard or reasonable security measures to safeguard personal data. 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. 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.

Litigation, government investigations, enforcement actions, and other legal or regulatory actions resulting from actual or perceived security incidents or other compromises may adversely affect our business, including through financial costs, reputational harm, and other negative consequences. For example, actual or perceived unauthorized access to our platform, systems, networks, or physical facilities, or those of third parties with whom we work, 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.

Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Our reliance on third parties introduces additional cybersecurity risks and vulnerabilities. For example, 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 sources of compromise 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 (or the failure to appropriately notify in the event of a security breach) could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs.

Any such breaches of security or other compromise 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 or other compromise 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.

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 when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. 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 $2.19 on December 17, 2025, and a low of $1.16 on August 20, 2025, in the year ended December 31, 2025. 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 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, though there continues to be more supply than demand for office space in the San Francisco Bay Area. 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 in our effort 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, "D*isruptions or other compromises of information technology systems or actual or perceived 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 27 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 25 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 5, 2026, we had 113 holders of record of our common stock.

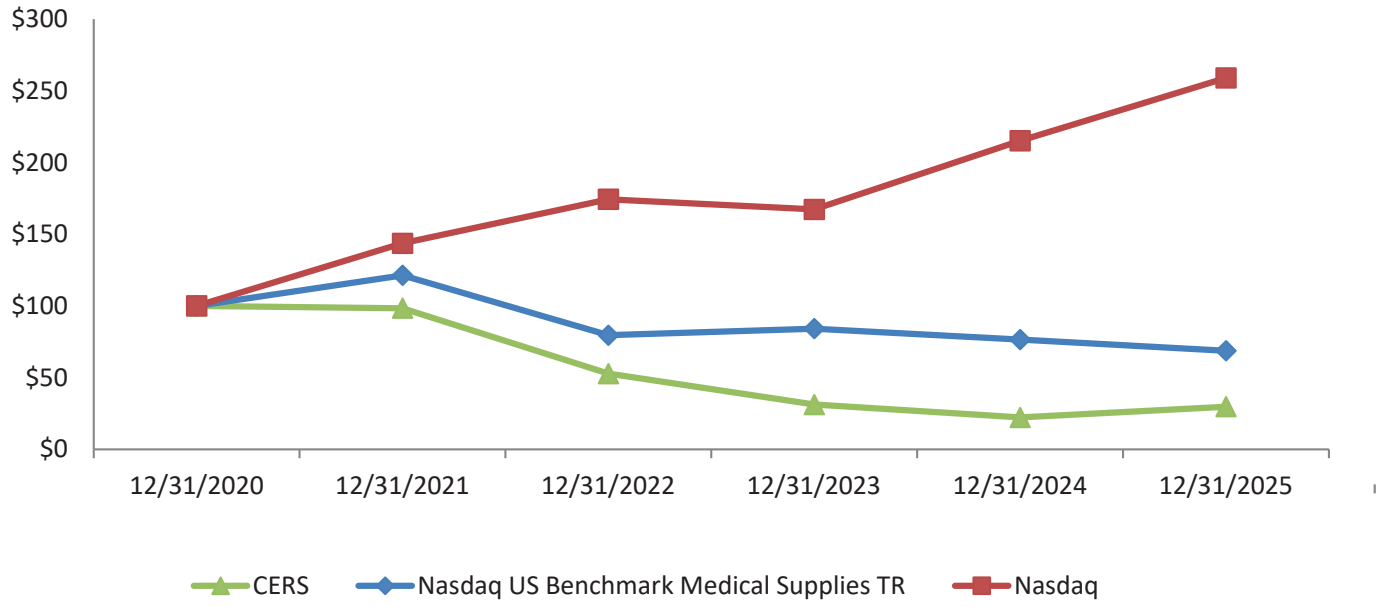
Dividends

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, 2020, and tracked the performance through December 31, 2025, 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,					
	2020	2021	2022	2023	2024	2025
Cerus Corporation	$ 100.00	$ 98.41	$ 52.75	$ 31.21	$ 22.25	$ 29.77
Nasdaq US Benchmark Medical Supplies TR	100.00	121.33	79.56	84.17	76.54	68.69
Nasdaq	100.00	143.64	174.36	167.30	215.22	259.03

[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, 2025. Operating results for the year ended December 31, 2025, 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, 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 successful completion of the conformity assessment and issuance of a CE Certificate of Conformity. In collaboration with TÜV-SÜD, we developed a plan for resubmission of our application and identified a new Competent Authority. We revised our MDR application to address the questions raised by CBG and submitted a new MDR application for the red blood cell system to TÜV-SÜD. In July 2025, we announced that TÜV-SÜD completed their clinical assessment of our new MDR application and transferred information regarding the active substances, or API, to the identified competent authority, the State Institute for Drug Control, or SÚKL. After discussions with TÜV-SÜD, we decided to transfer the review of the API from SÚKL to the French National Agency for Medicines and Health Products Safety, or ANSM. We cannot predict if or when a decision concerning certification would occur. In addition, as a result of the resubmission 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. In addition, in the first quarter of 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. 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, 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. 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, we anticipate that additional clinical trial data will be required to supplement our two Phase 3 clinical trials, ReCePI and RedeS. Enrollment of the RedeS clinical trial was completed in 2025 and we anticipate the completion of the trial in the second half of 2026. Discussion of the planned PMA module submissions with the FDA will not occur prior to the completion of the RedeS trial. 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 provide assurance 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 generate the additional 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. 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 are also planning a prospective, open-label, controlled Phase 2 study designed to determine whether INTERCEPT RBC transfusions into patients with pre-existing antibodies to INTERCEPT RBCs will result in increased antibody titer indicative of a secondary immune response. Subjects will have samples drawn pre-transfusion and over 90-days post transfusion to detect responses to INTERCEPT RBC. Clinical evidence of hemolysis will be evaluated using routine laboratory testing. If treatment emergent antibody reactions associated with hemolysis are observed, 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.

We have two 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 agreement entered in June 2016, or the 2016 BARDA Agreement, currently expires in September 2026 and the agreement entered in September 2024, or the 2024 BARDA Agreement, currently expires in September 2030. The ReCePI study was funded and the RedeS and other studies are being funded as part of our 2016 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 2024 BARDA Agreement or if we are unable to add additional options and respective reimbursement amounts to fund further activities that may be required to meet licensure requirements, we will need to self-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 experienced an acceleration in IFC kit sales to blood centers and a shift away from direct sales to hospitals. We expect this trend to continue and our IFC sales will predominately be kit sales to blood centers.

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 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 may opportunistically seek access to the equity capital markets to support our development efforts and operations, including through the Controlled Equity Offering℠ Sales Agreement, as amended, 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 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 experienced 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 tariffs imposed by the Trump administration and retaliatory tariffs imposed by China and other countries. Additionally, 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 resubmission of our MDR application and, as discussed above, transferring the review of the API from SÚKL to ANSM. 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, have adequate resources to assist customers with implementing the INTERCEPT Blood System, or need to increase prices to address existing and potential new or increased tariffs, 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 and certain in-country approvals 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, of which we have a limited number of devices available. Due to obsolescence of components of the existing illuminator, there is also a limited period of time during which we can continue to support and maintain the devices.

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 this agreement, we are reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. As of December 31, 2025, BARDA has committed to reimburse certain of our expenses related to the clinical development of the red blood cell system during a base period and under exercised 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. 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 2024, we entered into 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 to $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 standardized indirect rates, should the U.S. Federal Government impose similar rate 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 were reimbursed and would recognize revenue as qualified direct contract costs were incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permitted recovery of fringe benefits, overhead and general and administrative expenses. The agreement, which ended in September 2025, had a total contract value of $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 ("Lyo-Cryo") to treat bleeding due to trauma. In May 2023, we entered into an amendment to extend the agreement to February 2027 and increased the total contract value from $9.1 million to $17.8 million. In July 2025, we entered into an additional amendment with the DoD to extend the agreement to September 2028 to incorporate the Lyo-Cryo manufacturing advancement project phase III clinical study, which increased the total contract value by $7.2 million to $25.0 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, 2025 and December 31, 2024 items and year-to-year comparisons between 2025 and 2024, respectively. Discussions of 2023 items and year-to-year comparisons between 2024 and 2023 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, 2024, filed with the SEC on February 26, 2025.

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 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. 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.

Results of Operations

Years Ended December 31, 2025, 2024 and 2023

Revenue

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2025	2024	2023	2025 to 2024	2024 to 2023
Product revenue	$ 206,133	$ 180,270	$ 156,367	14%	15%
Government contract revenue	27,665	21,051	30,430	31%	(31%)
Total revenue	$ 233,798	$ 201,321	$ 186,797	16%	8%

Product revenue increased during the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to year-over-year sales volume increase of disposable platelet kit sales and IFC 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 and from sales of our IFC product 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 increased during the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to an increase in revenue from BARDA in 2025 relative to the same period in the prior year. The increase in revenue from BARDA is primarily due to the 2024 BARDA Agreement executed in the fourth quarter of 2024. We anticipate that government contract revenue will decrease in future periods due to the 2016 BARDA Agreement ending in September 2026.

Cost of Product Revenue

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

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2025	2024	2023	2025 to 2024	2024 to 2023
Cost of product revenue	$ 93,845	$ 80,748	$ 69,967	16%	15%

Cost of product revenue increased during the year ended December 31, 2025, compared to the year ended December 31, 2024, approximately 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 approximately 55% during both the years ended December 31, 2025 and December 31, 2024. 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. Geographic mix and by extension foreign exchange rates along with the impact of enacted import tariffs had an adverse effect on our gross margins. 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, import tariffs, 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)	2025	2024	2023	2025 to 2024	2024 to 2023
Research and development	$ 67,720	$ 58,907	$ 67,639	15%	(13%)

Research and development expenses increased during the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily driven by costs related to red blood cells for work performed under our BARDA agreements, workforce related costs, and costs to support our new LED-based illuminator, partially offset by the Employee Retention Credit refund received in 2025.

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, pursuing potential regulatory approvals for the LED illuminator in territories where the platelet and plasma systems are approved, 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 the new MDR application for our red blood cell system in the EU, new product development and product enhancements, including potential new label claims, further design efforts on our new LED-based illuminator for the U.S. market and ongoing software development, 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 existing and potential new or increased tariffs 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)	2025	2024	2023	2025 to 2024	2024 to 2023
Selling, general and administrative	$ 80,914	$ 75,891	$ 75,516	7%	0%

Selling, general, and administrative expenses increased during the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily driven by increased workforce costs, partially offset by the Employee Retention Credit refund received in 2025.

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):

(in thousands, except percentages)	Year Ended December 31, 2025	2024	2023	% Change 2025 to 2024	2024 to 2023
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.

(in thousands, except percentages)	Year Ended December 31, 2025	2024	2023	% Change 2025 to 2024	2024 to 2023
Foreign exchange (loss) gain	$ (1,275)	$ 370	$ (648)	(445%)	(157%)
Interest expense	(8,343)	(8,877)	(8,386)	(6%)	6%
Other income, net	3,016	1,976	1,765	53%	12%
Total non-operating expense, net	$ (6,602)	$ (6,531)	$ (7,269)	1%	(10%)

Foreign Exchange (Loss) Gain

We had foreign exchange loss during the year ended December 31, 2025, compared to foreign exchange gain during the year ended December 31, 2024. These were primarily due to foreign exchange variations between the Euro and the U.S. dollar.

Interest Expense

Interest expense decreased during the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to the decrease 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, Net

Other income, net increased during the year ended December 31, 2025, compared to the year ended December 31, 2024 primarily due to the increase of interest income from our investments in marketable securities.

Provision for Income Taxes

(in thousands, except percentages)	Year Ended December 31, 2025	2024	2023	% Change 2025 to 2024	2024 to 2023
Provision for income taxes	$ 354	$ 205	$ 325	73%	(37%)

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, 2025, 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, 2025.

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, 2025 and December 31, 2024, we had the following cash and cash equivalents, short-term investments and restricted cash (in thousands):

	December 31, 2025	December 31, 2024
Cash and cash equivalents	$ 19,961	$ 20,266
Short-term investments	62,918	60,186
Restricted cash	639	1,095
Total	$ 83,518	$ 81,547

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, 2025 and December 31, 2024, we had the following indebtedness (in thousands):

	December 31, 2025	December 31, 2024
Debt – current	$ 43,343	$ 19,297
Debt – non-current	40,545	64,862
Total	$ 83,888	$ 84,159

Operating Activities

	Year Ended	
(in thousands)	**December 31, 2025**	**December 31, 2024**
Net cash provided by operating activities	$ 4,837	$ 11,359

The decrease in net cash provided by operating activities for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily related to the increase in inventory related purchases partially offset by the reduction in our net loss and a net increase in cash related to the timing of cash collections and payments compared to the same period in 2024.

Investing Activities

	Year Ended	
(in thousands)	**December 31, 2025**	**December 31, 2024**
Net cash used in investing activities	$ (6,165)	$ (8,130)

The decrease in net cash used in investing activities for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to higher proceeds from the maturity and sale of our investments offset by increased investment in capital expenditures compared to the same period in 2024.

Financing Activities

	Year Ended	
(in thousands)	**December 31, 2025**	**December 31, 2024**
Net cash provided by financing activities	$ 231	$ 4,964

The decrease in net cash provided by financing activities for the year ended December 31, 2025 was primarily due to proceeds from the Term Loan Credit Agreement during the year ended December 31, 2024. 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, 2025**	**December 31, 2024**
Working capital	$ 73,214	$ 88,890

Working capital decreased as of December 31, 2025, compared to December 31, 2024, primarily due to net increases in accounts payable and accrued liabilities as a result of the timing of payments to our vendors offset by an increase in inventory and due to the reclassification of $24.3 million of long-term debt to short-term due to our amended Term Loan Credit agreement. Contract assets related to DoD of $0.4 million and zero as of December 31, 2025 and December 31, 2024, respectively, are excluded from working capital. Contract liabilities related to DoD of zero and $0.5 million as of December 31, 2025 and December 31, 2024, 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 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 in and 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 may 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, 2025, we did not sell shares of our common stock under the 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 a CE Certificate of Conformity following successful completion of our MDR application and the submission of a new MDR application and would also increase if existing clinical data is insufficient for us to potentially obtain approval of 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, 2025.

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, 2025, 2024 and 2023. 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, 2025, we held cash, cash equivalents, and short-term investments of $82.9 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, 2025, was 4.2%.

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 $19.0 million as of December 31, 2025, 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 2025 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, 2025, would have negatively impacted our annual financial results by $1.2 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, 2025, 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, 2025, 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, 2025, 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, 2025, 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, 2025, 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, 2025 and 2024, 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, 2025, and the related notes and our report dated March 2, 2026 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 Francisco, California

March 2, 2026

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

Insider Trading Arrangements

On November 14, 2025, 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 55,225 shares of the Company's stock until March 20,2026.

On November 21, 2025, 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 262,869 shares of the Company's stock until November 13,2026.

On December 15, 2025, Vivek Jayaraman, Chief Operating 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 300,000 shares of the Company's stock until March 16, 2027.

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 2026 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*

Other than as set forth below, 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(30)††	Amendment #2 to Amended and Restated Supply Agreement, effective January 1, 2025, by and between Cerus Corporation and Purolite Corporation.
10.4(29)††	Second Amended and Restated Supply and Manufacturing Agreement, dated December 9, 2024, by and between Cerus Corporation and Porex Corporation.
10.5(27)††	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.6(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

10.7(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.

10.8(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.

10.9(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.

10.10(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.

10.11†(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

10.12(13) † Lease, dated February 16, 2018, between Cerus Corporation and 1200 Concord LLC.

10.13(14) First Amendment to Lease, dated May 11, 2018, between Cerus Corporation and 1200 Concord LLC.

10.14(15) Second Amendment to Lease, dated August 10, 2018, between Cerus Corporation and 1200 Concord LLC.

10.15(16) Third Amendment to Lease, dated October 5, 2018, between Cerus Corporation and 1200 Concord LLC.

10.16(16) Fourth Amendment to Lease, dated November 30, 2018, between Cerus Corporation and 1200 Concord LLC.

Employment Agreements or Offer Letters

10.17(5)* Employment Letter, by and between Cerus Corporation and William M. Greenman, dated May 12, 2011.

10.18(8)* Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.

10.19(14)* Amendment to Employment Letter, by and between Cerus Corporation and William M. Greenman, dated April 17, 2018.

10.20(4)* Employment Letter for Kevin D. Green, dated May 1, 2009.

10.21(14)* Amendment to Employment Letter, by and between Cerus Corporation and Kevin Green, dated April 17, 2018.

10.22(8)* Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.

10.23(10)* Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPath, dated May 12, 2015.

10.24(12)* Employment Letter, by and between Cerus Corporation and Vivek Jayaraman, dated May 31, 2016.

Stock Plans and Related Forms

10.25(28)* Amended and Restated 1996 Employee Stock Purchase Plan, effective June 3, 2020.

10.26(24)* Amended and Restated 2008 Equity Incentive Plan, effective June 7, 2023.

10.27(6)* Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.

10.28(6)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.
10.29(6)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
10.30(11)*	Cerus Corporation Inducement Plan.
10.31(11)*	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Cerus Corporation Inducement Plan.
10.32(11)*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Cerus Corporation Inducement Plan.
10.33(14)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan, amended as of April 17, 2018.
10.34(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.
10.35(30)*	Cerus Corporation Amended and Restated 2024 Equity Incentive Plan, effective June 3, 2025.
10.36(28)*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the 2024 Equity Incentive Plan.
	Other Compensatory Plans or Agreements
10.37(8)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.38(14)*	Cerus Corporation Change of Control Severance Benefit Plan, amended as of April 17, 2018.
10.39(3)*	Form of Severance Benefits Agreement.
10.40*	Amended and Restated Non-Employee Director Compensation Policy, effective December 12, 2025.
10.41(17)*	Nonqualified Plan Service and Expense Agreement, by and between Cerus Corporation and Principal Life Insurance Company, dated May 21, 2020.
10.42(17)*	The Executive Nonqualified Excess Plan Adoption Agreement, dated May 21, 2020.
	Other Material Agreements
10.43(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.44(2)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.45(18)	Controlled Equity Offering^{SM} Sales Agreement, dated December 11, 2020, by and among Cerus Corporation, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated.
10.46(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.
10.47(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.
10.48(29)††	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(29)	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(31)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1(29)	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) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024.

(30) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025.

(31) 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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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, 2025, 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 March 2, 2026 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, 2025, the Company recognized $206.1 million of product revenue. As discussed in Note 2 to the consolidated financial statements, product revenue from the sale of illuminators, disposable kits (platelet and plasma systems), INTERCEPT Fibrinogen Complex, spare parts and storage solutions are recognized upon the transfer of control of the products to the customer for an amount that reflects the consideration which the Company expects to receive in exchange for those products. Auditing the Company's revenue recognition was challenging due to the volume of transactions across multiple geographies and customer types, including hospitals, blood centers, and government agencies. This included assessing whether revenue was recognized at the appropriate point in time based on transfer of control and verifying the accuracy of recorded transactions.
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 testing the automated controls which are applicable to processing of all transactions.

To test product revenue, our audit procedures included, among others, performing sample testing of selected sales transactions, and tracing such transactions to supporting third party documentation, and performing analytical procedures to trace revenue journal entries to accounts receivable and cash collections. We also tested a sample of cash collections to source documents.

/s/ Ernst & Young LLP

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

San Francisco, California

March 2, 2026

CERUS CORPORATION

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,961	$ 20,266
Short-term investments	62,918	60,186
Accounts receivable, net	30,374	29,777
Current inventories	56,101	38,150
Prepaid and other current assets	5,030	3,643
Total current assets	174,384	152,022
Non-current assets:		
Property and equipment, net	9,204	7,154
Operating lease right-of-use assets	10,124	8,384
Goodwill	1,316	1,316
Restricted cash	639	1,095
Non-current inventories	15,143	14,145
Other assets	11,049	16,801
Total assets	$ 221,859	$ 200,917
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 28,008	$ 21,695
Accrued liabilities	25,271	18,943
Debt – current	43,343	19,297
Operating lease liabilities – current	2,905	2,275
Deferred revenue	1,274	1,398
Total current liabilities	100,801	63,608
Non-current liabilities:		
Debt – non-current	40,545	64,862
Operating lease liabilities – non-current	10,153	11,663
Other non-current liabilities	5,395	3,888
Total liabilities	156,894	144,021
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized, issuable in series; zero shares issued and outstanding at December 31, 2025 and 2024, respectively	—	—
Common stock, $0.001 par value; 400,000 and 400,000 shares authorized; 192,142 and 185,766 shares issued and outstanding at December 31, 2025 and 2024, respectively	192	186
Additional paid-in capital	1,145,343	1,121,887
Accumulated other comprehensive loss	(156)	(400)
Accumulated deficit	(1,081,155)	(1,065,528)
Total Cerus Corporation stockholders' equity	64,224	56,145
Noncontrolling interest	741	751
Total liabilities and stockholders' equity	$ 221,859	$ 200,917

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

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

	Year Ended December 31,		
	2025	2024	2023
Product revenue	$ 206,133	$ 180,270	$ 156,367
Cost of product revenue	93,845	80,748	69,967
Gross profit on product revenue	112,288	99,522	86,400
Government contract revenue	27,665	21,051	30,430
Operating expenses:			
Research and development	67,720	58,907	67,639
Selling, general and administrative	80,914	75,891	75,516
Restructuring	—	—	3,728
Total operating expenses	148,634	134,798	146,883
Loss from operations	(8,681)	(14,225)	(30,053)
Non-operating expense, net:			
Foreign exchange (loss) gain	(1,275)	370	(648)
Interest expense	(8,343)	(8,877)	(8,386)
Other income, net	3,016	1,976	1,765
Total non-operating expense, net	(6,602)	(6,531)	(7,269)
Loss before income taxes	(15,283)	(20,756)	(37,322)
Provision for income taxes	354	205	325
Net loss	(15,637)	(20,961)	(37,647)
Net loss attributable to noncontrolling interest	(10)	(43)	(158)
Net loss attributable to Cerus Corporation	$ (15,627)	$ (20,918)	$ (37,489)
Net loss per share attributable to Cerus Corporation			
Basic and diluted	$ (0.08)	$ (0.11)	$ (0.21)
Weighted average shares outstanding:			
Basic and diluted	190,594	184,563	180,270

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2025	2024	2023
Net loss	$ (15,637)	$ (20,961)	$ (37,647)
Other comprehensive income (loss)			
Foreign currency translation adjustment	19	(14)	(85)
Unrealized gains on available-for-sale investments, net of taxes	225	888	1,598
Comprehensive loss	(15,393)	(20,087)	(36,134)
Comprehensive loss attributable to noncontrolling interest	(10)	(43)	(158)
Total comprehensive loss attributable to Cerus Corporation	$ (15,383)	$ (20,044)	$ (35,976)

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Interest	Equity
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
Issuance of common stock from vesting of restricted stock units and ESPP purchases	6,376	6	589	—	—	—	595
Stock-based compensation	—	—	22,867	—	—	—	22,867
Other comprehensive income	—	—	—	244	—	—	244
Net loss	—	—	—	—	(15,627)	(10)	(15,637)
Balance at December 31, 2025	192,142	$ 192	$1,145,343	$ (156)	$(1,081,155)	$ 741	$ 64,965

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2025	2024	2023
Operating activities			
Net loss	$ (15,637)	$ (20,961)	$ (37,647)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,426	1,855	2,599
Stock-based compensation	22,867	22,867	20,271
Non-cash operating lease cost	2,532	2,482	2,308
Net (gain) loss on sale of available-for-sale securities	(6)	7	54
Unrealized gain on investments	(204)	(135)	(170)
Loss on disposal of fixed assets	—	3	65
Impairment charges for facilities consolidation	—	—	1,698
Non-cash interest expense	398	398	374
Foreign currency remeasurement loss (gain)	290	(388)	(685)
Changes in operating assets and liabilities:			
Accounts receivable	(396)	5,504	(1,102)
Inventories	(14,682)	7,030	(14,947)
Prepaid and other assets	(1,627)	(3,025)	(994)
Accounts payable	5,725	(1,477)	(7,335)
Accrued liabilities and other non-current liabilities	4,275	(2,198)	(9,070)
Deferred revenue	(124)	(603)	1,413
Net cash provided by (used in) operating activities	4,837	11,359	(43,168)
Investing activities			
Capital expenditures	(3,729)	(2,837)	(4,597)
Purchases of investments	(42,777)	(42,975)	(2,486)
Proceeds from maturities and sale of investments	40,341	37,682	15,707
Net cash (used in) provided by investing activities	(6,165)	(8,130)	8,624
Financing activities			
Net proceeds from equity incentives	595	804	925
Net costs from public offerings	(35)	(137)	(175)
Net (payments on) proceeds from revolving line of credit	(329)	(703)	5,091
Proceeds from loans, net of issuance costs	—	5,000	4,832
Net cash provided by financing activities	231	4,964	10,673
Effect of exchange rates on cash, cash equivalents, and restricted cash	336	(191)	(128)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(761)	8,002	(23,999)
Cash, cash equivalents, and restricted cash, beginning of period	21,361	13,359	37,358
Cash, cash equivalents, and restricted cash, end of period	$ 20,600	$ 21,361	$ 13,359
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 8,521	$ 9,295	$ 9,210
Cash paid for income taxes	301	356	322

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").

Reclassifications

Certain items related to the categorization of product revenue by geographical location in the prior period have been reclassified to conform to the current period presentation. These reclassifications did not have any effect on prior year total revenue, net loss, or shareholders' equity.

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 of available-for-sale securities and accounts receivable, 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, 2025, 2024 and 2023, was as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Product revenue:			
North America	$ 135,875	$ 119,978	$ 98,550
Europe, Middle East and Africa	67,370	56,327	55,008
Other	2,888	3,965	2,809
Total product revenue	$ 206,133	$ 180,270	$ 156,367

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. As of December 31, 2025 and December 31, 2024, the Company had $0.4 million and zero, respectively, of contract assets related to DoD included within "Prepaid and other current assets" on the Company's consolidated balance sheets.

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, 2025 and December 31, 2024, the Company had zero and $0.5 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.

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, 2025 and December 31, 2024, $3.2 million and $2.8 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, 2025 and December 31, 2024, $3.8 million and $3.1 million, respectively, were included in "Other non-current liabilities", and $0.2 million and $0.2 million, respectively, were included in "Accrued liabilities" on the Company's consolidated balance sheets, which represent 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, 2025 and December 31, 2024, the Company's "Restricted cash" consisted primarily of a letter of credit relating to an office building lease. As of December 31, 2025 and December 31, 2024, 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, 2025, 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 three and one customer(s) that accounted for more than 10% of the Company's outstanding accounts receivable at December 31, 2025 and December 31, 2024, respectively. These customers cumulatively represented approximately 50% and 37% of the Company's outstanding accounts receivable at December 31, 2025 and December 31, 2024, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At December 31, 2025 and December 31, 2024, 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 fourth quarter of 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, 2025 and December 31, 2024, the Company had $0.6 million and $0.9 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, 2025, 2024 and 2023, the Company had non-cash purchases of capital expenditures of $0.6 million, less than $0.1 million and $0.8 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, 2025, 2024 and 2023, 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 awards 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 2005 through 2024, and California tax returns filed for years through 2024, 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, 2025, 2024 and 2023, 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, 2025, 2024 and 2023 (in thousands, except per share amounts):

	Year Ended December 31,		
	2025	2024	2023
Numerator for Basic and Diluted:			
Net loss attributable to Cerus Corporation	$ (15,627)	$ (20,918)	$ (37,489)
Denominator:			
Basic weighted average number of shares outstanding	190,594	184,563	180,270
Effect of dilutive potential shares	—	—	—
Diluted weighted average number of shares outstanding	190,594	184,563	180,270
Net loss per share attributable to Cerus Corporation:			
Basic and diluted	$ (0.08)	$ (0.11)	$ (0.21)

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, 2025, 2024 and 2023 (shares in thousands):

	Year Ended December 31,		
	2025	2024	2023
Weighted average number of anti-dilutive potential shares:			
Stock options	10,738	12,993	14,896
Restricted stock units	18,608	13,880	10,192
Employee stock purchase plan rights	300	349	396
Total	29,646	27,222	25,484

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, 2025 and December 31, 2024, 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, 2025 and December 31, 2024.

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 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, with the option to apply it retrospectively, for annual periods beginning after December 15, 2024. The Company adopted the new accounting standard on a prospective basis effective January 1, 2025. The adoption of this ASU had no material impact on the Company's consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

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.

In December 2025, the FASB issued ASU 2025-10, *Accounting for Government Grants Received by Business Entities*, to establish guidance on the recognition, measurement, and presentation of government grants received by business entities. The new guidance leverages the principles in the accounting framework for government assistance in IFRS, specifically IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*; makes certain targeted improvements; and modifies certain of the existing disclosure requirements in ASC 832, *Government Assistance*. The new guidance is effective for the Company's annual periods beginning after December 15, 2028, including interim periods within, with early adoption permitted. The guidance can be applied on a modified prospective basis, a modified retrospective basis, or a full retrospective basis. The Company is currently in the process of evaluating the impact of this pronouncement on the Company's related disclosures.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements (ASU 2025-11)*, to clarify interim disclosure requirements and the applicability of Topic 270. The guidance will be effective for interim periods beginning January 1, 2028. Early adoption is permitted. Upon adoption, the guidance can be applied prospectively or retrospectively. 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, 2025 (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$ 1,810	$ —	$ —	$ 1,810
United States government agency securities	23,431	49	(1)	23,479
Corporate debt securities	36,768	55	(1)	36,822
Mortgage-backed securities	2,795	7	(185)	2,617
Total available-for-sale securities	$ 64,804	$ 111	$ (187)	$ 64,728

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	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

Available-for-sale securities at December 31, 2025 and December 31, 2024, consisted of the following by contractual maturity (in thousands):

	December 31, 2025		December 31, 2024	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$ 46,128	$ 46,209	$ 38,174	$ 38,173
Greater than one year and less than five years	18,676	18,519	24,086	23,786
Total available-for-sale securities	$ 64,804	$ 64,728	$ 62,260	$ 61,959

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, 2025					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 3,203	$ (1)	$ —	$ —	$ 3,203	$ (1)
United States government agency securities	—	—	260	(1)	260	(1)
Mortgage-backed securities	214	(1)	2,219	(184)	2,433	(185)
Total	$ 3,417	$ (2)	$ 2,479	$ (185)	$ 5,896	$ (187)

	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)

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, 2025, 2024 and 2023, 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 years ended December 31, 2025, 2024 and 2023, respectively. The Company recorded less than $0.1 million of gross realized losses from the sale or maturity of available-for-sale investments during the years ended December 31, 2025, 2024 and 2023, 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, 2025, 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, 2025 (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	$ 1,810	$ 1,810	$ —	$ —
United States government agency securities	Short-term investments	23,479	—	23,479	—
Corporate debt securities	Short-term investments	36,822	—	36,822	—
Mortgage-backed securities	Short-term investments	2,617	—	2,617	—
Total short-term investments		$ 64,728	$ 1,810	$ 62,918	$ —

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 Company did not have any transfers among fair value measurement levels during the years ended December 31, 2025 and December 31, 2024.

Note 4. Inventories

Inventories at December 31, 2025 and December 31, 2024, consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Raw materials	$ 8,499	$ 8,641
Work-in-process	22,687	22,522
Finished goods	40,058	21,132
Total inventories	71,244	52,295
Less: non-current inventories	15,143	14,145
Total current inventories	$ 56,101	$ 38,150

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, 2025 and December 31, 2024, consisted of the following (in thousands):

	December 31,	
	2025	2024
Construction-in-progress	$ 2,901	$ —
Machinery and equipment	6,387	5,949
Computer equipment and software	3,593	3,969
Furniture and fixtures	1,859	2,008
Leasehold improvements	12,189	12,192
Consigned equipment	1,948	1,475
Total property and equipment, gross	28,877	25,593
Accumulated depreciation and amortization	(19,673)	(18,439)
Total property and equipment, net	$ 9,204	$ 7,154

Depreciation and amortization expense related to property and equipment, net was $2.0 million, $2.0 million and $2.4 million for the years ended December 31, 2025, 2024 and 2023, 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 years ended December 31, 2025 and 2024.

Note 6. Accrued Liabilities

Accrued liabilities at December 31, 2025 and December 31, 2024, consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued compensation and related costs	$ 18,261	$ 11,939
Accrued professional services	3,610	3,406
Other accrued expenses	3,400	3,598
Total accrued liabilities	$ 25,271	$ 18,943

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 year 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, 2024	Restructuring Charge	Cash Payments	Balance at December 31, 2025
One-time termination benefits	$ —	$ —	$ —	$ —
Other	206	—	(26)	180
Total	$ 206	$ —	$ (26)	$ 180

Note 8. Debt

Debt at December 31, 2025, consisted of the following (in thousands):

	Principal	Unamortized Discount	Net Carrying Value
Term Loan	$ 65,000	$ (80)	$ 64,920
Revolving Loan	18,968	—	18,968
Total debt	83,968	(80)	83,888
Less: current portion	43,343	—	43,343
Non-current portion	$ 40,625	$ (80)	$ 40,545

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

Principal, interest and fee payments on the Term Loan Credit Agreement (as defined below) at December 31, 2025, are expected to be as follows (in thousands):

Year ended December 31,	Principal	Interest and Fees	Total
2026	$ 24,375	$ 6,181	$ 30,556
2027	32,500	2,795	35,295
2028	8,125	1,448	9,573
Total	$ 65,000	$ 10,424	$ 75,424

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"), was 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, 2025 is approximately 10.7%.

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, 2025 and December 31, 2024, the Company had borrowed $19.0 million and $19.3 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, 2025. 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 2031, 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 year 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,		
	2025	2024	2023
Cash payments for operating leases	$ 3,726	$ 3,684	$ 4,188
Right-of-use assets obtained in exchange for operating lease obligations	4,125	231	1,476

	December 31, 2025	December 31, 2024
Weighted-average remaining lease term	4.1 years	4.8 years
Weighted-average discount rate	9.0%	8.6%

Future minimum non-cancelable payments under operating leases as of December 31, 2025, were as follows (in thousands):

	Operating Leases
2026	$ 3,749
2027	4,020
2028	3,351
2029	3,392
2030	859
Thereafter	—
Total future lease payments	$ 15,371
Less imputed interest	2,313
Present value of lease liabilities [(1)]	$ 13,058

[(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, 2025, 2024 and 2023, the Company recorded operating lease expenses of $4.0 million, $3.9 million and $3.5 million, respectively. As of December 31, 2025, 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, 2025, the Company had $40.3 million of short-term purchase commitments and $3.0 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 is 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, 2025, no shares of the Company's common stock were sold under the Amended Sales Agreement. At December 31, 2025, 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 of 1986, as amended (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, 2025, the Company had 1.9 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, 2025, 3.2 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 were initially 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 have or 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. In June 2025, the Company's stockholders approved an amendment and restatement of the 2024 Plan that increased the aggregate number of shares of common stock authorized for issuance by 10.0 million shares. 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 two to four years.

At December 31, 2025, the Company had approximately 27.5 million shares of its common stock subject to a combination of outstanding options and unvested RSUs under the Amended 2008 Plan and the 2024 Plan, of which approximately 10.0 million shares and 17.5 million shares were subject to outstanding options and unvested RSUs, respectively. At December 31, 2025, approximately 15.1 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, 2024	12,297	$ 5.10
Granted	—	—
Exercised	—	—
Forfeited/canceled	(2,270)	4.66
Balance at December 31, 2025	10,027	5.20

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, 2024	13,661	$ 2.73
Granted [1]	11,062	1.52
Vested [1]	(5,902)	2.97
Forfeited [1]	(1,317)	2.41
Balance at December 31, 2025	17,504	1.91

[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, 2025, 2024 and 2023, were $8.8 million, $8.4 million and $8.7 million, respectively.

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2025, was as follows (in thousands except weighted average exercise price and remaining contractual term):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2025				
Stock options outstanding	10,027	$ 5.20	3.14	—
Stock options vested and expected to vest	10,027	$ 5.20	3.14	—
Stock options exercisable	9,946	$ 5.19	3.11	—

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, 2025, 2024 and 2023. 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, 2025, 2024 and 2023, was as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Research and development	$ 5,554	$ 5,897	$ 5,823
Selling, general and administrative	17,313	16,970	14,448
Total stock-based compensation expense	$ 22,867	$ 22,867	$ 20,271

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, 2025, 2024 and 2023.

As of December 31, 2025, the Company expects to recognize the remaining unamortized stock-based compensation expense of $0.2 million related to non-vested stock options and $14.2 million related to RSUs, net of estimated forfeitures, over an estimated remaining weighted average period of 0.2 years and 1.0 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 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 fair value of RSUs is measured on the grant date based on the closing fair market value of the Company's common stock. The Company recognizes the grant-date fair value of the stock award as stock-based compensation expense generally 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. For performance-based awards, stock-based compensation expense is recognized over the expected performance achievement period of individual performance milestones when the achievement of each individual performance milestone becomes probable.

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, 2025, 2024 and 2023, was as follows:

	Year Ended December 31,		
	2025	2024	2023
Employee Stock Purchase Plan Rights:			
Expected term (in years)	0.74	0.75	0.75
Estimated volatility	65%	79%	70%
Risk-free interest rate	4.04%	4.66%	5.29%
Expected dividend yield	0%	0%	0%

There were no stock options granted during the years ended December 31, 2025, 2024, and 2023. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2025, 2024 and 2023, was $0.53 per share, $0.92 per share and $0.88 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. In 2025, the Company added an after-tax contribution election which is not eligible for the 401(k) match and is not counted towards the IRS maximum cap that is applicable to pre-tax and Roth contributions.

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, 2025 and December 31, 2024, $2.5 million and $2.4 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, 2025 and December 31, 2024, $0.6 million and $0.1 million, respectively, 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 agreement, which ended in September 2025, had a total contract value of $11.1 million. As of December 31, 2025 and December 31, 2024, zero 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 ("Lyo-Cryo") to treat bleeding due to trauma. In May 2023, the Company and the DoD entered into an amendment to extend the agreement to February 2027 and increased the total contract value from $9.1 million to $17.8 million. In July 2025, the Company and the DoD entered into an additional amendment to extend the agreement to September 2028 to incorporate the Lyo-Cryo manufacturing advancement project phase III clinical study, which increased the total contract value by $7.2 million to $25.0 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 the 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, 2025 and December 31, 2024, $0.4 million and zero, respectively of unbilled amount was included in "Prepaid and other current assets" on the Company's consolidated balance sheets related to DoD. As of December 31, 2025 and December 31, 2024, zero and $1.0 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, 2025 and December 31, 2024, zero and $0.5 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, 2025, 2024 and 2023, was as follows (in thousands):

	2025	2024	2023
Loss before income taxes:			
Domestic	$ (17,709)	$ (21,318)	$ (38,281)
International	2,426	562	959
Loss before income taxes	$ (15,283)	$ (20,756)	$ (37,322)

The provision for income taxes for the years ended December 31, 2025, 2024 and 2023, was as follows (in thousands):

	2025	2024	2023
Provision for income taxes:			
Current:			
Foreign	$ 338	$ 130	$ 285
Federal	—	—	—
State	11	70	36
Total current	349	200	321
Deferred:			
Foreign	—	—	—
Federal	3	3	2
State	2	2	2
Total deferred	5	5	4
Provision for income taxes	$ 354	$ 205	$ 325

A summary of cash paid for income taxes, net of refunds received, for the year ended December 31, 2025 was as follows (in thousands):

	2025
Federal	$ —
State	
Pennsylvania	34
Other states	27
Foreign	
Netherlands	198
France	42
Total cash paid for income taxes, net of refunds	$ 301

Significant components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	2025	2024
Deferred tax assets		
Net operating loss carryforwards	$ 132,585	$ 127,184
Research and development credit carryforwards	31,323	29,739
Capitalized research and development	27,362	35,861
Compensation items	10,425	9,437
Other	14,637	13,933
Total deferred tax assets	216,332	216,154
Less valuation allowance	(214,026)	(214,321)
Net deferred tax assets	2,306	1,833
Deferred tax liabilities		
Other	(236)	(226)
Right of use asset	(2,149)	(1,676)
Total deferred tax liabilities	(2,385)	(1,902)
Less valuation allowance	—	—
Net deferred tax liabilities	$ (79)	$ (69)

A reconciliation of the U.S. Federal statutory tax rate to our 2025 annual tax rate is as follows (in thousands):

	Amount	Tax Rate
U.S. federal statutory tax rate	$ (3,209)	21%
State income tax, net of federal benefit [1]	11	—
Foreign tax effects		
Netherlands		
Foreign currency related items	(222)	2
Other	51	—
Other foreign jurisdictions	(1)	—
Tax Credits		
Federal research credits[2]	(605)	4
Change in valuation allowance	(1,678)	11
Nontaxable or nondeductible items		
Stock compensation[3]	3,501	(23)
Other	(56)	—
Changes in unrecognized tax benefits	(30)	—
Other adjustments		
Expired federal carryovers of losses, credits and deductions	2,592	(17)
Total income tax expense	$ 354	(2%)

(1) State taxes in California, Florida, Massachusetts, and Pennsylvania make up the majority (greater than 50%) of the tax effect in this category.
(2) Current year amount generated net of prior year adjustments and expirations.
(3) Net effects of programs including shortfalls and executive items.

A reconciliation of the U.S. Federal statutory tax rate to our 2024 and 2023 annual tax rate is as follows (in thousands):

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

The valuation allowance decreased by $0.3 million for the year ended December 31, 2025, compared to the decrease of $2.6 million and increase $1.0 million for the years ended December 31, 2024 and 2023, 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, 2025, 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 2026-2028	Expires 2029-2035	Expires 2036-2045	No Expiration
Federal losses carryovers	$ 584,015	$ 82,920	$ 199,210	$ 74,375	$ 227,510
California loss carryovers	108,035	19,243	48,774	40,018	—
Other state loss carryovers	52,119	16	5,175	33,217	13,711
Federal research credits	17,852	1,117	2,533	14,202	—
California research credits	16,887	—	—	—	16,887
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 Sections 382 and 383 of the Internal Revenue Code, 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, 2025	December 31, 2024
Unrecognized tax benefits at beginning of period	$ 7,837	$ 7,924
Decreases related to expired carryforwards	(82)	(344)
Decreases related to administrative proceedings	—	(127)
Increases related to prior year tax positions	52	94
Increases related to current year tax positions	298	290
Unrecognized tax benefits at end of period	$ 8,105	$ 7,837

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, 2025, 2024 and 2023 (in percentages):

	Year Ended December 31,		
	2025	2024	2023
American Red Cross	33%	35%	35%
Établissement Français du Sang	10%	11%	12%

Revenues by geographical location were based on the location of the customer during the years ended December 31, 2025, 2024 and 2023, and was as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Product revenue:			
United States	$ 124,723	$ 109,256	$ 93,232
France	21,198	19,692	18,490
Other countries	60,212	51,322	44,645
Total product revenue	206,133	180,270	156,367
Government contract revenue:			
United States	27,665	21,051	30,430
Total government contract revenue	27,665	21,051	30,430
Total revenue	$ 233,798	$ 201,321	$ 186,797

Long-lived assets by geographical location at December 31, 2025 and December 31, 2024, were as follows (in thousands):

	December 31,	
	2025	2024
United States	$ 5,470	$ 6,807
Europe & other	3,734	347
Total long-lived assets	$ 9,204	$ 7,154

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 2nd day of March, 2026.

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 Chair of the Board of Directors *(Principal Executive Officer)*	March 2, 2026
/s/ KEVIN D. GREEN **Kevin D. Green**	Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 2, 2026
/s/ ERIC H. BJERKHOLT **Eric H. Bjerkholt**	Director	March 2, 2026
/s/ DEAN A. GREGORY **Dean A. Gregory**	Director	March 2, 2026
/s/ ANN LUCENA **Ann Lucena**	Director	March 2, 2026
/s/ TIMOTHY L. MOORE **Timothy L. Moore**	Director	March 2, 2026
/s/ JAMI NACHTSHEIM **Jami Nachtsheim**	Director	March 2, 2026
/s/ HUA SHAN, MD, PH.D. **Hua Shan, MD, Ph.D.**	Director	March 2, 2026
/s/ FRANK WITNEY, PH.D. **Frank Witney, Ph.D.**	Director	March 2, 2026