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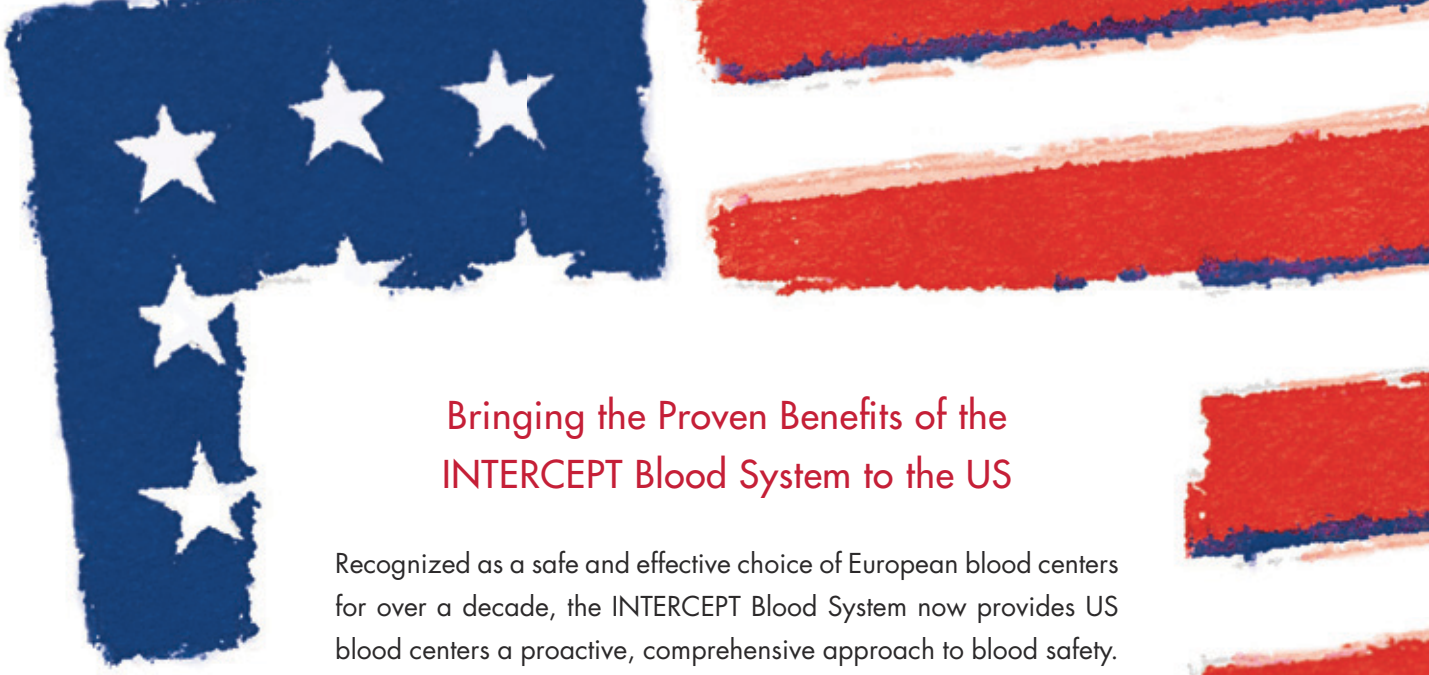
CERUS

2014 Annual Report



Bringing the Proven Benefits of the INTERCEPT Blood System to the US

Recognized as a safe and effective choice of European blood centers for over a decade, the INTERCEPT Blood System now provides US blood centers a proactive, comprehensive approach to blood safety. Below are key highlights for the US:

- **March 2015** – First patient enrolled in the TReatment UsE (TRUE) study to mitigate chikungunya and dengue risks in the Caribbean.
- **February 2015** – First two US customers sign agreements to purchase INTERCEPT for platelets and plasma.
- **December 2014** – US FDA approvals received for the INTERCEPT Blood System for plasma and platelets.
- **November 2014** – FDA accepts IDE supplement for INTERCEPT Blood System Treatment of Ebola convalescent plasma.
- **October 2014** - FDA accepts IDE supplement making the INTERCEPT Blood System available to address chikungunya and dengue blood safety risks.

This significant US progress for pathogen reduction comes in the midst of industry sentiment on the challenges faced with the bacterial contamination of platelets, including a recent FDA draft guidance document which emphasizes the need to minimize this risk. Pathogen reduction offers a timely solution with the ability to reduce bacterial transfusion-transmitted infectious risk while offering the potential to simplify platelet production logistics.

Dear Shareholder:

Significant achievements have come to fruition for Cerus, including FDA approvals of the INTERCEPT Blood System for platelets and plasma, agreements placed with our first two US customers, and the successful completion of two red cell trials, data for which is planned to go toward CE Mark submission. We believe that such developments coupled with our strong balance sheet affords us the needed flexibility and resources to support a successful US launch, as well as further expansion of our commercialization efforts for INTERCEPT in global markets.

FDA approves the first pathogen reduction system for platelets and plasma in the US

FDA approvals for the first pathogen reduction system for platelets and plasma were obtained for the INTERCEPT Blood System in late 2014. The approvals included strong, broad label claims that we believe place us in an excellent position to leverage INTERCEPT's value proposition, including the ability to reduce the risk of transfusion transmitted infection and sepsis, as well as the potential to reduce transfusion-associated graft versus host disease. We believe the strength of our label claims paves the way for centers to potentially replace current safety practices, such as bacterial detection, thus streamlining logistics. The approvals were quickly followed by the execution of purchase agreements with two US blood centers. Looking forward, we have a series of significant product claim extensions planned that we believe will provide US blood centers with optimum flexibility for blood component production.

TRUE Study Addresses Chikungunya and Dengue Blood Safety Risks in Endemic Areas in the US

The TReatment UsE (TRUE) study to make INTERCEPT platelets available to US regions with outbreaks of chikungunya and dengue virus under an Expanded Access Investigational Device Exemption (IDE) demonstrates how pathogen reduction can be implemented to mitigate risks from emerging pathogens for which no commercialized tests exist. With FDA's approval of the IDE, the Puerto Rico Department of Health was able to revise its administrative order to acknowledge pathogen reduction as an alternative safety measure to a 72-hour quarantine of donated blood. Through its participation in the study, the American Red Cross has been able to resume local production of platelet components, treated with INTERCEPT, to supply clinical trial sites. The outbreak in Puerto Rico parallels a similar situation in the French island of La Reunion where INTERCEPT was successfully implemented in 2006; since that time, there have been no documented cases of chikungunya transmitted through donated platelets in La Reunion.

Successful Completion of Two INTERCEPT Red Cell Clinical Trials

In December 2014 and January 2015, we announced that we had successfully met primary endpoints for our U.S. Phase II recovery and survival study and our European Phase III acute anemia trial, respectively. The U.S. Phase II study results met FDA criteria for 24-hour recovery for red cell components. The European Phase III trial demonstrated equivalence of hemoglobin content between INTERCEPT and conventional red cells and showed no statistical differences in adverse reaction rates between recipients of INTERCEPT-treated and control red cells. We plan to include data from both studies in a CE Mark application to support the safety and efficacy of the product, with an anticipated filing date of the application in the second half of 2016. We look forward to preparing for the potential launch of INTERCEPT red cells over the next two years. This product would enable INTERCEPT users to protect transfusion recipients across all three blood components.

Continued Commercial Expansion in Europe

The adoption of INTERCEPT continues to expand in Europe as demonstrated by recent contracts with the Belgian Red Cross Flanders and Stockholm's Karolinska University Hospital. We believe that the addition of these customers, coupled with the completed transition to direct sales in certain regions previously covered by distributors, as well as continued support through intensive training in our remaining distributor regions, puts us in a strong position to effectively support our efforts in EMEA in the coming year. We also remain optimistic about the potential for significant revenue opportunities, such as additional adoption in France and the UK. Finally, we believe the FDA approvals help bring confidence to the ability of pathogen reduction to improve blood safety and will encourage broader global adoption of INTERCEPT in the years to come.

Sincerely,

William "Obi" Greenman
President and Chief Executive Officer
April 30, 2015

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, 2014

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.)**
2550 Stanwell Dr. 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	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K, (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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 common stock held by non-affiliates of the registrant as of 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 $268.0 million. (1)

As of February 27, 2015, there were 95,177,692 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 2015 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, 2014, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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(1) Based on a closing sale price of $4.15 per share on June 30, 2014. Excludes 9.3 million shares of the registrant's common stock held by executive officers, directors and affiliates at June 30, 2014.

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PART I

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

- ***future sales of and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT Blood System, including our ability to comply with applicable United States, and foreign laws, regulations and regulatory requirements;***
- ***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;***
- ***our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;***
- ***the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions;***
- ***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;***
- ***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 ability of our products to inactivate the Ebola virus 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; and***
- ***our estimates regarding the sufficiency of our cash resources and our need for additional funding.***

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 our need for additional financing, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products, market acceptance of our products, reimbursement, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fresenius and third parties to manufacture certain components of the INTERCEPT Blood System,

incompatibility of our platelet system with some commercial platelet collection methods, our need to complete certain of our product components' 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, legal proceedings, and other factors discussed below and under the caption "Risk Factors," in Item 1A of this Annual Report on Form 10-K and in our other documents filed with the Securities and Exchange Commission. 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.

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.

We have worldwide rights for our INTERCEPT Blood System for three blood components: plasma, platelets, and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals, including U.S. Food and Drug Administration, or FDA, approval in the United States and Class III CE marks in the European Union and other jurisdictions that recognize CE mark approval, and are being marketed and sold in a number of countries around the world, including the U.S., certain countries in Europe, The Commonwealth of Independent States, or CIS, and the Middle East. We sell both the platelet and plasma systems using our direct sales force and through distributors. Although our revenues have grown over time, if we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including in the United States, we will have difficulties achieving profitability.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development. We recently announced that both our U.S. Phase II recovery and lifespan study of the red blood cell system and our European Phase III clinical trial of the red blood cell system for acute anemia patients met their respective primary endpoints. Based on the results of the recently-completed European Phase III acute anemia clinical trial, we plan to file for CE mark approval of the red blood cell system in the European Union in the second half of 2016.

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 increased selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

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

Product Development

Background

The INTERCEPT Blood System is designed to broadly target and inactivate blood-borne pathogens, such as viruses (for example, HIV, West Nile, SARS, hepatitis B and C), bacteria and parasites, as well as potentially harmful white blood cells, while preserving the therapeutic properties of platelet, plasma and red blood cell transfusion products. The INTERCEPT Blood System has been shown to inactivate a broad array of pathogens and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective, 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

We have worldwide commercial rights for all INTERCEPT Blood System products. 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 a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world, and approved for commercialization in the United States, with our first customer contracts in the United States announced in February 2015
INTERCEPT Blood System—Plasma	• Commercialized in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world, and approved for commercialization in the United States, with our first customer contracts in the United States announced in February 2015
INTERCEPT Blood System—Red Blood Cells	• Phase I clinical trial completed in 2010 • European Phase III clinical trial for acute anemia and U.S. Phase II recovery and lifespan study completed in 2014 • European chronic anemia clinical trial ongoing • European CE mark submission planned for second half of 2016 • Further U.S. *in vitro* studies planned

INTERCEPT Blood System for Platelets and Plasma

The platelet system is designed to inactivate blood-borne pathogens in platelets donated for transfusion. The platelet system has received CE mark approval in Europe and is marketed and sold in a number of countries around the world including those in Europe, the CIS, the Middle East and selected countries in other regions of the world. Separate approvals for use of INTERCEPT-treated platelet 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, several centers have obtained such approvals. Many countries outside of Europe accept the CE mark and have varying additional administrative or regulatory processes before the platelet 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.

We completed a Phase III clinical trial of the platelet system in the United States in March 2001 and a supplemental analysis of data from this trial was completed in 2005. In 2013, we reached agreement with the

FDA that our existing clinical trial and European haemovigilance data was sufficient to submit a modular Premarket Approval Application, or PMA, submission without the need to complete additional Phase III clinical trials.

We submitted our final module of the platelet PMA in the second quarter of 2014 and in December 2014, the FDA approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease. As part of the FDA's approval of the platelet system, we are required to successfully conduct and complete a post-approval hemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT treated platelets.

The plasma system is designed to inactivate blood-borne pathogens in plasma donated for transfusion. The plasma system has received CE mark approval in Europe and is marketed and sold in a number of countries around the world including those in Europe, the CIS, the Middle East and selected countries in other regions around the world. Separate approvals for use of INTERCEPT-treated plasma products have been obtained in France and Switzerland. In Germany and Austria, approvals must be obtained by individual blood centers for use of INTERCEPT-treated plasma. One such center in Germany has received such an approval. Many countries outside of Europe accept the CE mark and have varying additional administrative or regulatory processes before the 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 plasma system.

We completed Phase III clinical trials of the plasma system in the United States, reports for which were filed with the FDA during 2005. We submitted our final module of the plasma PMA in the fourth quarter of 2013 and in December 2014, the FDA 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 begun the combined commercial launch of the plasma and platelet systems in the United States and announced our first two customer contracts for the sale of the INTERCEPT Blood System for platelets and plasma in February 2015. Prior to broader customer adoption in the United States, U.S.-based blood centers will need to complete their process validations and obtain site-specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, before making INTERCEPT-treated blood products available to their interstate hospital customers. Further, the hospital customers of these blood centers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may result in further delay. We plan to work with U.S.-based blood centers to support these activities and anticipate implementation of INTERCEPT in blood center operations in the first half of 2015. As a result, despite these early adopters of INTERCEPT, we do not anticipate meaningful revenue in 2015 from sales of the plasma and platelet systems in the United States and our commercial activities in 2015 will largely be focused on supporting initial customer adoption and implementation. In addition, in order to address the entire market in the United States, we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. For example, in the United States, we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. In addition, we understand that a significant portion of the U.S. blood centers store their platelet components suspended in 100% plasma. Further, we estimate that the majority of platelets used in the United States 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. In order to gain FDA approval for a pathogen reduction system compatible with triple dose collections, platelets suspended in 100% plasma, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials, and will need to obtain FDA approval of a PMA supplement. These development activities will increase our costs significantly and may not be successful. Our failure to obtain FDA and foreign regulatory approvals of these new configurations could significantly limit revenues from sales of the platelet system.

During the year ended December 31, 2014, we submitted and received approval from the FDA for a Phase I clinical study protocol under an investigational device exemption, or IDE, to treat plasma derived from convalesced patients that were previously infected with the Ebola virus and have recovered from the disease according to the criteria set by the Centers for Disease Control and Prevention. The transfusion of convalesced plasma from Ebola survivors is believed to pass on antibodies to the disease from the survivor to the recipient of the plasma transfusion. INTERCEPT use under this IDE is limited to pathogen reduction claims that rely on existing clinical data that we have regarding reduction of certain pathogens in donated plasma, and we do not have any clinical or commercial data on the efficacy of INTERCEPT to inactivate the Ebola virus and therefore do not know the effectiveness of INTERCEPT to inactivate the Ebola virus. In addition, we have submitted and received approval from the FDA for a separate, expanded use IDE, to conduct a study using INTERCEPT to treat platelet donations in areas of the U.S. that have outbreaks of the chikungunya and dengue viruses. Both of these studies are on-going.

INTERCEPT Blood System for Red Blood Cells

The red blood cell system is designed to inactivate blood-borne pathogens in red blood cells donated for transfusion. We completed a series of *in vitro* and *in vivo* tests with the red blood cell system, including successfully completing recovery and survival studies measuring red cell recovery twenty-four hours after transfusion. Previously, we terminated Phase III 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 in two patients in the trial for chronic anemia. The antibody eventually cleared and the patients had no adverse health consequences. After unblinding the data from the original Phase III clinical trials, we found that we had met the primary end-point in the clinical trial for acute anemia. We evaluated the antibodies detected and developed process changes to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. There has been no antibody reactivity associated with INTERCEPT-treated red blood cells in any of the subsequent configurations, studies or trials we have completed since modifying the process used in the red blood cell system. Accordingly, we received authorization from European regulators to proceed with Phase III clinical trials for acute anemia and, separately, chronic anemia. Although the Phase III clinical trial of the red blood cell system in Europe for chronic anemia patients is ongoing, we recently completed the Phase III clinical trial of the red blood cell system for acute anemia patients and plan to submit for CE mark approval of the red blood cell system using the collective data in the second half of 2016.

In January 2015, we announced that the completed Phase III clinical trial of red blood cells treated with the INTERCEPT Blood System for acute anemia in cardiovascular surgery patients met its primary endpoint, with preliminary analysis demonstrating that the mean hemoglobin content (53.1g) of INTERCEPT-treated red blood cell components, or 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 III 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 patients at two German clinical trial sites to evaluate transfusion efficacy and overall safety. Patients undergoing procedures for either coronary artery bypass grafting, valve repair or combined procedures received study transfusions during a seven-day treatment period that included the day of surgery and six days post-operatively. The patients received either INTERCEPT-treated RBCs or control RBCs not treated for pathogen inactivation. The primary endpoint of equivalence of mean hemoglobin content between INTERCEPT treated RBCs and conventional RBCs was met within the protocol specified 5g equivalence margin based on over 750 study RBC components manufactured. The secondary efficacy endpoints also demonstrated suitability for transfusion based on mean hematocrit of 60.4% (acceptance range: 55-70%) and mean end of storage hemolysis of 0.28% (acceptance range < 0.8%). There were no statistical differences in the adverse event rates between recipients of INTERCEPT-treated and control RBCs. 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 patients of similar age and with advanced

cardiovascular diseases undergoing cardiovascular surgery requiring red cell transfusion. No patients exhibited an immune response to INTERCEPT-treated RBCs. Based on the results of this trial, we plan to file for CE mark approval in the European Union in the second half of 2016. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing chronic anemia Phase III clinical trial may also be required for our red blood cell system to achieve broad market acceptance. As part of our development and chemistry, manufacturing and control, or CMC, activities, we will need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe.

In the United States, the FDA has required us to complete at least one additional Phase II recovery and lifespan study, which we recently completed, and will likely require at least one additional Phase III clinical trial before we would be able to potentially obtain approval for INTERCEPT-treated RBCs in the United States. In December 2014, we announced that our recently completed U.S. Phase II recovery and lifespan study of RBCs treated with the INTERCEPT Blood System met its primary endpoint, with the preliminary analysis demonstrating that greater than 75% of treated RBCs continued to circulate 24 hours following transfusion. This randomized, single-blind, controlled, multi-center Phase II clinical trial of the red blood cell system evaluated 26 healthy subjects at two clinical trial sites in the United States. Each subject received two transfusions of the subject's own RBCs, one INTERCEPT-treated, and the other a control not treated for pathogen reduction. Red blood cell units were stored for 35 days prior to transfusion. The primary endpoint of the study, a mean INTERCEPT red blood cell recovery of greater than 75% at 24 hours post-transfusion, was met. The INTERCEPT treated RBCs had a recovery of 83% compared to 85% for control RBCs, and both INTERCEPT-treated and control RBCs met the criteria for red blood cell recovery recommended by the FDA. We plan to complete certain other prerequisites, as well as to complete our development and CMC activities and planned CE mark submission, before proposing a Phase III clinical trial protocol for the red blood cell system in support of potential regulatory approval in the United States.

Additional information regarding our interactions with the FDA, and potential future clinical development of the INTERCEPT Blood System in Europe and in the United States can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled *"Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country's regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue in that country. Our investigational red blood cell system requires extensive additional testing and development."*

Information regarding our revenues for the years ended December 31, 2014, 2013 and 2012 can be found in "Item 7—*Management's Discussion and Analysis of Financial Condition and Results of Operations*", and "Item 15(a)—*Exhibits and Financial Statement Schedules—Financial Statements*" of this Annual Report on Form 10-K.

INTERCEPT Blood System Technology

Both our platelet system and plasma system employ the same technology. Platelet or plasma components collected from blood donors are transferred into plastic INTERCEPT disposable kits and are mixed with our proprietary compound, amotosalen, a small molecule compound which 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 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 act 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 cellular function. The red blood cell system uses another of our proprietary compounds, S-303. Unlike the platelet and plasma systems, the chemical bonds from S-303 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, S-303 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 previously demonstrated with the red blood cell system in the clinical setting. We plan on conducting additional pathogen-inactivation studies of the red blood cell system, broadening our understanding of the pathogens the system may be able to inactivate.

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

We believe that, due to their mechanisms of action, the platelet system, plasma system, and red blood cell system will potentially inactivate blood-borne pathogens that have not yet been tested with our systems, including emerging and future threats to the blood supply. We do not claim, however, that our INTERCEPT Blood System will inactivate all pathogens, including prions, and our inactivation claims are limited to those contained in our product specifications.

Collaborations

Baxter International, Inc., Fenwal, Inc., and Fresenius Kabi

We collaborated with Baxter International, Inc., or Baxter, on the development and commercialization of the INTERCEPT Blood System commencing in 1993. We obtained exclusive worldwide commercialization rights to the red blood cell system from Baxter in February 2005. In February 2006, we entered into a restructuring of our

agreements with Baxter pursuant to which we obtained exclusive worldwide commercialization rights to the platelet and plasma systems, excluding certain Asian countries where the commercialization rights had been licensed to BioOne Corporation, or BioOne. In March 2007, Baxter sold its transfusion therapies business, the unit of Baxter that performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to Fenwal, Inc., or Fenwal, which in turn, was acquired by Fresenius Kabi AG, or Fresenius in 2012. Fresenius has assumed Fenwal's rights and obligations under our agreements. In this report, references to Fresenius include references to its predecessors-in-interest, Fenwal and Baxter. The 2006 agreements provide that we pay Fresenius royalties on INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system.

Investment in Aduro Biotech

In November 2007, we spun-off our former immunotherapy business to Anza Therapeutics, Inc., or Anza Therapeutics. In August 2009, we entered into a three-way license agreement with Anza Therapeutics and Aduro Biotech, or Aduro, and separate agreements with each of Anza Therapeutics and Aduro, which we refer to collectively as the Assignment Agreements. In November 2009, Anza Therapeutics transferred all of its intellectual property to Aduro pursuant to the terms of the Assignment Agreements. In exchange for agreeing to the transfer and relinquishment of our shares in Anza Therapeutics, and releasing any claims against Anza Therapeutics, we received $0.8 million in cash, preferred stock representing 10% of Aduro's capital, and a 1% royalty on any future sales resulting from the transferred technology. To date we have not recorded any value associated with our ownership interest in Aduro nor have we received any royalty payments from Aduro pursuant to this agreement. As of December 31, 2014, our ownership in Aduro was less than 1% on a fully diluted basis. Since receiving preferred stock in Aduro, we have carried our investment in Aduro at zero on our consolidated balance sheet.

William Greenman, our President and Chief Executive Officer, is on the Board of Directors of Aduro in his individual capacity and does not represent Cerus' interests.

Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the devices, disposable kits and inactivation compounds that make up the INTERCEPT Blood System for use in clinical trials and for commercialization. We rely solely on Fresenius for the manufacture of INTERCEPT Blood System disposable kits and on other contract manufacturers for the production of our inactivation compounds, compound adsorption components of the disposable kits and UVA illuminators used in the INTERCEPT Blood System. We currently do not have alternate manufacturers for the components in our products or product candidates beyond those that we currently rely on, but are currently in the process of identifying potential alternate manufactures. In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The amended terms also provide for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. At the current and expected near term production volumes, pricing is expected to be at the lowest tier. In addition, the amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination

rights, including termination for material breach. We do not currently have plans to terminate our amended manufacturing and supply agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended manufacturing and supply agreement.

Components of compound adsorption devices used in platelet and plasma disposable kits are manufactured by Porex Corporation, or Porex. In December 2014, we amended our agreement for the manufacture of such components with Porex. Under the amended agreement, we are obligated to meet certain annual purchase order requirements. The term of the amended supply agreement with Porex extends through December 31, 2016. We are party to a development agreement with another manufacturer for the development of compound adsorption devices that would be equivalent to those manufactured by Porex. Although we are actively seeking to develop alternative manufacturers and components, commercially viable alternatives are likely at least a year away.

We also have contracts with suppliers of raw materials used to make the compound adsorption devices, which includes such companies as Brotech Corporation d/b/a Purolite Company, or Purolite. We entered into an amended and restated supply agreement with Purolite in April 2014, which extends through April 2021.

Pursuant to a contract that we and NOVA Biomedical Corporation, or NOVA, entered into in September 2008, NOVA is manufacturing illuminators for us. The term of our agreement with NOVA automatically renews for successive one year terms each September in the event neither party delivers written notice of its intent to terminate twelve months prior to each September renewal date. We do not currently have plans to terminate our agreement with Nova and believe that Nova currently plans to continue operating under the agreement for the foreseeable future. In addition, we are developing an upgraded version of the illuminator focused on utilizing certain more readily available components than the first generation utilized. The upgraded version of the illuminator will not be in production for at least a year.

In September 2011, we amended our manufacturing and supply agreement with Ash Stevens, Inc., or Ash Stevens, for the synthesis of amotosalen, the inactivation compound used in our platelet and plasma systems. Under this amended agreement, we are not subject to minimum annual purchase requirements. However, if specified quantities of amotosalen are not purchased in any year, we are required to pay a maintenance fee of up to $50,000 for such year. We have incurred these maintenance fees in the past. The term of the amended manufacturing and supply agreement with Ash Stevens extends through December 31, 2015, and will automatically renew thereafter for a period of two additional years, unless terminated by either party upon providing at least one year prior written notice, in our case, or at least two years prior written notice, in the case of Ash Stevens. Neither party has delivered notice of its intent to terminate the agreement.

We and our contract manufacturers, including Fresenius and NOVA, purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound adsorption devices and UVA illuminators from a limited number of suppliers. Some of our 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.

Marketing, Sales and Distribution

The market for the INTERCEPT Blood System, including the U.S. market, is dominated by a relatively small number of blood collection organizations. Accordingly, there may be an extended period during which some potential U.S.-based customers may first choose to validate our technology or run experience studies themselves before deciding to adopt the system for commercial use, which may never occur. The American Red Cross represents the largest single portion of the blood collection market in the United States. Although we currently have an agreement with the American Red Cross to support our IDE study in Puerto Rico to treat platelet donations with the INTERECEPT Blood System, there is no guarantee that the American Red Cross will

continue to use our products commercially in conjunction with or following our IDE study, even if we successfully enroll and complete this study. 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 obtaining CE marks allow us to sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute or PEI, a German governmental regulatory body overseeing the marketing authorization of certain medical products, before being allowed to sell platelet and plasma components treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, several blood centers in Germany have received such requisite approvals and authorizations for the platelet system and/or the plasma system. Given the competitive nature of the German blood banking market, pricing for blood components is relatively low compared to other markets. This dynamic, in turn, requires us to focus our marketing efforts on the potential economic and logistical benefits of using INTERCEPT compared to conventional blood components as well as the potential safety benefits of INTERCEPT-treated blood components.

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, and then on a broad-based national supply contract being awarded. In 2011, we entered into a two-year contract with the EFS to supply platelet and plasma disposable kits, which was extended until November 2015. We understand that the EFS is considering taking action to further protect platelet components from bacterial contamination, including potential use of bacterial culture detection methods or broader use of the platelet system. We cannot provide any assurance that a new supply agreement with the EFS will be entered into prior to the expiration of the current agreement in a timely manner or with reasonable terms, if at all. If we fail to enter into a new supply agreement with the EFS or we enter into a new supply agreement with the EFS with less favorable terms, including pricing, our financial results may be adversely impacted.

In England, decisions on product adoption are centralized in the National Blood Service, which collects, tests, processes and supplies blood products to hospitals in England and North Wales. The National Blood Service has implemented and used bacterial detection for platelets for the past several years instead of pathogen inactivation. More recently, the National Blood Service has implemented the INTERCEPT Blood System for platelets in one of its centers for validation of the technology. Commercial use of INTERCEPT would be dependent on a successful validation, a central decision by the National Blood Service to use INTERCEPT, and the successful negotiation of a commercial supply agreement between us and the National Blood Service.

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 in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. 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.

Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, and/or other third party payors. In many jurisdictions, budget and reimbursement discussions generally occur among blood centers, healthcare facilities such as hospitals, 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, our ability to successfully commercialize our products will depend in part on helping blood centers to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by the economic austerity programs implemented in European countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In the United States, our products are not yet subject to reimbursement by governmental or commercial third party payors for health care services. 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 related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedure and/or products at the site of patient care. Outpatient transfusions are becoming increasingly common. Our ability to market and sell our product for use in outpatient settings in the United States may be dependent on our ability to obtain a separate reimbursement code and pricing for INTERCEPT-treated blood products under the Healthcare Common Procure Coding System, or HCPCS.

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 United States and the Netherlands that supports our commercialization efforts as well as medical science liaisons, or MSLs, to help educate hospitals and physicians on our products, clinical trial history and publications.

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. Areas where we have entered into geographically exclusive distribution agreements include certain countries in the CIS, southern Europe, the Middle East, the People's Republic of China and Latin America. Our success in these regions is dependent on our ability to support our distributors and our distributor's ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements account for a significant amount of our revenues. As such, declining performance or the outright termination or loss of certain distributor relationships could harm our existing business, may impact our growth potential, and could result in higher operating costs for us. For example, due to continued declining performance by certain of our distributors during 2013 and 2014, we experienced weaker than expected growth during 2014. 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. For instance, over the course of 2013 and 2014, we implemented several changes designed to improve market penetration in our distributor territories, including by adding additional sales, technical and marketing support, as well as by providing supplementary training to improve the effectiveness of distributor field personnel. In 2014, we began transitioning certain territories to new distribution partners who we feel are capable of improved performance relative to their predecessors as well as transitioned some of these territories to a Cerus direct sales effort, which we believe will provide us with better visibility into and control of sales execution. As a result of these changes, we experienced a temporary decrease in the volume of INTERCEPT disposable kit sales for the impacted territories as those distribution partners sold through their disposable kit inventory. We expect that it may take longer for us to be paid with some distributors or customers taking longer to pay invoices than the payment terms we have historically experienced. However, we believe that the strategic actions implemented in 2013 and 2014 will allow us to maintain and potentially improve pricing and therefore, margins, creating a potentially healthier business and improved operating contribution from these territories.

Competition

Our products face a wide variety of competition from entities competing directly with alternative pathogen reducing technologies for platelets and/or plasma, as well as from entities developing and selling diagnostic screening products to detect and prevent contaminated products from being transfused, and from process and procedural decisions involving blood banking operations including but not limited to shortened shelf-life of blood components. Many of our competitors have mature, well-established products, other products which are sold to blood centers and more resources than we have. In addition, competitors may choose to seek a lower class of approval than our products, which may be easier and less costly for them to maintain and may be perceived as sufficient by the marketplace. We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen reduction methods that are either on the market or 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.

In Europe, several companies, including Grifols S.A., Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has been issued Class II CE marks for a pathogen reduction system for both platelets and plasma. We understand that Terumo BCT is also developing a pathogen reduction system for whole blood. Terumo BCT's product candidates, if successful, may offer competitive advantages over our INTERCEPT Blood System.

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

In the United States, INTERCEPT—treated plasma faces competition from Octapharma AG, which received approval from the FDA to begin selling treated fresh frozen plasma, as well as from diagnostic and testing companies currently approved for the detection of pathogens in donated blood products, including bacterial and viral pathogens. Our platelet product faces competition from a number of diagnostic and testing companies currently approved for the detection of pathogens including bacterial and viral pathogens in donated blood products and may face competition from other technologies if approved.

In Japan, we understand that Terumo BCT's platelet and plasma pathogen reduction product is currently being evaluated by the Japanese Red Cross. Terumo Corporation is a large Japan-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo's resources and their pre-existing relationships with regulators and customers. Should Terumo BCT's product be approved for use and commercialized in Japan, we would likely directly compete with them and we believe we would likely need to either establish operations in Japan or partner with a local Japanese company. We believe that the primary competitive factors in the market for pathogen reduction of blood products include the breadth and effectiveness of pathogen reduction processes, the amount of demonstrated reduction in transfusion related adverse events subsequent to adopting pathogen reduction technology, robustness of treated blood components upon transfusion, the scope and enforceability of patent or other proprietary rights, perceived product value relative to perceived risk, product supply, perceived ease of use, perception of safety, efficacy and economics of pathogen reduction systems, and marketing and sales capability. In addition, we believe the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval are also important competitive factors. We believe that the INTERCEPT Blood System will compete favorably with respect to these factors, although there can be no assurance that it will be able to do so. Our success will depend in part on our ability to

convince prospective customers of the benefits of and need to adopt pathogen reduction technology and specifically our system relative to other technologies, our ability to obtain and retain regulatory approvals for our products, and our ability to continue supplying quality and effective products to our customers and prospective customers.

Patents, Licenses and Proprietary Rights

Our commercial success will depend in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States 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, 2014, we owned approximately 12 issued or allowed United States patents and approximately 99 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2015 and 2031. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2015 and 2024. Due to the complexity of our products, we believe it is the protection afforded to our products by the portfolio of intellectual property rights that best protect our proprietary system rather than any one particular patent or trade secret. Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

We are aware of a United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exists 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 infringe this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages, cease the use and sale of our platelet and plasma systems and/or obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all. 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 our customers' needs are not based on seasonal trends, seasonality does not have a material effect on our business although purchasing patterns and inventory levels can fluctuate.

Inventory Requirements and Product Return Rights

Our platelet and plasma disposable kits have received regulatory approval for two-year shelf lives. Illuminators and replacement parts do not have regulated expiration dates, although certain components are no longer routinely manufactured. We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our consolidated balance sheet, may potentially take over one year to complete production before being utilized in finished disposable kits. In 2014, under our amended agreement with Fresenius, we began selling certain levels of work-

in-process to Fresenius, somewhat mitigating the impact on our consolidated balance sheet. We maintain inventory based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory would be consumed for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for our production cycle for inventory to exceed twelve months. Instead, we use our best judgment to factor in lead times for the production of our finished units to meet our current demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. Inventory is recorded at the lower of cost, determined on a first in, first out basis, or market value. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. We rely on our direct sales team and distributors to provide accurate forecasts of sales in their territory. If our forecasts or those of our distributors are inaccurate, we could face backlog situations or conversely, may produce and carry an abundance of inventory that would consume cash faster than we have currently planned. Generally, we write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use to net realizable value in the period that it is first recognized, by using a number of factors, including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods.

We sell the INTERCEPT Blood System directly to blood banks, hospitals, universities, and government agencies, as well as to distributors in certain regions. Generally, our contracts with our customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product.

Customers and Financial Information about Geographic Areas

Our customers are concentrated and consist of blood collection organizations, some of which are nationalized, public and private hospitals, and distributors. Distributors that purchase our products and sell to end-user customers comprise a significant amount of our existing sales. The loss of any one of our customers would have an adverse impact on our business. The following table illustrates concentration of sales over the past three years:

	Year Ended December 31,		
	2014	2013	2012
Etablissement Francais du Sang	25%	17%	20%
Grifols	*	18%	19%
Delrus Inc.	*	*	12%

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

To date, we have not experienced collection difficulties from these customers. While we have not experienced collection difficulties from any of these customers, we have recently experienced collection difficulties associated with approximately $0.1 million from our exclusive distributor in Russia. Prior to 2014, Delrus, Inc. was our exclusive distributor in Russia. For additional details about these customers for the years ended December 31, 2014, 2013 and 2012, as well as information regarding our net revenues by geographical location and location of our long-lived assets, see Note 17 in the Notes to Consolidated Financial Statements under “Item 15 (a)—*Exhibits and Financial Statement Schedules—Financial Statements*” of this Annual Report on Form 10-K.

Research and Development Expenses

A significant portion of our operating expenses is related to research and development and we intend to maintain a strong commitment to our research and development efforts. We have incurred total research and development expenses of $21.8 million, $15.2 million and $7.6 million for the years ended December 31, 2014, 2013 and 2012, respectively. As we look ahead, we anticipate that the regulatory submission processes for

supplemental PMA applications for the plasma and platelet systems in the United States and elsewhere, will require continued investment in research and development activities, as will our ongoing clinical, development and CMC work for our red blood cell system. See Note 2 in the Notes to Consolidated Financial Statements under "Item 15(a)—*Exhibits and 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, 2014, 2013 and 2012.

Government Regulation

We and our products are comprehensively regulated in the United States by the FDA and by comparable governmental authorities in other countries.

Our European investigational plan has been based on the INTERCEPT Blood System being categorized as Class III drug/device combination under the Medical Device Directives, or the MDD, of the European Union.

The European Union requires that medical devices affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with the MDD. We initially received the CE mark for our platelet system and separately for our plasma system in 2002 and 2006, respectively. We will need to obtain a CE mark extension in our name from European Union regulators for both our platelet and plasma systems every five years. The CE mark for the platelet system is effective through May 2017 while the CE mark for the plasma system is effective through September 2016. A separate CE mark certification must be received for the red blood cell system to be sold in the European Union and in other countries recognizing the CE mark. 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 United States 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.

In December 2014, the FDA 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 to potentially reduce the risk of transfusion-associated graft versus host disease, or TA-GVHD. Also in December 2014, the FDA 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 are conducting *in vitro* studies for our platelet system to expand our label claims to include, among others, platelets suspended in 100% plasma in addition to platelets stored in storage solution, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections.

As a condition to the FDA approval of the platelet systems, we are required to conduct a post-approval clinical study of the platelet system. If we are unable to complete this study or the results of this study reveal

unacceptable safety risks, we could be required to perform additional studies, which may be costly, and even lose U.S. marketing approval of the platelet and/or plasma systems. In addition to these studies, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources. In addition, there is a risk that these 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 clearances or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, due to the obsolescence of certain parts, we are undergoing a redesign of the illuminator used in the platelet and plasma systems. We will need to seek regulatory approval of the redesigned illuminator and if we are unable to obtain approval, our operations and financial results will be adversely affected. In addition, in order to address the entire market in the United States, we will need to develop and test additional configurations of the platelet system, including to make the platelet system compatible with platelets suspended in 100% plasma, triple dose collections and random donor platelets. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations could significantly limit revenues from sales of the platelet and plasma systems.

With FDA approval of our platelet and plasma systems, we are required to continue to comply with applicable FDA and other regulatory requirements related to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory agency requirements, including, in the United States, 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. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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

CBER is principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our blood safety products, CBER also regulates the blood collection centers and would regulate any blood products

that they prepare using the INTERCEPT Blood System. Prior to broader customer adoption in the United States, U.S.-based blood centers will need to complete their process validations and obtain site-specific licenses from CBER before making INTERCEPT-treated blood products available to their interstate hospital customers. Additionally, the hospital customers of any of our new blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may result in further delay of customer adoption in the United States. We plan to work with U.S.-based blood centers to support these activities as any delay in obtaining these licenses would adversely impact our ability to sell products in the United States.

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

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

Further discussion of our regulatory and clinical trial status can be found in "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled: *"Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country's regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue in that country. Our investigational red blood cell system requires extensive additional testing and development."*

Health Care Reimbursement and Reform

Our ability to commercialize our products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of the products and related treatment are obtained. The United States Patient Protection and Affordable Care Act and ongoing cost saving efforts in the United States and in other regions of the world may have an impact on our ability to profitably commercialize the INTERCEPT Blood System in the United States and elsewhere. For instance, the health care reform in the United States has placed downward pressure on the pricing of medical products and has introduced new taxation on medical devices, which could further impact our profit margins.

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 or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory approval of our products and to produce, market and distribute our products after approval is obtained*" and "*We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business.*"

Employees

As of December 31, 2014, we had 144 employees, 48 of whom were engaged in research and development and 96 in selling, general and administrative activities. Of the 96 employees engaged in selling, general, and administrative activities, 43 were employed by our European subsidiary, Cerus Europe B.V. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

Available Information

We maintain a website at *www.cerus.com*; however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission.

Financial Information

Our financial information including our consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of stockholders' equity, consolidated statements of cash flows, and the related footnotes thereto, can be found under "Item 15—*Exhibits and 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 report. 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.

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

We have invested a significant portion of our efforts and financial resources on the development of the INTERCEPT Blood System for platelets and plasma for the United States market. As a result, our business is substantially dependent on our ability to successfully commercialize the INTERCEPT Blood System in the United States in a timely manner. We only recently received U.S. regulatory approval of the INTERCEPT Blood System for platelets and plasma and although the INTERCEPT Blood System is now commercially available in the United States, we have no prior experience commercializing any products in the United States and we may be unable to commercialize the INTERCEPT Blood System in the United States successfully or in a timely manner, or at all. In addition, due to the manufacturing lead time to produce products specific for use in the United States, we do not expect to generate revenue from commercializing the INTERCEPT Blood System for its approved labeled indications of use in the United States prior to the end of the first quarter of 2015, at the earliest. Prior to purchasing the INTERCEPT Blood System, among other things, potential customers in the United States, based on our experience in other foreign jurisdictions, may first choose to validate our technology or conduct experience studies of the INTERCEPT Blood System prior to deciding whether to adopt the INTERCEPT Blood System for commercial use. In addition, potential customers must obtain site-specific licenses from CBER prior

to engaging in interstate transport of blood components processed using the INTERCEPT Blood System, which could significantly delay or preclude our ability to successfully commercialize the INTERCEPT Blood System to those customers for the portion of their business involved in interstate commerce. Further, the hospital customers of any of our new blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may result in further delay of customer adoption in the United States. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the United States, we may never generate substantial revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected.

Our ability to successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States 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;
- create market demand for the INTERCEPT Blood System through our education, marketing and sales activities;
- hire, train, deploy and support 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 and test 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 and plasma in the United States is subject to a number of risks and uncertainties, including those related to:

- the highly concentrated U.S. blood collection market that is dominated by a small number of blood collection organizations;
- regulatory and licensing requirements, including the CBER licensing process that U.S.-based blood centers will need to follow in order to obtain 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;
- obtaining reimbursement codes under the Healthcare Common Procure Coding System, or HCPCS, and pricing for outpatient use of INTERCEPT-treated blood components;
- any supply or manufacturing problems or delays arising with any of our suppliers, many of whom are our sole suppliers for the particular product or component they manufacture, including the ability of such 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;
- 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 and effective from the broad constituencies involved in the healthcare system.

In addition to the above, our ability to successfully commercialize the INTERCEPT Blood System in the United States is dependent on our ability to operate without infringing on the intellectual property rights of others. For example, we are aware of a United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exists 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 infringe this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages, cease the use and sale of our platelet and plasma systems and/or obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all.

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

The INTERCEPT Blood System may not achieve broad market adoption.

In order to increase market adoption of the INTERCEPT Blood System and to create market demand in the United States, 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 outweigh their risks.

The use of the platelet system results in some processing loss of platelets. If the loss of platelets leads to increased costs for our customers, our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, prospective customers may not adopt our platelet system. 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 efficacy.

The INTERCEPT Blood System does not inactivate all known pathogens, and the inability of the INTERCEPT Blood System to inactivate certain pathogens may limit its market adoption. For example, our products have not been demonstrated to be effective in the reduction of certain non-lipid-enveloped viruses, including hepatitis A and E viruses, due to these viruses’ biology. In addition, our products have not demonstrated a high level of reduction for human parvovirus B-19, which is also a non-lipid-enveloped virus. Although we have shown high levels of reduction of a broad spectrum of lipid-enveloped viruses, prospective customers may choose not to adopt our products based on considerations concerning inability to inactivate, or limited reduction, of certain non-lipid-enveloped viruses. Similarly, although our products have been demonstrated to effectively inactivate spore-forming bacteria, our products have not shown to be effective in inactivating bacterial spores once formed. In addition, our products do not inactivate prions since prions do not contain nucleic acid. While transmission of prions has not been a major problem in blood transfusions, and we are not aware of any competing products that inactivate prions, the inability to inactivate prions may limit market adoption of our products. Furthermore, due to limitations of detective tests, we cannot exclude that a sufficient quantity of pathogen or pathogens may still be present in active form, which could present a risk of infection to the transfused patient. Such uncertainty may limit the market adoption of our products.

We submitted and received approval from the FDA for a Phase I clinical study protocol under an investigational device exemption, or IDE, to treat plasma derived from convalesced patients that were previously

infected with the Ebola virus and have recovered from the disease according to the criteria set by the Centers for Disease Control and Prevention. The transfusion of convalesced plasma from Ebola survivors is believed to pass on antibodies to the disease from the survivor to the recipient of the plasma transfusion. INTERCEPT use under this IDE is limited to pathogen reduction claims that rely on existing clinical data that we have regarding reduction of certain pathogens in donated plasma, and we do not have any clinical or commercial data on the efficacy of INTERCEPT to inactivate the Ebola virus and therefore do not know the effectiveness of INTERCEPT to inactivate the Ebola virus. This may negatively impact a customer's desire to adopt INTERCEPT in those countries where addressing the Ebola virus outbreak is the primary concern.

We have conducted studies of our products in both *in vitro* and *in vivo* environments using well-established tests that are accepted by regulatory bodies. When an *in vitro* test was not generally available or not well-established, we conducted *in vivo* studies in mammalian models to predict human responses. Although we have no reason to believe that the *in vitro* and *in vivo* studies are not predictive of actual results in humans, we cannot be certain that the results of these *in vitro* and *in vivo* studies accurately predict the actual results in humans in all cases. To the extent that actual results in human patients differ, 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. In addition, there is a risk that further studies that we or others may conduct, including the post-approval study we are required to conduct as a condition to the FDA approval of the platelet system, will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease use of our products. In addition, some hospitals may decide to purchase and transfuse both INTERCEPT-treated blood components and conventional blood components. Managing such a dual inventory of blood products may be challenging; hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination with hospital suppliers and our customers, the blood centers, which in-turn may cause delay in market adoption. Further, in certain markets, potential customers may require us to develop, sell, and support a data management application for their operations before they would consider adopting INTERCEPT. Such development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Failure to do so may limit market adoption in geographies where we commercialize the INTERCEPT Blood System, including the United States.

Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, and/or other third 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 the economic austerity programs implemented in European countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, including the United States, our products are not yet subject to reimbursement by governmental or commercial third party payors for health care services. 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 related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedure and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even where our products receive regulatory approval and reimbursement is available, failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. In addition, the lack of widespread adoption of the INTERCEPT Blood System has adversely affected and may in the future adversely affect further market adoption of the INTERCEPT Blood System. Moreover, the market for pathogen reduction systems in the United States is highly concentrated and dominated by a small number of blood collection organizations. Accordingly, there may be an extended period during which some potential U.S.-based customers may first choose to validate our technology or run experience studies themselves before deciding to adopt the system for commercial use, which may never occur. In the United States, the American Red Cross represents the largest single portion of the blood collection market. Although we currently have an agreement with the American Red Cross to support our IDE study in Puerto Rico to treat platelet donations with the INTERCEPT Blood System, there is no guarantee that the American Red Cross will continue to use our products commercially in conjunctions with or following our IDE study, even if we successfully enroll and complete this study. 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 and subsequent reimbursement 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. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other territories where we rely on CE mark approval, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. While INTERCEPT-treated platelets and plasma have received in-country regulatory approval and reimbursement rates have been established in France, adoption throughout France has been limited to certain blood centers. In 2011, we entered into a two-year contract with the EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France, to supply platelet and plasma disposable kits, which was extended until November 2015. We understand that the EFS is considering taking action to further protect platelet components from bacterial contamination, including potential use of bacterial culture detection methods or broader use of the platelet system. We cannot provide any assurance that a new supply agreement with the EFS will be entered into prior to the expiration of the current agreement in a timely manner or with reasonable terms, if at all. If we fail to enter into a new supply agreement with the EFS or we enter into a new supply agreement with the EFS with less favorable terms, including pricing, our financial results may be adversely impacted. Decisions on product adoption in England are centralized with the National Blood Service and we understand that the National Blood Service has implemented bacterial detection testing for platelets without first considering pathogen reduction. In Japan, the Japanese Red Cross controls a significant majority of blood transfusions and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. Before the Japanese Red Cross considers our products, we understand that we may need to commit to making certain product configuration changes, which may not be economically or technologically feasible for us to accomplish.

We expect to continue to generate losses.

We may never achieve a profitable level of operations. Our research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems have only recently been approved in the United States and are not approved in many countries around the world. Although platelet and plasma systems have been approved in the United States, we do not expect to generate revenue from commercializing the INTERCEPT Blood System for its approved labeled indications of use in the United States prior to the end of the first quarter of 2015 at the earliest. The red blood cell system is in the development stage and may never emerge from the development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which may reduce or altogether eliminate our gross profit on sales. At our present and expected near-term sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, and support the systems are and are expected to continue to be in excess of our revenue. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur. In addition to increased selling, general and administrative expenses in connection with the commercial launch of the platelet and plasma systems in the United States, we expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval study and the studies under our IDEs, 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 United States, and completing chemistry, manufacturing and control, or CMC, activities to support a potential CE Mark submission for our red blood cell system in Europe, which is planned for the second half of 2016, which costs could be substantial and could extend the period during which we expect to operate at a loss.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Healthcare reform in the United States has also placed downward pressure on the pricing of medical products and has introduced new taxation on medical devices that could further impact our profit margins once we begin selling our products in the United States.

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 economies and credit and financial markets, including the sovereign debt crisis in certain countries in Europe and disruptions due to political instability or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for the INTERCEPT Blood System. In addition, there have recently been concerns for the overall stability and suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European Union, or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect our product revenue.

Additionally, a meaningful amount of our revenue currently comes from sales to our distributor in Russia. Low worldwide oil prices and the current political conflict stemming from tensions in the Ukraine have significantly devalued the Russian Ruble and may continue to have a negative impact on the Russian economy, particularly if sanctions continue to be levied against Russia or strengthened from those currently in place from either the European Union, United States or both. While our agreement with our Russian distributor calls for sales, invoicing and collections to be denominated in Euros, if significant sanctions continue or are strengthened, if worldwide oil prices continue to remain low and/or if measures taken by the Russian government to support the Ruble fail, the Russian economy and value of the Ruble may further weaken, and our business in Russia and elsewhere may be negatively impacted.

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

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 United States and by foreign regulatory bodies. These regulations are wide-ranging and govern, among other things:

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

Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes in order for the FDA and international regulatory authorities to approve them for commercial use. For our product candidates, we must provide the FDA and international regulatory authorities with preclinical, clinical and manufacturing data demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale. The process of obtaining required regulatory approvals is expensive, uncertain and typically takes a number of years. We may continue to encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all. In addition, our labeling claims may not be consistent across markets. For instance, in Europe, our label permits storage of platelets treated with the INTERCEPT Blood System in both storage solution as well as suspended in 100% plasma, both of which are common practices with the preparation of conventional platelet components. Our approved label from the FDA for the platelet system only permits storage in platelet additive solutions, which may result in limited market adoption in the United States. If we are unable to provide sufficient data to the FDA to support a label expansion request to include platelets suspended in 100% plasma, market acceptance of our products may be negatively impacted and our growth prospects would be materially and adversely affected.

Clinical and Preclinical

Clinical trials are particularly expensive and have a high risk of failure. Any of our product candidates may fail or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we will begin or complete clinical trials on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board, ministry of health or ethical committee approval to conduct a study at a prospective clinical site, delays in recruiting subjects to participate in a study and delays in the conduct of the clinical trial by personnel at the clinical site. Each of these factors has adversely impacted our ongoing European Phase III trial for the red blood cell system in chronically transfused recipients. Significant delays in clinical testing could also materially impact our clinical trials. 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 have impacted the speed with which we have been able to enroll patients for our ongoing Phase III red blood cell system trial in chronic anemia in Europe. Consequently, we may be unable to recruit suitable patients into clinical trials on a timely basis, if at all, which may lead to higher costs or the inability to complete the clinical trials. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

We have conducted many toxicology studies to demonstrate the safety of the platelet and plasma systems, and we have conducted and plan to conduct toxicology studies for the red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay or preclude commercialization. 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 United States, the FDA may require one or more post-approval clinical studies as a condition of approval, such as the post-approval clinical study we are required to conduct in connection with the approval of the platelet system, which could involve significant expense and may require us to secure adequate funding to complete. Other regulatory authorities outside of the United States may also require post-marketing studies. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

Outside the United States, regulations vary by country, including the requirements for regulatory and marketing approvals or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore and elsewhere, may require, among other requirements, that our products be widely adopted commercially in Europe and the United States, or approved by the FDA before they are considered for approval or may delay approval decisions until our products are more widely adopted commercially and approved by the FDA. 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 United States, Germany, Canada, Austria, Australia and other countries, applicable to prospective customers of INTERCEPT Blood System products, 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. For example, in the United States, blood centers will be required to obtain site-specific licenses from CBER prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System. These requirements or regulators' delays in approving license applications or supplements may deter some blood centers from using our products. Blood centers that do submit applications or supplements for manufacturing and sale may face disapproval or delays in approval that could further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

Red Blood Cell System

Our red blood cell system is currently in development and has not been commercialized anywhere in the world. Significant development and financial resources will be required to progress the red blood cell system into a commercially viable product and to obtain the necessary regulatory approvals for the product. Development of the red blood cell system and completion of CMC activities may take many years to complete and failure can occur any time during the process. Any failure or delay in completing the development and CMC activities for the red blood cell system would prevent or delay its commercialization, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Many of the factors described above that can contribute to the failure or delay of a clinical trial could impact the trials we conduct for our red blood cell system. Even if we are successful in earlier clinical trials, the results of those early trials may not be predictive of results obtained in later and larger clinical trials of the red blood cell system. In those cases, the FDA or foreign regulatory agencies may require we engage in additional clinical trials or conduct further studies or analysis which may be costly and time-consuming. 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 and CMC 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. Additionally, if we, our contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our trials may be deemed unreliable and the FDA or foreign regulatory agencies may require us to perform additional clinical trials before approving the red blood cell system for commercialization. We cannot assure you that, upon inspection, regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the United States. Our failure or the failure of our product manufacturers to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

In 2003, we terminated Phase III 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 Phase III clinical trial for chronic anemia.

Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. In a subsequent Phase I clinical trial that we initiated in the fourth quarter of 2008 to evaluate recovery and survival of treated red blood cells with the modified process, there were no adverse events reported. Based on the results from that trial, we obtained approval for and commenced two Phase III clinical trials in Europe using the modified process in patients with acute and chronic anemia. We recently completed one of these Phase III clinical trials, with the INTERCEPT Blood System for red blood cells meeting its primary endpoint. However, we cannot assure you that the adverse events observed in the terminated 2003 Phase III clinical trials of our earlier red blood cell system will not be observed in the ongoing Phase III or any future clinical trials of our red blood cell system. In addition, although our recently-completed Phase III clinical trial in acute anemia patients using our modified process met its primary endpoint, we cannot assure you that the same or similar results will be observed in our ongoing Phase III or any potential future clinical trials using our modified process.

The FDA has required that we successfully complete an additional Phase II recovery and survival study, which we completed in December 2014, prior to reaching agreement on any Phase III clinical trial protocol which we would likely need to successfully conduct and complete before the FDA would consider our red blood cell product for approval. We also understand that one or more additional *in vitro* studies will be required to be successfully completed and submitted to the FDA prior to any initiation of a potential Phase III clinical trial. We currently plan to complete our development and CMC activities and planned CE Mark submission, as well as such additional *in vitro* studies and any other prerequisites, before proposing a Phase III clinical trial protocol to the FDA in support of a potential regulatory approval of the red blood cell system in the United States. There can be no assurance that we will be able to successfully satisfy any such prerequisites, nor can there be any assurance that we and the FDA will agree to any trial protocol we propose or that we will otherwise obtain FDA clearance to initiate a potential Phase III clinical trial.

We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another European Phase III clinical trial of our red blood cell system for chronic anemia patients ongoing. Although we plan to undertake additional development and CMC activities to support an anticipated CE Mark submission planned for the second half of 2016, such studies, including any additional studies required by the FDA prior to its review of any proposed U.S. Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a few years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing Phase III chronic anemia clinical trial may also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and the significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain regulatory approval for the product. A number of trial design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials. As part of our development and CMC activities, we will need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe and may have to complete additional activities prior to receiving regulatory approvals in the United States. Many of these activities may require capital beyond that which we currently have, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our research and development expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we continue to experience delays in testing, conducting trials or approvals, our product development costs will increase. Even if we were to successfully complete and receive approval for our

red blood cell system, potential customers may object to working with a potent chemical, like S-303, 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.

Platelet and Plasma Systems

In 2007, we obtained a CE mark approval (extended in 2012) from European Union regulators for our platelet system and will need to obtain an extension every five years. We or our customers have received approval for the sale and/or use of INTERCEPT-treated platelets in France, Switzerland, Germany and Austria. We or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals.

In 2006, we obtained a CE mark approval (extended in 2011) from European Union regulators for our plasma system. We or our customers have received approval for the sale and/or use INTERCEPT-treated plasma in France, Switzerland, and Germany. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval. If we or our customers are unable to obtain or maintain regulatory approvals for the use and sale or continued sale and use of INTERCEPT-treated platelets or plasma, market adoption of our products will be negatively affected and our growth prospects would be materially and adversely impacted.

In December 2014, the FDA approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease, or TA-GVHD. Also in December 2014, the FDA 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 are conducting *in vitro* studies for our platelet system to expand our label claims to include, among others, platelets suspended in 100% plasma in addition to platelets stored in storage solution, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. Failure to obtain any of these label expansion claims may negatively affect market adoption and our growth prospects would be materially and adversely affected.

As a condition to the FDA approval of the platelet systems, we are required to conduct a post-approval clinical study of the platelet system. If we are unable to complete this study or the results of this study reveal unacceptable safety risks, we could be required to perform additional studies, which may be costly, and even lose U.S. marketing approval of the platelet and/or plasma systems. In addition to these studies, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. In addition, there is a risk that these studies will show results inconsistent with our previous studies. Should this happen, potential customers may delay or choose not to adopt the INTERCEPT Blood System and existing customers may cease use of the INTERCEPT Blood System.

In addition, we have submitted and received approval from the FDA for an expanded use IDE to conduct a study using INTERCEPT to treat platelet donations in areas of the United States that are currently experiencing outbreaks of the chikungunya and dengue viruses. We also have submitted and received FDA approval for a Phase I clinical study protocol under the IDE to treat plasma derived from convalesced patients that were previously infected with the Ebola virus. Planning, execution and completion of these studies will result in additional costs, and will require attention and resources from our clinical, regulatory and management teams, which may result in a distraction from our commercialization efforts and other regulatory and clinical programs.

Post-Marketing Approval

We are also required to continue to comply with applicable FDA and other regulatory requirements now that we have obtained approval for the INTERCEPT Blood System for platelets and plasma. These requirements relate to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory agency requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to current cGMP and QSR requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We are also required to report certain adverse events and production problems, if any, to the FDA and foreign regulatory authorities, when applicable, and 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, 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, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

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

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;
- refusal to grant export or import approval for our products;
- withdrawing marketing approvals that have already been granted, resulting in prohibitions on sales of our products; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from selling our products and harm our business. In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to successfully commercialize and generate additional revenues from our platelet and plasma systems or any future products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results

will be adversely affected. Additionally, if we are unable to continue to generate revenues from the sale of our platelet and plasma systems, our potential for achieving operating profitability will be diminished and the need for additional capital to fund our operations will be increased.

In addition, the regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

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

In order to be used in clinical studies or sold in the United States, our products are required to be manufactured in FDA-approved facilities. If any of our suppliers fail to comply with FDA's good manufacturing practice 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 revenue from the sale of our platelet or plasma system in the United States and achieve operating profitability.

We and our third-party suppliers are also required to comply with the FDA-mandated cGMP and QSR requirements, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with cGMP and QSR requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. If we or our suppliers fail to adhere to cGMP and QSR requirements, have significant non-compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us, which could delay production of our products and may include:

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

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing approval in the United States or elsewhere, our suppliers will have to pass an audit by the FDA or other regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits. Such audits and any audit remediation may be costly. Failure to pass such audits by any of our suppliers would affect our ability to obtain licensure in the United States or elsewhere.

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

Any modifications to the platelet 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 approval of a new premarket approval application, or 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 clearances or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, due to the obsolescence of certain parts, we will likely need to redesign the illuminators used in the platelet and plasma systems. In addition, in order to address the entire market in the United States, we will need to develop and test additional configurations of the platelet system, including to make the platelet system compatible with platelets suspended in 100% plasma, triple dose collections and random donor platelets. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations could significantly limit revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales and negatively impact our profitability potential and future growth prospects.

We operate a complex global commercial organization, with limited experience in many countries, including the United States. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies.

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

We have a wholly-owned subsidiary, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in Europe, the CIS and the Middle East. Our commercial activities for the United States, Latin and South America and Asia are based out of our headquarters in Concord, California with certain individuals servicing Latin and South America and Asia, domiciled outside of the United States. We have recently begun building out our commercial organization in the United States and as a result our team based in the United States has limited to no experience selling and marketing our platelet and plasma systems. We will need to maintain and continue to increase our competence in a number of functions, including sales, 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 United States, European Union, South American, Asian and local standards and practices, including regulatory, legal and tax requirements, with some of which we have limited experience. In this regard, should we obtain regulatory approval in an increased number of geographies, we will need to ensure that we maintain a sufficient number of personnel or develop new business processes to ensure ongoing compliance with the multitude of regulatory requirements in those territories. Hiring, training and retaining new personnel is costly, time consuming and distracting to existing employees and management. We have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all. In addition, in some cases, the cost of obtaining approval and maintaining compliance with certain regulations and laws may exceed the revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition.

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

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain and maintain any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may impact our financial results. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of 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. Agreements with our distributors typically require the distributor to maintain quality standards that are compliant with standards generally accepted for medical devices. We may be unable to ensure that our distributors are compliant with such standards. Further, we have limited visibility into the identity and requirements of blood banking customers these distributors may have. Accordingly, we may be unable to ensure our distributors properly maintain illuminators sold or provide quality technical services to the blood banking customers to which they sell. In addition, although our agreements with our distributors generally require compliance with local anti-corruption laws, the U.S. Foreign Corrupt Practices Act, and other local and international regulations, we have limited ability to control the actions of our distributors to ensure they are in compliance. Noncompliance by a distributor could expose us to civil or criminal liability, fines and/or prohibitions on selling our products in certain countries.

Currently, a fairly concentrated number of distributors make up a significant portion of our 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 2013 and 2014, we experienced weaker than expected growth due to declining performance by certain of our distributors. We have recently transitioned certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors. Because these are new distribution partners who have limited experience marketing and selling our products, we cannot be certain that these new distribution partners will perform better than their predecessors. In other territories, we transitioned to a Cerus direct sales model. We believe this transition will provide us with better visibility into and control of sales execution. Implementing such changes has negatively impacted the volume of INTERCEPT disposable kit sales as distribution partners sell through their disposable kit inventory and may continue to negatively impact the volume of INTERCEPT disposable kit sales in future periods. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. The loss of these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us which may be difficult to do in a timely manner, or at all. We expect that our product revenues will be adversely impacted with the loss or transition of one or more of these distributors. If we chose to terminate additional 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. Doing so may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense and 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.

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.

Our products are a novel technology in the United States and blood centers and clinicians have little to no experience with pathogen reduction systems. Further, we have no prior experience commercializing products in the United States. We may be unable to develop and maintain an effective and qualified U.S.-based commercial organization or educate blood centers or clinicians. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our platelet and plasma systems in the United States.

Our ability to generate significant revenue from our platelet and plasma systems depends in part on our ability to achieve market acceptance of, and to otherwise effectively market, our platelet and plasma systems in the United States. As a company, we have no prior experience in commercializing any products in the United States. We are also still in the process of establishing a U.S. based sales and marketing organization. In addition, we intend to hire additional medical science liaisons, or MSLs, to help educate hospitals and physicians on our products, clinical trial history and publications. MSLs are highly educated and trained professionals and the hiring market for MSLs is highly competitive. As such, we will need to commit significant additional management and other resources to building out our MSL team as well as the growth of our sales and marketing organization. We may be unable to develop and maintain adequate MSL, sales and marketing capabilities for the U.S. market and we also may not be able to devote sufficient resources to the advertising, promotion and sales efforts for the platelet and plasma systems in the United States. We will also have to compete with other life sciences and medical device companies to recruit, hire, train and retain the MSL, sales and marketing personnel that we anticipate we will need in the future. For these and other reasons, we may be unable to develop and maintain an effective and qualified U.S.-based commercial organization in a cost-effective manner or realize a positive return on our investment. If we are unable to develop and maintain an effective and qualified U.S.-based commercial organization in a timely manner or at all, we may fail to realize the full sales potential of our platelet and plasma systems in the United States.

Our manufacturing supply chain exposes us to significant risks.

We do not own our own manufacturing facilities, but rather manufacture our products using a number of third party suppliers, many of whom are our sole suppliers for the particular product or component that we procure. We rely on various contracts and our relationships with these suppliers to ensure that the sourced products are manufactured in sufficient quantities, timely, to our exact specifications and at prices we agree upon with the supplier. The price that we pay to some of our suppliers is dependent on the volume of products or components that we order. If we are unable to meet the volume tiers that afford the most favorable pricing, our margins will decrease.

In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufactures. The amended terms also provide for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. In addition, the amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and

maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business. In October 2014, Fresenius announced plans to cease manufacturing certain of its non-Cerus product lines and to significantly reduce its workforce at the manufacturing facility at which our products are made. Disruptions to our supply chain as a result of any potential ensuing protests, strikes or other work-stoppages would be detrimental to our business and operating results. We do not currently have plans to terminate our amended agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement. However, in the event Fresenius refuses or is unable to continue operating under the amended agreement, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected.

We also have contracts with other third-party suppliers, including Ash Stevens for the manufacture of amotosalen, our proprietary compound for inactivating pathogens using our platelet and plasma systems; Purolite, and separately, Porex, for the manufacture of components of the compound adsorption devices used in our platelet and plasma systems; and NOVA for the manufacture of illuminators and certain components of the INTERCEPT Blood System. These independent suppliers are currently our sole qualified suppliers for such components.

Our manufacturing and supply agreement with Ash Stevens extends through December 31, 2015, and is automatically renewable thereafter for periods of two years each, but may be terminated by Ash Stevens provided that Ash Stevens notifies us in writing at least two years in advance. Although we are not subject to minimum annual purchase requirements under the manufacturing and supply agreement with Ash Stevens, we may be required to pay a maintenance fee of up to $50,000 a year if specified quantities of amotosalen are not purchased in any year. We have incurred these maintenance fees in the past and may incur these maintenance fees in future periods.

Our supply agreement with Porex was amended in December 2014 and now expires on December 31, 2016. Porex is our sole supplier for certain components of the compound adsorption devices. We are subject to certain minimum annual purchase requirements under our agreement with Porex and are required to compensate Porex if we do not meet such minimum annual purchase requirements. We entered into an amended and restated supply agreement with Purolite, which supplies other components of the compound adsorption devices, in April 2014. The amended supply agreement expires in April 2021 and will automatically renew for an additional year unless either party has provided notice not to renew at least two years prior to the expiration. Under the terms of the amended agreement, pricing is volume based and is subject to annual, prospective adjustments based on a Producer Price Index subject to an annual cap. Our agreement with NOVA, which manufacturers our illuminators, extends through September 2015 and is automatically renewable for one year terms, but may be terminated by NOVA on at least twelve months' prior written notice.

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. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. Although we are actively evaluating alternate suppliers for certain of our products and components, we do not have qualified suppliers beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. Identification and qualification of alternate suppliers will be time consuming and costly. If we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient.

Currently NOVA is manufacturing illuminators to meet customer demand and maintain our own inventory levels. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. Certain of our components are in limited supply and are used as spare parts for the maintenance of illuminators used by our customers. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. Certain parts used in our illuminator are obsolete. Accordingly, our product lifecycle management plans include development of upgraded versions of the illuminator, initially focused on utilizing more readily available components. The upgraded version of the illuminator is not expected to be in production until at least the first half of 2016. Although we have sufficient inventory of parts to manufacture the current generation of illuminators for anticipated demand in the United States and other geographies, the successful completion of the upgraded versions of the illuminator may be expensive and will require approval of a new PMA or PMA supplement. Our failure to obtain FDA and foreign regulatory approvals of a new illuminator could significantly limit revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive these approvals could reduce our sales and negatively impact our profitability potential and future growth prospects. In addition, our illuminators contain embedded proprietary software that runs on software code we have developed and that we own. Changes to certain components due to obsolescence, illuminator redesign or market demand, may require us to modify the existing software code or to develop new illuminator software. Our ability to develop new illuminator software, correct coding flaws and generally maintain the software code is reliant on third-party contractors who, in some cases, have sole knowledge of the software code. Our ability to develop and maintain the illuminator software may be impaired if we are not able to continue contracting with those key third-party contracted developers or if we are unable to source alternate employees or consultants to do so.

In the event that alternate manufacturers are identified and qualified, we will need to transfer know-how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers; 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 sources of supply to Fresenius, NOVA, or other 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. Fresenius is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms favorable to those that we currently have with our manufacturers. Many of the existing agreements we have with suppliers contain provisions that we have been operating under for an extended period of time, including pricing. Should we enter into agreements or amend agreements with any manufacturer with less favorable terms, including pricing, our results of operations may be impacted, our recourse against such manufacturers may be limited, and the quality of our products may be impacted.

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In several instances over the past two years, nonconformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. Non-conformities can increase our expenses and reduce gross margins. Should non-conformities occur in the future, we may be unable to manufacture products to meet customer demand, which would result in lost sales and could cause irreparable damage to our customer relationships. Later discovery of problems with a product, manufacturer or facility may result in additional

restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations could be harmed and we would incur unforeseen losses.

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

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, manufacturing overhead variances or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or may not accurately forecast demand ourselves for the INTERCEPT Blood System. 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. We have entered into certain public tenders, some which call for us to maintain certain minimum levels of inventory. If our suppliers fail to produce components or our finished products satisfactorily, timely, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non-compliance with certain public tenders which may in turn result in permanent harm to our customer relations or loss of customers. 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. Our platelet and plasma systems' disposable kits have a two-year shelf life from the date of manufacture. 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 migrate supply disruptions. We will need to destroy or consume the outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs or reduced gross margins.

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

We are subject to a number of laws that affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians, healthcare providers or other potential purchasers of our products. These laws are often broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. For example, within the European Union, the control of unlawful marketing activities is a matter of national law in each of the member states. The member states of the European Union closely monitor perceived unlawful marketing activity by companies. We could face civil, criminal and administrative sanctions if any member state determines that we have breached our obligations under its national laws. 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 and state healthcare regulatory laws, including, but not limited to, anti-kickback laws, false claims laws, privacy laws, and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, hospitals, physicians, healthcare providers and our customers are or will be subject to scrutiny under these laws. Violations of these laws can subject us to 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, and the curtailment of our operations. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or 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 that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, and which may apply to entities that provide coding and billing advice to customers;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented, a claim to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements 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 certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, 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 law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; U.S. state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government or otherwise restrict payments that may be made to healthcare providers; U.S. state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and U.S. state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

agents or distributors to comply with these laws, rules and regulations could delay our expansion into high-growth markets, could damage market perception of our business and could adversely affect our existing business operations. Increased business in higher risk countries could also subject us and our officers and directors to increased scrutiny and increased liability.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, among other things, amends the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

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

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

In addition, there has been a recent trend of increased U.S. federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. On February 8, 2013, the Centers for Medicare & Medicaid Services, or CMS, released its final rule implementing section 6002 of the Affordable Care Act known as the Physician Payment Sunshine Act that imposes new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for "knowing failures." The period between August 1, 2013, and December 31, 2013 was the first reporting period, for which manufacturers were required to report aggregate payment data to CMS by March 31, 2014. Manufacturers also will be required to report to CMS detailed payment and transfers of value data and submit legal attestation to the accuracy of such data during Phase 2 of the program, which began May 2014 and extends for at least 30 days. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year. Due to the difficulty in complying with the Physician Payment Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device

manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

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

Most of these laws apply to not only the actions taken by us, but also actions taken by our distributors. We have limited knowledge and control over the business practices of our distributors, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition.

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

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

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

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

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among

other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2024, unless additional congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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.

Our platelet products and product candidates are not compatible with some collection and storage methods or combinations thereof.

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 United States and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. 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 United States. 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, although our label indications in the United States do not currently provide for platelets suspended in 100% plasma. Fresenius is the exclusive manufacturer of InterSol and MacoPharma of SSP+, both widely-used platelet additive solutions. Many of our customers and prospective customers use InterSol or SSP+ in connection with INTERCEPT treatment. Similarly, many of our customers combine multiple plasma components from whole blood donations before treating the combined product with INTERCEPT. Grifols makes such a product (Plasmix). Customers' ability to use our INTERCEPT products may be impaired should manufacturers of those products, including those sold by Grifols, not provide access to the products allowing for the combination of multiple components. Should Fresenius, MacoPharma, or Grifols fail to obtain or maintain regulatory approval for InterSol, SSP+, or Plasmix, respectively, or if any should decide to cease distribution of those respective products to customers and prospective customers, our ability to sell the INTERCEPT Blood System may be impaired.

In order to address the entire market in the United States, Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the United States, we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. In the United States, our platelet system is currently only approved for apheresis collections and for use with platelets suspended in a storage solution. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, platelets suspended in 100% plasma, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials, and will require approval of a PMA supplement. Our failure to obtain FDA and foreign regulatory approvals of these new configurations could significantly limit revenues from sales of the platelet system. In any event, delays in receipt or failure to receive approval could reduce our sales and negatively impact our profitability potential and future growth prospects. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma systems. In addition, we will need to continue to generate acceptable data in order to conform with the evolving collection practices such as automated whole-blood collection. If we are unable to conform to evolving collection practices our ability to address those portions of the market may be

compromised. These development activities will increase our costs significantly and may not be successful. We may need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations. Delays in obtaining any future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability.

We have used prototype components in our preclinical studies and clinical trials of the red blood cell system and have not completed the components' commercial design. We will be required to identify and enter into agreements with third parties to further develop and manufacture the red blood cell system. Failure to maintain these relationships, poor performance by these third parties or disputes with these third parties could negatively impact our business.

The red blood cell systems that have been used and are currently being used in our clinical trials have been and are prototypes of the system expected to be used in the final product. As a result, we plan to perform additional preclinical studies and clinical trials using the commercial version of the system to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial product, which will increase our expenses and delay the potential commercialization of our red blood cell system. We may determine that the red blood cell system may not be commercially feasible from potential customers' perspectives. If we fail to develop commercial versions of the red blood cell system in a timely manner, our potential revenue would be delayed or diminished and our potential competitors may be able to bring products to market before we do.

The design and engineering effort required to complete the final commercial version of our red blood cell system will likely be substantial and time-consuming. As with any complex development effort, we expect to encounter design, engineering and manufacturing issues, which issues could be exacerbated if the partners with whom we will be working have competing or conflicting priorities or ideas on the development and design of the system. Such issues have previously arisen, sometimes unexpectedly, and solutions to these issues have not always been readily forthcoming. We cannot guarantee that if such issues arise, they will be resolved in a commercially viable manner. Additional unforeseen design, engineering and manufacturing issues may arise in the future, which could increase the development cost and delay commercialization of our red blood cell system. We will need to identify and contract with manufacturers who can develop processes to manufacture components and the compounds used in the red blood cell system. For commercial manufacturing, we will need to demonstrate to regulatory authorities that the commercial scale manufacturing processes comply with government regulations and that the compounds are equivalent to originally licensed compounds. It may be difficult to economically manufacture the red blood cell system on a commercial scale and such costs may ultimately exceed the price the market is willing to pay for such a system.

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

We expect our products will continue to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use and may compete with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to customer and prospective customer needs, successfully receive and maintain regulatory approvals, and adapt to medical and technological changes brought about by the development and introduction of new products. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures. If competitors' 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 inactivating certain types of pathogens from blood products, including certain non-lipid-enveloped viruses, such as hepatitis A and E viruses, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, which is also a non-lipid-enveloped virus, for which our products have not demonstrated a high level of inactivation. While studies have demonstrated that our products can effectively inactivate a broad spectrum of pathogens in blood components, market adoption of our products may be reduced if customers determine that competitors' products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. In addition, customers and prospective customers may believe that our competitors' products are safer, more cost effective or easier to implement and incorporate into existing blood processing procedures than INTERCEPT Blood System products. In Europe, several companies, including Grifols S.A., Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has been issued CE marks for its system for both platelets and plasma. We understand that Terumo BCT is also developing a pathogen reduction system for whole blood and further understand that Terumo BCT has recently completed a clinical trial of its whole blood system in Ghana, although the results of the trial are currently unavailable to the public. Terumo BCT's product candidates, if successful, may offer competitive advantages over our INTERCEPT Blood System. Terumo Corporation is a large Japanese-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo's resources and their pre-existing relationships with regulators and customers. Should Terumo BCT's product be approved for use and commercialized in Japan, our products would likely directly compete with their products and we believe we would likely either need to establish operations in Japan or partner with a local Japanese company.

Octapharma AG received FDA approval in January 2013 to sell treated fresh frozen plasma for certain indications and is currently commercially available. Should Octapharma enter into exclusive agreements with key customers, our plasma system may encounter market resistance and we will have a more limited market into which we can sell.

Other companies developing competing products may also offer and sell other blood-banking products and services. As a result, competitors may have pre-existing long-term relationships with customers and may be able to offer synergies for both pathogen reduction and non-pathogen reduction products that we are unable to offer. Regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets.

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

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. We may be liable if any of our products cause injury, illness or death. Although we will have completed preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that

we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in preclinical and clinical testing could be discovered after a marketing approval has been received. For example, in cases where we have obtained regulatory approval for our products, we have demonstrated pathogen reduction to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. 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. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. In addition, should personnel at clinical study sites or ultimately, potential customers, be harmed by S-303, or believe they have been or could be harmed by S-303, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. S-303 is considered a potent chemical and is the active compound of our red blood cell system.

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

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

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. 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. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to supply our products in a cost-effective and timely manner in order to meet our customers' demands. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future

that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device 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. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. If we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products, whether in the United States 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.

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

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercial launch of our platelet and plasma systems, costs associated with planning, enrolling and completing the ongoing studies under our IDEs, and the post-approval study we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, including our ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities related to our platelet, plasma and red blood cell systems, including the post-approval study we are required to conduct in connection with FDA approval of the platelet system, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, as well as to collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that our available cash and cash equivalents and short-term investments, together with expected availability under our loan and security agreement with Oxford Finance LLC, or Oxford Finance, as well as cash received from product sales, will be sufficient to meet our capital requirements for at least the next twelve months. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of

amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

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

As a result of economic conditions, general global economic uncertainty and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we will need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. Apart from the proposed studies under our IDEs, we do not plan on conducting any additional randomized controlled clinical trials of the red blood cell, platelet or plasma systems unless and 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 loan and security agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the loan and security agreement.

Our loan and security agreement with Oxford Finance provides for up to $30.0 million in term loans due on June 1, 2019, of which $10.0 million in term loans has been borrowed to date. All of our current and future assets, except for intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., are secured for our borrowings under the loan and security agreement. The loan and security agreement requires 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 loan and security 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 loan and security agreement. If we are unable to repay those amounts, the lenders under the loan and security 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 covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5% penalty and restrict access to additional borrowings under the loan and security agreement. Moreover, while we currently have the ability to borrow an additional $10.0 million under the loan and security agreement, our ability to access the final $10.0 million under the loan and security agreement is subject to our ability to achieve a certain revenue threshold, which condition we may not be able to meet and which and could adversely affect our liquidity. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt

capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

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

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

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

We are highly dependent upon our executive management team and other critical personnel, including our specialized research and development, regulatory and operations personnel, many of whom have been employed with us for many years and have a significant amount of institutional knowledge about us and our products. We do not carry “key person” insurance. If one or more members of our executive management team or other key personnel were to retire or resign, our ability to achieve development, regulatory or operational milestones for commercialization of our products could be adversely affected if we are unable to replace them with employees of comparable knowledge and experience. In addition, we may not be able to retain or recruit other qualified individuals, and our efforts at knowledge transfer could be inadequate. If knowledge transfer, recruiting and retention efforts are inadequate, significant amounts of internal historical knowledge and expertise could become unavailable to us.

We also rely on our ability to attract, retain and motivate skilled and highly qualified personnel in order to grow our company. Competition for qualified personnel in the medical device and pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, results of operations and growth prospects could be adversely affected. Even if we are able to identify and hire qualified personnel commensurate with our growth objectives and opportunities, the process of integrating new employees is time consuming, costly and distracting to existing employees and management. Such disruptions may have an adverse impact on our operations, our ability to service existing markets and customers, or our ability to comply with regulations and laws.

All of the employees of our subsidiary, Cerus Europe B.V., are employed outside the United States, 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 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.

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

Our business is increasingly dependent on complex and interdependent information technology systems, including internet-based systems, databases and programs, to support our business processes as well as internal and external communications. These computer systems are potentially vulnerable to breakdown, malicious intrusion and computer viruses which may result in the impairment of production and key business processes or loss of data or information. Additionally, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

In addition, our previous enterprise resource planning system, a critical system used to run our business, is no longer supported by the developer of that system. Accordingly, we recently implemented a new enterprise resource planning system (the ERP System). The new ERP System is extremely complex and impacts a significant number of our business processes. Should we experience unforeseen difficulties with our new ERP System, we may experience disruptions to our operations, increased costs in troubleshooting and resolving the issues, and erosion in confidence from customers and employees, any of which could have a material adverse effect on our business and operations.

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, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. In addition, utilization of NOL carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions, which may result in the expiration of NOL carryforwards before future utilization. In general, under the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research and development credit carryforwards) to offset its post-change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. Although we have completed studies to provide reasonable assurance that an ownership change limitation would not apply, we cannot be certain that a taxing authority would reach the same conclusion. If, after a review or audit, an ownership change limitation were to apply, utilization of our domestic NOL and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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 a United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exists 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 infringe this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages, cease the use and sale of our platelet and plasma systems and/or obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all. Our patents expire at various dates between now and 2031. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates from 2015 to 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products, including in connection with our planned commercialization of the platelet and plasma systems in the United States. 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 United States, including the CIS countries, China and India, jurisdictions where we are currently expanding our commercialization efforts through distributors. In certain countries, compulsory licensing laws exist that may be used to compel a patent owner to grant licenses to third parties, for reasons such as non-use of the patented subject matter within a certain period of time after patent grant or commercializing in a manner that is cost-prohibitive in the country. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license for INTERCEPT to a third party, which could materially diminish the value of such patents. This could adversely impact our potential 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 United States 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.

As our international operations grow, we may be subject to adverse fluctuations in exchange rates between the United States dollar and foreign currencies.

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

Product sales of the INTERCEPT blood system are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of other income, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States 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, our revenues and expenses denominated in Euros 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.

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

Our shares of common stock are currently quoted on the Nasdaq Global Market under the symbol “CERS.” The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered, which may limit our ability to effectively raise money. In addition, due to the limitations of our market and the volatility in the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to sell. As a result of this lack of trading activity, the quoted price for our common stock is not necessarily a reliable indicator of its fair market value.

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

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

Complying with Section 404 requires a rigorous compliance program as well as adequate time and resources. As a result of expanding our commercialization efforts, developing, improving and expanding our core information technology systems as well as implementing new systems to support our sales, supply chain activities and reporting capabilities, all of which require significant management time and support, we may not be able to complete our internal control evaluation, testing and any required remediation in a timely fashion. Additionally, if we identify one or more material weaknesses in our internal control over financial reporting, we will not be unable to assert that our internal controls are effective. For example, our management concluded that our internal control over financial reporting was ineffective as of December 31, 2014, because material weaknesses existed in our internal control over financial reporting related to the valuation of our inventory and cost of product revenue and the timeliness and accuracy of recording adjustments to certain accrued liabilities as reported on our consolidated balance sheets and statements of operations. If we are unable to remediate these material weaknesses, or other material weaknesses are identified in the future or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be materially misstated, we would continue to receive an adverse opinion regarding our internal controls over financial reporting from our independent registered public accounting firm, and we could be subject to investigations or sanctions by regulatory authorities, which would require additional financial and management resources, and the value of our common stock could decline. In addition, because we have concluded that our internal control over financial reporting is not effective, and to the extent we identify future weaknesses or deficiencies, there could be material misstatements in our consolidated financial statements and we could fail to meet our financial reporting obligations. As a result, 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 stockholder rights plan, our compensatory arrangements and Delaware law could make it more difficult for a third party to acquire us, even if the offer may be considered beneficial by our stockholders.

Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti-takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. In addition, Section 203 of the Delaware General Corporation Law, unless its application has been waived, provides certain default anti-takeover protections in connection with transactions between the company and an “interested stockholder” of the company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent stockholders. Our board of directors has also adopted a stockholder rights plan, or “poison pill,” which would significantly dilute the ownership of a hostile acquirer. 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 acquiror 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. This leased facility includes laboratory space for blood safety research and supports general administrative, marketing and technical support functions. We also lease a facility in Amersfoort, the Netherlands, which is used for selling and administrative functions. We believe that our current facilities will be adequate for the foreseeable future. The following table summarizes the properties we lease and their location, size, term and primary functions as of December 31, 2014.

Location	Square Footage	Lease Expiration Date	Primary Functions
Concord, CA, United States	36,029	November 2019[1]	Administrative and research
Concord, CA, United States	21,440	August 2015[2]	Sales, administrative, marketing and technical support
Amersfoort, Netherlands	7,300	January 2018[3]	Sale and administrative

(1) The lease may be terminated by us no earlier than January 2015.
(2) In March 2015, we exercised our option to extend this lease through August 2017.
(3) The lease may be terminated by us no earlier than February 2016.

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." The following table sets forth, for the periods indicated, the high and low intra-day sales prices for our common stock as reported by the Nasdaq Global Market:

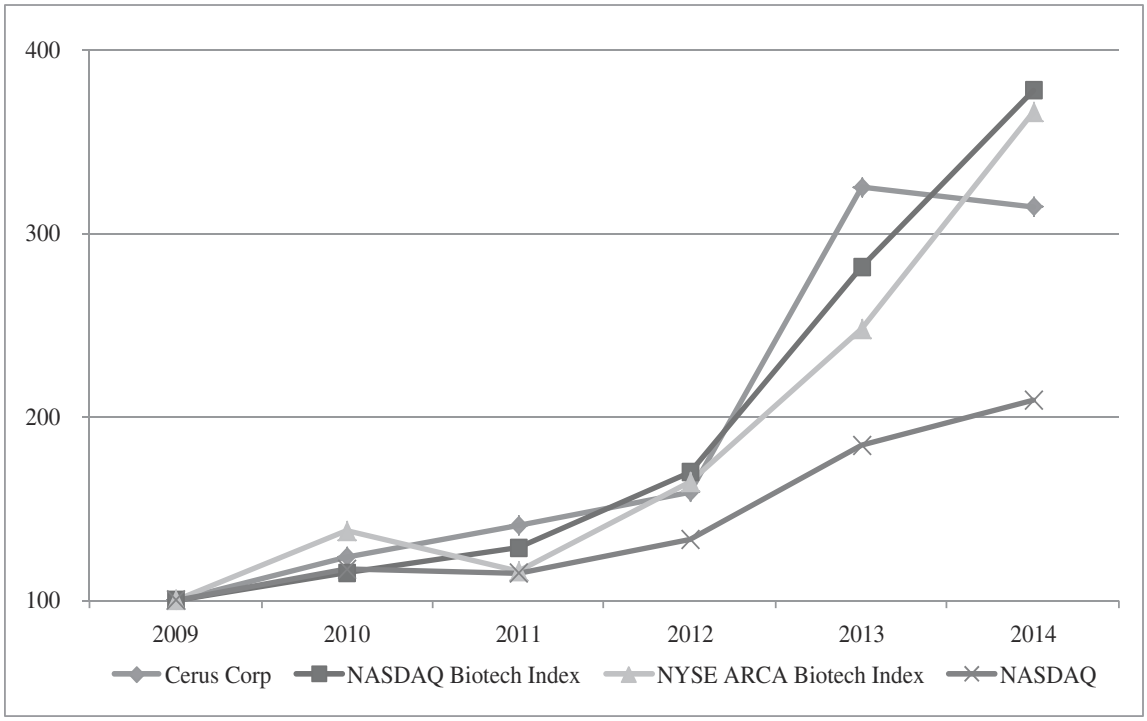
	High	Low
Year Ended December 31, 2014:		
First Quarter	$8.00	$4.76
Second Quarter	5.19	3.74
Third Quarter	4.36	3.48
Fourth Quarter	6.93	3.60
Year Ended December 31, 2013:		
First Quarter	$4.55	$2.90
Second Quarter	5.58	4.16
Third Quarter	6.77	4.34
Fourth Quarter	7.13	5.61

On February 27, 2015, the last reported sale price of our common stock on the Nasdaq Global Market was $4.78 per share. On February 27, 2015, we had approximately 149 holders of record of common stock. 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. Additionally, any cash dividends declared or paid would require prior written consent under the terms of the loan and security agreement entered on June 30, 2014, with Oxford Finance LLC.

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, 2009, and tracked the performance through December 31, 2014, for (i) our common stock, (ii) the NASDAQ Biotechnology Stocks Index, (iii) the NYSE ARCA Biotech Index, and (iv) 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,					
	2009	2010	2011	2012	2013	2014
Cerus Corporation	$100.00	$123.62	$140.70	$158.79	$324.12	$313.57
NASDAQ Biotech Index	100.00	115.01	128.59	169.61	280.89	376.68
NYSE ARCA Biotech Index	100.00	137.73	115.85	164.21	247.36	365.04
NASDAQ	100.00	116.91	114.81	133.07	184.06	208.71

(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 or the Securities Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

Item 6. *Selected Financial Data*

The following table summarizes certain selected financial data for the five years ended December 31, 2014, which has been derived from audited consolidated financial statements. The information presented below may not be indicative of future results and should be read in conjunction with "Item 7—*Management's Discussion and Analysis of Financial Condition and Results of Operations*," and the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
(in thousands, except per share amounts)	**2014**	**2013**	**2012**	**2011**	**2010[1]**
Consolidated Statements of Operations Data:					
Product related:					
Product revenue	$ 36,416	$ 39,657	$ 36,695	$ 30,602	$ 21,677
Cost of product revenue	21,188	22,602	20,616	18,535	12,046
Gross profit on product revenue	15,228	17,055	16,079	12,067	9,631
Government grants and cooperative agreements revenue	0	0	91	2,442	1,432
Loss from operations	(44,503)	(28,299)	(17,300)	(15,924)	(15,958)
Net loss	(38,755)	(43,337)	(15,917)	(16,982)	(16,911)
Net loss per share:					
Basic	$ (0.52)	$ (0.64)	$ (0.29)	$ (0.35)	$ (0.42)
Diluted	$ (0.61)	$ (0.64)	$ (0.33)	$ (0.35)	$ (0.42)
Weighted average common shares outstanding used for calculating loss per share:					
Basic	74,767	67,569	54,515	48,050	40,300
Diluted	76,534	67,569	55,061	48,050	40,300

	December 31,				
(in thousands)	**2014**	**2013**	**2012**	**2011**	**2010**
Consolidated Balance Sheets Data:					
Cash, cash equivalents and short-term investments	$51,294	$57,676	$26,696	$25,784	$30,009
Working capital	45,698	38,730	18,383	18,625	22,052
Total assets	81,776	83,381	48,919	45,367	48,167
Long-term obligations	11,068	1,162	4,199	5,940	4,732
Total stockholders' equity	41,521	42,795	19,107	18,313	23,732

(1) The statements of operations data for the year ended December 31, 2010 included (i) acquisition related costs of $0.5 million related to our acquisition of certain assets of BioOne in August 2010 and (ii) a gain of $0.3 million associated with relinquishing our shares in BioOne as part of the consideration for the acquisition of BioOne.

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

This discussion and analysis should be read in conjunction with our audited consolidated financial statements and the accompanying notes thereto included in this Annual Report on Form 10-K for the year ended December 31, 2014. Operating results for the year ended December 31, 2014 are not necessarily indicative of results that may occur in future periods.

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of the INTERCEPT Blood System. The INTERCEPT Blood System is designed for three blood components: platelets, plasma and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received CE marks and are being marketed and sold in a number of countries around the world including those in Europe, the Commonwealth of Independent States, or CIS, the Middle East and selected countries in other regions around the world.

In December 2014, we received approval of our premarket applications, or PMAs from the United States Food and Drug Administration, or FDA, for the INTERCEPT Blood System for platelet, and our INTERCEPT Blood System for plasma. The platelet system is approved for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease or TA-GVHD. The plasma system is approved for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

In addition to the PMAs that we filed with the FDA, we submitted and received approval from the FDA for a Phase I clinical study protocol under an investigational device exemption, or IDE, to treat plasma derived from convalesced patients that were previously infected with the Ebola virus and have recovered from the disease according to the criteria set by the Centers for Disease Control and Prevention. The transfusion of convalesced plasma from Ebola survivors is believed to pass on antibodies to the disease from the survivor to the recipient of the plasma transfusion. INTERCEPT use under this IDE is limited to pathogen reduction claims that rely on existing clinical data that we have regarding reduction of certain pathogens in donated plasma, and we do not have any clinical or commercial data on the efficacy of INTERCEPT to inactivate the Ebola virus and therefore do not know the effectiveness of INTERCEPT to inactivate the Ebola virus. In addition, we have submitted and received approval from the FDA for a separate, expanded use IDE, to conduct a study using INTERCEPT to treat platelet donations in areas of the U.S. that have outbreaks of the chikungunya and dengue viruses. Both of these studies are ongoing.

Our red blood cell system is currently in development and has not been commercialized anywhere in the world. We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another European Phase III clinical trial of our red blood cell system for chronic anemia patients ongoing. Although we plan to undertake additional development and CMC activities to support an anticipated CE mark submission planned for the second half of 2016, such studies, including any additional studies required by the FDA prior to its review of any proposed U.S. Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a few years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing Phase III chronic anemia clinical trial may also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain regulatory approval for the product. As part of our development and

CMC activities, we will need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe and may have to complete additional activities prior to receiving regulatory approvals in the U.S. Many of these activities may require capital beyond that which we currently have, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we continue to experience delays in testing, conducting trials or approvals, our product development costs will increase.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercial launch of our platelet and plasma systems, costs associated with planning, enrolling and completing the ongoing studies under our IDEs and post-approval study we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., including our ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities related to our platelet, plasma and red blood cell systems, including the post-approval study we are required to conduct in connection with FDA approval of the platelet system, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, as well as to collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that our available cash and cash equivalents and short-term investments, together with expected availability under our loan and security agreement with Oxford Finance LLC, or Oxford Finance, as well as cash received from product sales, will be sufficient to meet our capital requirements for at least the next twelve months. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

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

As a result of economic conditions, general global economic uncertainty and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we will need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. Apart from the

proposed studies under our IDEs, we do not plan on conducting any additional randomized controlled clinical trials of the red blood cell, platelet or plasma systems unless and until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Although we have begun the combined commercial launch of the plasma and platelet systems in the United States and announced our first two customer contracts for the sale of the INTERCEPT Blood System for platelets and plasma in February 2015, we do not expect to recognize meaningful revenues from sales in the United States in 2015, and our commercial activities for 2015 in the United States will be focused on supporting initial customer adoption and implementation. Significant revenue from customers in the U.S. may not occur until we have been able to successfully implement INTERCEPT and demonstrate that it is economic, safe and efficacious for potential customers. 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. 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 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.

On February 26, 2015, we announced our fourth quarter and year ended December 31, 2014 financial results. In connection with the announcement, we reported product revenue of $9.7 million and $36.5 million for the fourth quarter and year ended December 31, 2014, respectively. Subsequent to the announced results, we learned that collection from one of our customers in Russia was at risk. As such, and in accordance with our policy on revenue recognition, we determined that product revenue from this customer should be lowered by the amount at risk, totaling $0.1 million. Consequently, fourth quarter revenue was revised to $9.6 million and revenue for the year ended December 31, 2014 was revised to $36.4 million. This revision of revenue, combined with a $0.1 million increase in research and development expenses and a $0.1 million decrease in selling, general and administrative expenses, netted to an increase in net loss of $0.2 million for both the fourth quarter and year ended December 31, 2014, or $0.01 per diluted share for both the fourth quarter and year ended December 31, 2014. All necessary adjustments to our consolidated financial statements are reflected in the consolidated financial statements included in this Annual Report on Form 10-K.

Fresenius

We pay royalties to Fresenius Kabi AG, or Fresenius on INTERCEPT Blood System product sales under certain agreements that arose from the sale of the transfusion therapies division of Baxter International Inc., or Baxter, in 2007 to Fenwal Inc., or Fenwal (Fenwal was subsequently acquired by Fresenius in 2012), at rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Fresenius has assumed Fenwal's rights and obligations under those agreements, including our manufacturing and supply agreement. In this report, references to Fresenius include references to its predecessors-in-interest, Fenwal and Baxter.

We also paid Fresenius certain costs associated with the manufacture of our platelet and plasma system disposable kits pursuant to our amended manufacturing and supply agreement with Fresenius prior to the November 2013 amendment to such agreement. In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The amended terms also provide for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. At the current and expected near term production volumes, pricing is expected to be at the lowest tier. In addition,

the amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. In October 2014, Fresenius announced plans to cease manufacturing certain of its non-Cerus product lines and to significantly reduce its workforce at the manufacturing facility at which our products are made. We do not currently have plans to terminate our amended manufacturing and supply agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement. However, in the event Fresenius refuses or is unable to continue operating under the amended 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. Likewise, if we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others 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.

Equity and Debt Agreements

Cantor

On March 21, 2014, we entered into Amendment No. 1 to the Controlled Equity Offering℠ Sales Agreement, dated August 31, 2012, which we refer to as the Amended Cantor Agreement, with Cantor Fitzgerald & Co. or Cantor, that provides for the issuance and sale of shares of its common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to $70.0 million through Cantor. Under the Amended Cantor Agreement, Cantor acts as our sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of our common stock. The issuance and sale of these shares by us pursuant to the Amended Cantor Agreement are deemed an “at-the-market” offering and are registered under the Securities Act of 1933, as amended. During the year ended December 31, 2014 and 2013, approximately, 4.3 million and 5.4 million shares, respectively, of our common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of $18.6 million and $23.5 million, respectively. At December 31, 2014, we had approximately $22.5 million of common stock available to be sold under the Amended Cantor Agreement.

Debt Agreement

We entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, with Comerica Bank, which we refer to as the Amended Credit Agreement. The Amended Credit Agreement provided for a formula-based revolving line of credit, or RLOC, of up to $7.0 million. At December 31, 2013, we had $3.4 million outstanding under the RLOC, which was repaid in May 2014, and on June 30, 2014, the Amended Credit Agreement expired.

On June 30, 2014, we entered into a five year loan and security agreement with Oxford Finance, or the Term Loan Agreement, to borrow up to $30.0 million in term loans in three equal tranches, or the Term Loans. On June 30, 2014, we received $10.0 million from the first tranche, or Term Loan A. The second tranche of $10.0 million, or Term Loan B, was contingent upon the approval by the FDA of our PMA for either the plasma or platelet system, which occurred in December 2014. The availability of Term Loan B expires on June 15, 2015. The third tranche of $10.0 million, or Term Loan C, will be available from July 1, 2015 through December 31, 2015, contingent upon our achieving trailing six months’ revenue at a specified threshold, or Revenue Event. Term Loan A bears an interest rate of 6.95%. Term Loan B and Term Loan C will bear an interest rate calculated

at the greater of 6.95% or 6.72% plus the three month U.S. London Interbank Offered Rate, or LIBOR in effect three business days prior to the applicable Term Loan funding date. All of the Term Loans mature on June 1, 2019. We are required to make interest only payments through December 2015 followed by forty-two months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than November 30, 2015, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. We are also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. We pledged all current and future assets, excluding our intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at December 31, 2014.

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 revenue recognition, inventory valuation, certain accrued liabilities, valuation and impairment of purchased intangibles and goodwill, valuation of warrants, valuation of stock options under share-based payments, valuation allowance of our deferred tax assets and uncertain income tax positions. 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**—We recognize revenue in accordance with Accounting Standards Codification ("ASC") Topic 605-25, *"Revenue Recognition—Arrangements with Multiple Deliverables,"* as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is reasonably assured.

Revenue related to product sales is generally recognized when we fulfill our obligations for each element of an agreement. For all sales of our INTERCEPT Blood System products, we use a binding purchase order and signed sales contract as evidence of a written agreement. We sell its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. For revenue arrangements with multiple elements, we determine whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control. Once we determine if the deliverable meets the criteria for a separate unit of accounting, we must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because we have no vendor specific objective evidence or third party evidence for our systems due to our variability in our pricing across the regions into which we sell our products, the allocation of revenue is based on best estimated selling price for the platelet and plasma systems sold. The objective of best estimated selling price is to determine the price at which we would transact a sale, had the product been sold on a stand-alone basis. We determine best estimated selling price for its platelet and plasma systems by considering multiple factors, including, but not limited to, features and functionality of the system, geographies, type of customer, and market conditions. We regularly review best estimated selling price.

Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *"Accounting for Shipping and Handling Fees and Costs."* Value-added-taxes ("VAT") that we invoice to our customers and remits to governments are recorded on a net basis, which excludes such VAT from product revenue.

•**Inventories**—We own certain components of INTERCEPT disposable kits in the form of work-in-process inventory and finished goods, UVA illuminators, and certain replacement parts for our illuminators. While it is not customary for our inventory production cycle to exceed twelve months, under the Original Supply Agreement with Fresenius, our supply chain for certain of these components, held as work-in-process on our consolidated balance sheets, could potentially take in excess of one year to complete production before being utilized in finished INTERCEPT disposable kits. We maintain an inventory balance based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory will be consumed in production of finished units in order to sell to existing and prospective customers within the next twelve-month period. We use judgment to factor in lead times for the production of our finished units to meet forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year.

Under the Original Supply Agreement with Fresenius, our carrying value of INTERCEPT disposable kits was comprised of an annually set base price. In addition, at the end of each year, volume driven manufacturing overhead was either paid to or refunded to us by Fresenius if manufacturing volumes were higher or lower than the anticipated manufacturing volumes at the time the base price was established. As a result, manufacturing overhead could fluctuate and required us to use judgment in accruing the manufacturing overhead, which affected the per unit carrying cost of our finished goods. In addition, we used judgment in determining whether the manufacturing overhead was a cost of our inventory and recoverable when product is sold. We used significant judgment and evaluated manufacturing variances incurred during periods of abnormally low production by considering a variety of factors including the reasons for low production volumes, anticipated future production levels that correlate to and offset volumes experienced during abnormally low production cycles and contractual requirements. We recorded manufacturing variances incurred during periods without production as a component of "Cost of product revenue" on our consolidated statements of operations.

Under the 2013 Amendment with Fresenius, Fresenius is obligated to sell, and we are obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The amended terms also provides for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and adsorption media from us at fixed prices.

Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Our platelet and plasma systems' disposable kits generally have a two-year shelf life from the date of manufacture.

Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. Generally, we write-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 our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in "Cost of product revenue" on our consolidated statements of operations. We also wrote-down the value of certain unsalable inventory related to the products covered under the warranty claims against Fresenius.

•**Accrued expenses**—We record accrued liabilities for expenses related to certain contract research activities and development services, including those related to clinical trials, preclinical safety studies and external laboratory studies, as well as development activities being performed by third parties. Some of those accrued liabilities are based on estimates because billings for these activities may not occur on a timely basis consistent with the performance of the services. Specifically, accruals for clinical trials require us to make estimates surrounding costs associated with patients at various stages of the clinical trial, pass through costs to clinical sites, contract research organization costs including fees, database development, and reporting costs, among others.

•**Goodwill and intangible assets**—In August 2010, we acquired certain assets from BioOne. We accounted for the acquisition as a business combination in accordance with ASC Topic 805, *"Business Combinations."* In connection with the acquisition, we used significant judgment, including, but not limited to, judgments as to cash flows, discount rates, and economic lives, in identifying the assets acquired and in determining the fair values to record the purchased assets on our consolidated balance sheets. In addition, under ASC Topic 805, we were required to assess the fair value of the non-controlling interest that we held in BioOne prior to the acquisition. We determined that a considerable amount of the purchase consideration was goodwill, which represents value unique to us as the holder of worldwide rights to the INTERCEPT Blood System. We may be unable to realize the recorded value of the acquired assets and our assumptions may prove to be incorrect, which may require us to write-down or impair the value of the assets if and when facts and circumstances indicate a need to do so. We perform an impairment test on our goodwill annually on August 31 of each fiscal year or more frequently if indicators of impairment exist. If we determine that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, we must then proceed with performing the quantitative two-step process to test goodwill for impairment; otherwise, goodwill is not considered impaired and no further testing is warranted. We may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative two-step process; however, we may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The first step of the two-step process compares the fair value of each reporting unit with the respective carrying amount, including goodwill. We have determined that we operate in one reporting unit and estimate the fair value of our one reporting unit using the enterprise approach under which we consider our quoted market capitalization as reported on the Nasdaq Global Market. We consider quoted market prices that are available in active markets to be the best evidence of fair value. We also consider other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds the carrying amount, goodwill of the reporting unit is not considered impaired and, therefore, the second step of the impairment test is unnecessary. The second step of the two-step process, which is used to measure the amount of impairment loss, compares the implied fair value of each reporting unit's goodwill with the respective carrying amount of that goodwill. 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. On August 31, 2014, we performed our annual review of goodwill as described above and determined that goodwill was not impaired during the year ended December 31, 2014. We will continue to monitor events and changes in circumstances that could indicate carrying amounts of our intangible assets may not be recoverable. When such events or changes in circumstances occur, we assess 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, we then measure the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets. No events or changes in circumstances arose during the year ended December 31, 2014, which would require us to test the recoverability of our intangible assets.

•**Warrants**—In August 2009 and November 2010, we issued warrants to purchase 2.4 million and 3.7 million shares of common stock, respectively. The material terms of the warrants were identical under each issuance except for the exercise price, date issued and expiration date. In August 2014, all outstanding warrants issued in August 2009 were exercised and were no longer outstanding as of December 31, 2014. The fair value of the outstanding warrants issued in November 2010 is classified as a liability on our consolidated balance sheets as the warrants contain certain material terms which require us (or our successor) to purchase the warrants for

cash in an amount equal to the value of the unexercised portion of the warrants in connection with certain change of control transactions. In addition, we may also be required to pay cash to a warrant holder under certain circumstances if we are unable to timely deliver the shares acquired upon warrant exercise to such holder.

The fair value of these outstanding warrants outstanding as of December 31, 2014, is calculated using the Black-Scholes option-pricing model and prior to 2014, using a binomial-lattice option-pricing model; both models used inputs adjusted accordingly at each reporting period. Option-pricing models require that we use significant assumptions and judgment to determine appropriate inputs to the model. Some of the assumptions that we rely on include the volatility of our stock over the life of the warrant, risk-free interest rate and the probability of a change of control occurring. The binomial-lattice option-pricing model also considers a certain number of share price movements and the probability of each outcome happening.

Changes resulting from the revaluation of warrants to fair value are recorded as "Gain (loss) from revaluation of warrant liability" in the consolidated statements of operations. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants are reclassified from a liability to stockholders' equity on our consolidated balance sheets and no further adjustment to the fair value would be made in subsequent periods.

•**Stock-based compensation**—We issue stock-based awards to our employees, contractors and members of our Board of Directors, as strategic, long-term incentives. We also maintain an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. We record stock-based compensation expense for employee awards in accordance with ASC Topic 718, *"Compensation—Stock Compensation."* We use the Black-Scholes option pricing model to determine the grant-date fair value of stock-based awards. The Black-Scholes option pricing model requires that we use assumptions regarding a number of complex and subjective variables to determine appropriate inputs to the model, which include the expected term of the grants, actual and projected employee stock option exercise behaviors, including forfeitures, our expected stock price volatility, the risk-free interest rate and expected dividends. The grant-date fair value of stock-based awards is then recognized as stock-based compensation expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

We apply the provisions of ASC Topic 505-50, *"Equity Based Payment to Non-Employees"* for our stock-based awards issued to non-employees. Under those provisions, the measurement date at which the fair value of the stock-based award is measured is the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee's performance is complete.

•**Income taxes**—Since our inception, we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carry forwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. We do 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 the derecognition of a tax position. We recognize accrued interest and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our consolidated statements of operations, nor have we accrued for or made payments for interest and penalties. We continue to carry a full valuation allowance on all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed. Our tax years 2010 through 2013 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

Results of Operations

Years Ended December 31, 2014, 2013 and 2012

Revenue

(in thousands, except percentages)	Year Ended December 31, 2014	2013	2012	% Change 2014 to 2013	2013 to 2012
Product revenue	$36,416	$39,657	$36,695	(8)%	8%
Government grants and cooperative agreements revenue	0	0	91	0%	(100)%
Gross revenue	$36,416	$39,657	$36,786	(8)%	8%

Product revenue decreased by $3.2 million during the year ended December 31, 2014, compared to the year ended December 31, 2013, primarily as a result of lower unit sales volume of our disposable platelet and plasma system kits and the deterioration in the Euro relative to the U.S. dollar in the latter half of 2014, partially offset by increased average selling prices for both our disposable platelet and plasma system kits and higher unit sales volume for our illuminator devices. In early 2014, we transitioned certain markets in southern Europe from an exclusive distributor to our direct sales force. This transition resulted in lower revenue in the territory as the distributor sold down its remaining inventory to end-user customers in the territory contributing to the year-over-year reduction in demand for INTERCEPT disposable kits by approximately 5%.

Product revenue increased by $3.0 million during the year ended December 31, 2013, compared to the year ended December 31, 2012, primarily as a result of higher unit sales volume of our disposable plasma system kits and increased average selling prices for our disposable platelet system kits, partially offset by a slight decrease in unit sales volume of the platelet kits. Also contributing to the increase in product revenue was higher unit sales volume for our illuminator devices partially offset by a slight decrease in the average illuminator selling price.

We anticipate product revenue for both our platelet and plasma systems will increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway, including anticipated contribution from U.S. sales. The historical results may not be indicative of INTERCEPT Blood System revenue in the future.

There was no revenue from government grants and cooperative agreements during the years ended December 31, 2014 and 2013. The remaining award balance available under our Department of Defense grant was exhausted during the year ended December 31, 2012. We do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

Cost of Product Revenue

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

(in thousands, except percentages)	Year Ended December 31, 2014	2013	2012	% Change 2014 to 2013	2013 to 2012
Cost of product revenue	$21,188	$22,602	$20,616	(6)%	10%

Cost of product revenue decreased by $1.4 million during the year ended December 31, 2014, compared to the year ended December 31, 2013, primarily due to the lower volume of platelet and plasma disposable kits sold

during 2014 compared to 2013. To a lesser extent, the lower cost of product revenue during the year ended December 31, 2014 was also due to the November 2013 amendment to our agreement with Fresenius which, in part, altered product pricing to no longer include volume-driven overhead absorption starting in 2014. In addition we experienced lower scrap charges during 2014 compared to 2013, which was partially offset by higher freight charges.

Cost of product revenue increased by $2.0 million during the year ended December 31, 2013, compared to the year ended December 31, 2012, primarily due to the higher volume of plasma disposable kits and illuminators sold during 2013 compared to 2012. This was partially offset by lower scrap charges for 2013 compared to 2012.

Our realized gross margin on product sales was 42% during the year ended December 31, 2014. The decrease in gross margins on product sales was primarily due to higher average selling prices for platelet and plasma kits sold in 2014 as compared to 2013, which was offset by decreased margins on illuminators sold in support of IDE study efforts.

Our realized gross margins on product sales were 43% during the year ended December 31, 2013, down from 44% during the year ended December 31, 2012. The decrease in gross margin on product sales was due to higher unit sales volume of plasma disposable kits and lower unit sales volume of platelet kits in 2013 compared to 2012.

Changes in our gross margins are affected by various factors, including manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which product is sold, and the exchange rate of the Euro relative to the U.S dollar, our reporting currency. Generally, we offer our distributors tiered volume discounts of varying magnitudes, depending on their annual purchases. We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, manufacturing overhead variances or delays in manufacturing products. Our gross margins may be impacted in the future based on all of these criteria.

We expect to maintain inventory levels that will be sufficient to meet forecasted demand for a relatively short time period and plan to manufacture at levels above those produced in 2014. Manufacturing disposable kits at levels above the levels produced in 2014 should result in a continuing lower per unit cost of goods sold when the product is ultimately sold; however, actual manufacturing levels may differ from our assumptions.

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)	2014	2013	2012	2014 to 2013	2013 to 2012
Research and development	$21,800	$15,187	$7,603	44%	100%

Research and development expenses increased by $6.6 million during the year ended December 31, 2014, compared to the year ended December 31, 2013, and increased by $7.6 million during the year ended December 31, 2012, compared to the year ended December 31, 2012, primarily due to increased costs associated with clinical development of our red blood cell system, pursuit of our PMA approvals with the FDA for the platelet and plasma systems and our IDE studies. Of the total research and development expenses incurred, non-cash stock-based compensation expenses represented $1.0 million, $0.5 million and $0.6 million for the years ended December 31, 2014, 2013 and 2012, respectively.

We anticipate our research and development spending will continue to increase over the near term as we attempt to accelerate and complete enrollment in our Phase III chronic anemia clinical trial in Europe and as we undertake research and development activities to expand our label claims in the United States and further develop additional configurations of our products, including our illuminator. In addition, we have undertaken and plan to perform certain additional *in vitro* studies and clinical development in the U.S. which would result in further increased research and development spending. Subject to our ability to fund further development, clinical and regulatory efforts, we may also perform additional research and development activities in order to pursue regulatory approval for our products in the U.S. In addition, we may choose to invest in ongoing research and development efforts for our existing INTERCEPT products, including a full or partial redesign of the INTERCEPT illuminator. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, uncertainty of future preclinical studies and clinical trial results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under "Item 1A—*Risk Factors*" in Part I of this Annual Report on Form 10-K.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, non-cash stock based compensation, expenses for our commercialization efforts in a number of countries around the world including those in U.S., Europe, the CIS and the Middle East, Asia, Latin America, and expenses for accounting, tax, and internal control, legal and facility and infrastructure related expenses, and insurance premiums.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	**2014**	**2013**	**2012**	**2014 to 2013**	**2013 to 2012**
Selling, general and administrative	$37,729	$29,965	$25,665	26%	17%

Selling, general, and administrative expenses increased by $7.8 million during the year ended December 31, 2014, compared to the year ended December 31, 2013, primarily due to increased spending related to general corporate services, including continued spend in 2014 related to preparatory activities for the U.S. launch of our plasma and platelet systems, and to a lesser extent, higher workforce costs. Selling, general, and administrative expenses increased by $4.3 million during the year ended December 31, 2013, compared to the year ended December 31, 2012, primarily due to increased spending in 2013 related to general corporate services, and beginning phase preparatory activities for the U.S. launch of our plasma and/or platelet systems. Of the total selling, general and administrative expenses incurred, non-cash stock-based compensation represented $4.2 million, $2.8 million and $2.0 million for the years ended December 31, 2014, 2013 and 2012, respectively.

We anticipate our selling, general, and administrative spending to increase over the coming year, as we continue to on-board commercial capabilities in the U.S., including incremental back-office support, sales, marketing and MSLs.

Amortization of Intangible Assets

Amortization of intangible assets relates to a license to commercialize the INTERCEPT Blood System in certain Asian countries. These intangible assets are being amortized over an estimated useful life of ten years and will be reviewed for impairment.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	**2014**	**2013**	**2012**	**2014 to 2013**	**2013 to 2012**
Amortization of intangible assets	$202	$202	$202	0%	0%

Amortization of intangible assets remained flat during the year ended December 31, 2014, compared to the years ended December 31, 2013 and 2012, as there were no changes to the composition of our intangible assets or the assumptions used to determine the useful lives. In addition, no impairment charges were recognized related to our intangible assets during the years ended December 31, 2014, 2013 and 2012.

We expect that the amortization of our intangible assets to remain relatively consistent in future periods, unless facts and circumstances arise which may result in our intangible assets being impaired.

Non-Operating Income (Expense), Net

Non-operating income (expense), net consists of mark-to-market adjustments related to the calculated fair value of our outstanding warrants, foreign exchange gain (loss), interest charges incurred on our debt, interest earned from our short-term investment portfolio, and other non-operating gains and losses.

	Year Ended December 31,			% Change	
(in thousands, except percentages)	**2014**	**2013**	**2012**	**2014 to 2013**	**2013 to 2012**
Gain (loss) from revaluation of warrant liability	$ 7,708	$(15,099)	$2,059	151%	(833)%
Foreign exchange (loss) gain	(1,296)	533	86	(343)%	520%
Interest expense	(599)	(332)	(551)	80%	(40)%
Other income, net	130	78	31	67%	152%
Total non-operating income (expense), net	$ 5,943	$(14,820)	$1,625	(140)%	1,012%

Warrant liability

In August 2009 and November 2010, we issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively, in connection with offerings of our common stock. In August 2014, all 2.4 million warrants issued in August 2009 were exercised and were no longer outstanding at December 31, 2014. The fair value of the November 2010 outstanding warrants, which uses the Black-Scholes model, is classified as a liability on our consolidated balance sheets and is adjusted at each subsequent reporting period, until such time the instruments are exercised or otherwise modified to remove the provisions which require this treatment. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders' equity and no further adjustment to the fair value would be made in subsequent periods. Further changes in stock price will result in similar adjustment as needed.

We recorded a non-cash gain from the revaluation of the warrant liability of $7.7 million for the year ended December 31, 2014, compared to a non-cash loss of $15.1 million for the year ended December 31, 2013, for a net change of $22.8 million. This change is primarily due to the change in our underlying stock price as compared to the strike price of the warrants and the exercise of warrants during the current year. The net change in the revaluation of the warrant liability of $17.2 million decreased from a non-cash gain of $2.1 million during the year ended December 31, 2013, compared to the year ended December 31, 2012, primarily due to the change in our underlying stock price compared to the strike price of the warrants.

Foreign exchange gain (loss)

Foreign exchange loss increased to $1.3 million during the year ended December 31, 2014, compared to a gain of $0.5 million during the year ended December 31, 2013, primarily attributable to unfavorable foreign currency variations between the Euro and U.S. dollar, our functional currency. For the year ended December 31, 2013 compared to the year ended December 31, 2012, we experienced foreign exchange gain $0.4 million due to favorable foreign currency variations period over period between the Euro and U.S. dollar.

Interest expense

Interest expense increased by $0.3 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, primarily due a higher effective interest rate and larger outstanding debt balance under our Term Loan Agreement (see Debt section below), which commenced on June 30, 2014, compared to the credit facility that was outstanding in the prior periods. Interest expense decreased by $0.2 million during the year ended December 31, 2013, compared to the year ended December 31, 2012, primarily in connection with the early repayment of our term loan with Comerica in April 2013 and the remaining unaccreted balance of the loan's final payment fee and the unamortized discount were charged to interest expense.

Other income, net

Other income, net increased $0.05 million and $0.05 million for the year ended December 31, 2014, compared to December 31, 2013, and the year ended December 31, 2013, compared to December 31, 2012, respectively, primarily as a result of higher cash and investment balances period over period.

Provision for Income Taxes

	Year Ended December 31,			% Change	
(in thousands, except percentages)	**2014**	**2013**	**2012**	**2014 to 2013**	**2013 to 2012**
Provision for income taxes	$195	$218	$242	(11)%	(10)%

Provision for income taxes for the years ended December 31, 2014, 2013 and 2012 primarily consists of foreign taxes as our wholly-owned subsidiary headquartered in Europe drives the commercialization efforts of the platelet and plasma systems in Europe, the CIS and the Middle East. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations as we intend to permanently reinvest such earnings outside the U.S. We also incurred income taxes associated with timing differences for acquired goodwill that is amortizable for tax purposes.

Liquidity and Capital Resources

In recent years, our sources of capital have primarily consisted of public offerings and private placements of equity securities, debt instruments, and to a lesser extent, contribution from product sales and U.S. government grants and cooperative agreements, net of expenses.

At December 31, 2014, we had cash and cash equivalents of $22.8 million. Our cash equivalents primarily consist of money market instruments, which are classified for accounting purposes as available-for-sale.

Operating Activities

Net cash used in operating activities was $39.8 million for the year ended December 31, 2014, compared to $26.7 million during the year ended December 31, 2013. The increase in net cash used in operating activities was primarily related to the level of cash spent for PMA submission processes, development activities for our red blood cell program and illuminators and preparation for the U.S. commercial launch of our platelet and plasma systems. Also impacting this increase in net cash used in operating activities were changes in working capital with a net increase in the combined total for our accounts payable and accrued liabilities as a result of the timing of payments, and a decrease in accounts receivable during the year ended December 31, 2014, relative to the corresponding period in 2013. The increase in net cash used in operating activities was further impacted by a higher rate of inventory build during the year ended December 31, 2014, compared to the corresponding period in 2013.

Net cash used in operating activities was $26.7 million for the year ended December 31, 2013, compared to $13.9 million during the year ended December 31, 2012. The increase in net cash used in operating activities was

primarily related to additional operating expenditures in support of the business. Also impacting this increase in net cash used in operating activities were changes in working capital with a net increase in the combined total for our accounts payable and accrued liabilities as a result of the timing of payments, and an increase in accounts receivable during the year ended December 31, 2013, relative to the corresponding period in 2012 due to a heavy concentration of sales transactions in the final weeks of the year ended December 31, 2013, as well as a higher rate of inventory build during the year ended December 31, 2013, compared to the corresponding period in 2012.

Investing Activities

Net cash used in investing activities was $3.3 million for the year ended December 31, 2014, compared to $29.2 million during the year ended December 31, 2013. The change was primarily the result of the fewer investment purchases period over period offset by greater maturities of investments during the year ended December 31, 2014, in short-term available-for-sale investments. The change was further impacted by increases in capital expenditures during the year ended December 31, 2014, relative to the same period in 2013.

Net cash used in investing activities was $29.2 million for the year ended December 31, 2013, compared to $0.2 million provided by investing activities during the year ended December 31, 2012. The change was primarily the result of our decision to invest proceeds from our March 2013 public offering of our common stock into short-term available-for-sale investments.

Financing Activities

Net cash provided by financing activities was $36.5 million during the year ended December 31, 2014, compared to $58.6 million during the year ended December 31, 2013. The decrease in net cash provided by financing activities was primarily due to the proceeds received during the year ended December 31, 2013, from our March 2013 public offering of our common stock, which generated $38.0 million (net of $1.8 million in underwriter's discounts and $0.5 in offering costs) and, to a lesser extent, fewer sales of our common stock pursuant to the Amended Cantor Agreement during the year ended December 31, 2014. The overall decrease was partially offset by increased proceeds from the exercise of warrants and stock options and increased borrowings in 2014.

Net cash provided by financing activities was $58.6 million during the year ended December 31, 2013, compared to $14.9 million during the year ended December 31, 2012. The increase in net cash provided by financing activities was primarily due to proceeds received from our March 2013 public offering of our common stock and an additional $23.5 million received from sales of our common stock offerings pursuant to the Amended Cantor Agreement, offset slightly by repayment of debt principal.

Working Capital

Working capital increased to $45.7 million at December 31, 2014, from $38.7 million at December 31, 2013, primarily due to decreases in the liability for outstanding warrants. This was partially offset by lower balances in cash and investments, which was substantially the result of cash used in operations, including payment of accounts payables and accrued liabilities outstanding at year end at December 31, 2013, and increases in our inventories, prepaid assets, and other current assets. Working capital increased to $38.7 million at December 31, 2013, from $18.4 million at December 31, 2012, primarily due to proceeds from our March 2013 public offering of our common stock as well as sales of our common stock pursuant to the Amended Cantor Agreement, offset by cash used in operations. This was partially offset by increases in our warrant liability.

Capital Requirements

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection

with the continuing U.S. commercial launch of our platelet and plasma systems, costs associated with planning, enrolling and completing the ongoing studies under our IDEs, and the post-approval study we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., including our ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities related to our platelet, plasma and red blood cell systems, including the post-approval study we are required to conduct in connection with FDA approval of the platelet system, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, as well as to collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that our available cash and cash equivalents and short-term investments, together with expected availability under our loan and security agreement with Oxford Finance, as well as cash received from product sales, will be sufficient to meet our capital requirements for at least the next twelve months. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

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

As a result of economic conditions, general global economic uncertainty and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we will need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. Apart from the proposed studies under our IDEs, we do not plan on conducting any additional randomized controlled clinical trials of the red blood cell, platelet or plasma systems unless and until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Other Information

On March 2014, we amended the Amended Cantor Agreement to provide for the issuance and sale of our common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to $70.0 million through Cantor as our sales agent. During the year ended December 31, 2013, approximately 5.4 million shares, respectively, of our common stock was sold under the Amended Cantor Agreement for aggregate proceeds of $23.5 million. During the year ended, December 31, 2014, 4.3 million shares of our

common stock was sold under the Amended Cantor Agreement for aggregate net proceeds of $18.6 million. At December 31, 2014, we had approximately $22.5 million of common stock available to be sold under the Amended Cantor Agreement.

In August 2014, we filed a shelf registration statement on Form S-3 to offer and sell up to $250.0 million of common stock, preferred stock, warrants, and/or debt securities, less amounts sold under the Cantor Agreement following the effectiveness of the shelf registration statement and less the gross proceeds of $80.5 million of common stock sold in our January 2015 public offering. The net proceeds from this offering were approximately $75.7 million, net of underwriting discounts and other issuance costs of $5.1 million.

Commitments and Off-Balance Sheet Arrangements

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements as of December 31, 2014 or 2013.

Contractual Commitments

The following summarizes our contractual commitments at December 31, 2014:

(in thousands)	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Minimum purchase requirements	$ 10,828	$ 8,498	$ 2,330	$ 0	$ 0
Debt	12,690	695	6,454	5,541	0
Operating leases	1,172	891	256	25	0
Other commitments	1,029	467	287	275	0
Total contractual obligations	$ 25,719	$ 10,551	$ 9,327	$ 5,841	$ 0

Minimum purchase requirements

Our minimum purchase commitments include certain components of our INTERCEPT Blood System which we purchase from third party manufacturers.

Operating leases

We generally lease our office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. Our lease payments have increased as we exercised a ten year extension option on December 10, 2009, to extend the term of our Concord, California lease and exercised a five year extension option in January 2012, to extend the term of our Amersfoort, the Netherlands lease for an additional five years following the original lease expiration of January 2013. However, we have the right to early terminate our original Concord, California lease and our Amersfoort, the Netherlands lease, which could have occurred as early as January 2015 and February 2015, respectively. In June 2013, we executed a new two year lease for additional space in Concord, California. The term of this new lease commenced on August 1, 2013 and extends for two years with four (4) two year options for us to renew, the first of which we exercised in March 2015. Our facility leases qualify as operating leases under ASC Topic 840, *"Leases"* and as such, are not included on our consolidated balance sheets.

Other commitments

Our other commitments primarily consist of obligations for landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space. We pay for the financed

leasehold improvements as a component of rent and are required to reimburse our landlords over the remaining life of the respective leases. If we exercise our right to early terminate the Concord, California lease, we would be required to pay for any remaining portion of the landlord financed leasehold improvements at such time. At December 31, 2014, we had an outstanding liability of $0.6 million related to these leasehold improvements. Our agreements with Fresenius require us to pay royalties on sales of the INTERCEPT Blood System at rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Such royalties are calculated based on future product sales and are not provided for in the table above as they are dependent on events that have not yet occurred.

Debt

On June 30, 2014, we entered into the Term Loan Agreement with Oxford Finance to borrow up to $30.0 million in term loans in three equal tranches of Term Loans. On June 30, 2014, we received $10.0 million from Term Loan A. The second tranche of $10.0 million, Term Loan B, was contingent upon the approval by the FDA of our PMA for either the plasma or platelet system, which occurred in December 2014. The availability of Term Loan B expires on June 15, 2015. The third tranche of $10.0 million, Term Loan C, will be available from July 1, 2015 through December 31, 2015, contingent upon our achieving the Revenue Event. Term Loan A bears an interest rate of 6.95%. Term Loan B and Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. LIBOR rate in effect three business days prior to the applicable Term Loan funding date. All of the Term Loans mature on June 1, 2019. We are required to make interest only payments through December 2015 followed by forty-two months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than November 30, 2015, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. We are also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. The costs associated with the final payment will be recognized as interest expense over the principle life of the Term Loans. We may prepay the Term Loans subject to declining prepayment fees over the term of the Term Loan Agreement. We paid the lender a $0.2 million commitment fee related to the Term Loan Agreement which has been recorded as a discount on the Term Loans and is being amortized to interest expense using the effective interest method over the life of the Term Loans. In addition, we paid $0.1 million of the lender legal fees, which are capitalized in prepaid expenses on our condensed consolidated balance sheets and is being recognized using the effective interest method over the life of the Term Loans. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at December 31, 2014. We pledged all current and future assets, excluding its intellectual property and 35% of our investment in its subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. All principal and interest payments related to Term Loan have been included in the table above.

While we currently have the ability to borrow an additional $10.0 million under the loan and security agreement, our ability to access the final $10.0 million under the loan and security agreement is subject to our ability to achieve the Revenue Event, which condition we may not be able to meet, which could adversely affect our liquidity. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

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. Historically, our available-for-sale securities related to corporate debt and U.S. government agency securities were 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 other-than-temporary impairment losses during the years ended December 31, 2014, and 2013. Adverse global economic conditions, including the sovereign debt crisis in Europe, 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, 2014, we held cash, cash equivalents and short-term investments of $51.3 million. We do not believe our exposure to interest rate risk to be material given we held cash in interest-bearing accounts with financial institutions and the short-term nature of our investment portfolio consisted of highly liquid money market instruments and corporate debt and U.S. government agency securities with short-term maturities. The weighted average interest rates of our cash and cash equivalents at December 31, 2014 were 0.27%.

Our exposure to market rate risk for changes in interest rates relates primarily to our money market instruments, corporate debt securities and any amounts borrowed pursuant to the Term Loan Agreement. Under the terms of our Term Loan Agreement with Oxford Finance, a 1.0% change in the U.S. LIBOR rate would increase net interest expense by approximately $0.2 million, if we were to draw down both Term Loan B and Term Loan C. 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.

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 Euros. 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 Euros and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of non-operating income (expense), net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. An unfavorable 10% change in foreign currency exchange rates for our accounts receivable, accounts payable and accrued liabilities that are denominated in foreign currencies at December 31, 2014, would have negatively impacted our annual financial results by $0.2 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 reports 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, including and under the supervision of our principal executive officer and principal financial officer, is responsible for establishing and maintaining "disclosure controls and procedures" (as defined in Rule 13a-15(e) and Rule 15d-15(e), promulgated under the Securities Exchange Act of 1934, as amended) for our company. We conducted an evaluation as of December 31, 2014, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation as of December 31, 2014, our principal executive officer and principal financial officer have concluded as of such date, our disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting discussed below.

Changes in Internal Control over Financial Reporting. During the last quarter of our fiscal year ended December 31, 2014, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting. Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2014, is discussed in the Management's Report on Internal Control over Financial Reporting included below.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining effective internal control over the Company's financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control—Integrated Framework (2013 Framework). Based on this assessment, management has concluded that, as of December 31, 2014, the Company's internal control over financial reporting was ineffective because material weaknesses existed in our internal control over financial reporting related to the design and operating effectiveness of certain controls over (i) the valuation of our inventory and cost of product revenue as reported on our consolidated balance sheets and statements of operations; and (ii) the timeliness and accuracy of recording adjustments to certain accrued liabilities reported on our consolidated balance sheets and statements of operations, in each case, as further described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, we identified a design deficiency in the internal controls executed to determine and review the valuation of inventory using appropriate foreign exchange rates in effect at the time inventory was purchased and reported on our consolidated balance sheets and appropriately accounting for such purchase price variances in inventory and cost of product revenue on our consolidated statements of operations. In addition, we identified a material weakness in the design and operating effectiveness in the timeliness and accuracy of recording adjustments to certain accrued liabilities related to vendor invoices received for 2014 activities, which would have resulted in understated operating expense and accrued liabilities if they had not been identified and corrected. The material weaknesses resulted in certain audit adjustments which impacted our inventory and accrued liabilities on our consolidated balance sheets, as well as the cost of product revenue and operating expenses on our consolidated statements of operations for the year ended December 31, 2014.

Additionally, these material weaknesses could result in a further misstatement of the aforementioned account balances or disclosures that would result in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected.

The Company's independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. Ernst and Young LLP's attestation report on internal control over financial reporting is included herein.

The Company's internal control system is designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Accordingly, our internal control systems are designed to provide reasonable, not absolute, assurance that the objectives of our internal control systems are met; however, based on the assessment discussed above, management has concluded that, as of December 31, 2014, our internal control over financial reporting was ineffective.

Management's Remediation Initiatives. Subsequent to December 31, 2014, and in light of the material weaknesses in our internal control over financing reporting described above, we have taken steps to remediate our material weaknesses. In this regard, we are in the process of developing specific controls to: (i) provide reasonable assurance that inventory is valued under a first-in-first-out basis and utilizes appropriate historical foreign exchange rates at the time inventory is purchased if still on hand at each balance sheet date and further to ensure that product sold during any reporting period is recorded under appropriate first-in-first-out accounting at historical rates; and (ii) modify and expand our internal controls over timely and accurate identification of adjustments to accruals based on information received after year-end. The successful remediation of these

material weaknesses will require review and evidence of the effectiveness of the related internal controls as part of our next annual assessment of our internal controls over financial reporting as of December 31, 2015. As we continue these remediation efforts, we may determine that additional measures should be taken to address these or other control deficiencies, and/or that we should modify the remediation plan described above.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives; however, as noted above, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective at the "reasonable assurance" level.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Cerus Corporation

We have audited Cerus Corporation's internal control over financial reporting as of December 31, 2014, 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"). Cerus Corporation'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Management has identified a material weakness in the design and operating effectiveness of controls related to the valuation of the Company's inventory and cost of product revenue and the timeliness and accuracy of recording adjustments to certain accrued liabilities. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cerus Corporation as of December 31, 2014, and 2013, and 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, 2014. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2014 financial statements, and this report does not affect our report dated March 16, 2015, which expressed an unqualified opinion on those financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Cerus Corporation has not maintained effective internal control over financial reporting as of December 31, 2014 based on the COSO criteria.

/s/ ERNST & YOUNG LLP

Redwood City, California
March 16, 2015

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

On March 13, 2015, we exercised the first of four options to extend the lease for our facility at 2411 Stanwell Drive, Concord, California, under the terms of our lease for an additional two years. We will file our exercise notice with our quarterly report on Form 10-Q for the quarter ended March 31, 2015.

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 2015 annual meeting of stockholders, or the Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

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

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

Code of Ethics

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

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

Item 11. *Executive Compensation*

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

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

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

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

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

Item 14. *Principal Accountant Fees and Services*

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

(a) *Financial Statements*.

	Page
Report of Ernst & Young LLP, Independent Registered Public Accounting Firm	85
Consolidated Balance Sheets as of December 31, 2014 and 2013	86
Consolidated Statements of Operations for the three years ended December 31, 2014	87
Consolidated Statements of Comprehensive Loss for the three years ended December 31, 2014	88
Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2014	89
Consolidated Statements of Cash Flows for the three years ended December 31, 2014	90
Notes to Consolidated Financial Statements	91

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

(b) *Exhibits*.

Exhibit Number	Description of Exhibit
2.1(20)†	Asset Purchase and Redemption Agreement by and between Cerus Corporation and BioOne Corporation, dated as of August 24, 2010.
3.1(31)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(31)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(31)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4(38)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(9)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(15)	Rights Agreement, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
4.3(17)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
4.4(16)	Form of 2009 Warrant to Purchase Common Stock.
4.5(21)	Form of 2010 Warrant to Purchase Common Stock.
	Supply and/or Manufacturing Agreements
10.1(7)†	Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.
10.2(39)†	Amended and Restated Supply Agreement, dated April 21, 2014, by and between Cerus Corporation and Purolite Corporation.
10.3(7)†	Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus Corporation and Porex Corporation.

Exhibit Number	Description of Exhibit
10.4(33)†	First Amendment to Supply and Manufacturing Agreement, dated November 28, 2012, by and between Cerus Corporation and Porex Corporation.
10.5#	Amendment #2 to Supply and Manufacturing Agreement, dated December 23, 2014, by and between Cerus Corporation and Porex Corporation.
10.6(35)†	Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Fenwal, Inc.).
10.7(35)†	Amendment No. 1 to the Amended and Restated Manufacturing and Supply Agreement, dated November 22, 2013, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.8(11)†	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.9(25)†	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.10(34)†	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
	Loan and Security Agreements
10.11(25)†	Loan and Security Agreement, dated as of September 30, 2011, by and between Cerus Corporation and Comerica Bank.
10.12(29)†	First Amendment to Loan and Security Agreement, dated as of December 13, 2011, by and between Cerus Corporation and Comerica Bank.
10.13(29)	Second Amendment to Loan and Security Agreement, dated as of June 30, 2012, by and between Cerus Corporation and Comerica Bank.
10.14(38)†	Loan and Security Agreement, dated as of June 30, 2014, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
	Real Estate Lease Agreements
10.15(4)	Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.
10.16(10)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.17(18)	Letter to California Development, Inc. exercising option to extend the lease term from the Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.18(35)	Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
	Employment Agreements or Offer Letters
10.19(22)*	Employment Letter, by and between Cerus corporation and William M. Greenman, dated May 12, 2011.
10.20(33)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.21(35)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.

Exhibit Number	Description of Exhibit
10.22(19)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.23(15)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.24(26)*	Employment Agreement for Caspar Hogeboom, dated March 6, 2006.
10.25(26)*	Promotion Letter for Caspar Hogeboom, dated December 11, 2009 and executed on September 21, 2010.
10.26(26)*	Addendum to Employment Agreement for Caspar Hogeboom, dated February 17, 2011.
10.27(26)*	Healthcare Contribution Letter for Caspar Hogeboom, dated December 18, 2007.
10.28(26)*	Home Telephone and Internet Expenses Letter for Caspar Hogeboom, dated January 11, 2012.
10.29(36)*	Equity Change in Control Agreement with Caspar Hogeboom, dated March 7, 2014.
10.30(33)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.31(35)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
	Stock Plans and Related Forms
10.32(1)*	1996 Equity Incentive Plan.
10.33(1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.34(1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.35(1)*	1996 Employee Stock Purchase Plan.
10.36(29)*	Employee Stock Purchase Plan, as amended, effective June 6, 2012.
10.37(2)*	1998 Non-Officer Stock Option Plan.
10.38(3)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.39(5)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.40(8)*	2008 Equity Incentive Plan, approved by stockholders June 2, 2008.
10.41(24)*	2008 Equity Incentive Plan, as amended, reapproved by stockholders June 1, 2011.
10.42(32)*	2008 Equity Incentive Plan, as amended, effective June 12, 2013.
10.43(28)*	Form of Option Agreement for employees under the 2008 Equity Incentive Plan, as amended.
10.44(28)*	Form of Option Agreement for non-employee directors under the 2008 Equity Incentive Plan, as amended.
10.45(28)*	Form of Restricted Stock Unit Agreement under the 2008 Equity Incentive Plan, as amended.
	Other Compensatory Plans or Agreements
10.46(33)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.47(12)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.48(14)*	Form of Severance Benefits Agreement.

Exhibit Number	Description of Exhibit
10.49(36)*	Amended and Restated Non-Employee Director Compensation Policy.
10.50(35)*	International Bonus Plan for 2013.
10.51	International Bonus Plan.
10.52(36)	2013 and 2014 Executive Officer Compensation Arrangements.
	Other Material Agreements
10.53(23)	At-The-Market-Issuance Sales Agreement, dated June 3, 2011, by and between Cerus Corporation and MLV & Co. LLC.
10.54(27)	Amendment to At-The-Market-Issuance Sales Agreement, dated January 4, 2012, by and between Cerus Corporation and MLV & Co. LLC.
10.55(30)	Amendment No. 2 to At-The-Market-Issuance Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and MLV & Co. LLC.
10.56(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.57(13)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.58(16)	Form of Subscription Agreement.
10.59(30)	Controlled Equity Offering[SM] Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.60(37)	Amendment No 1. to Controlled Equity Offering[SM] Sales Agreement, dated March 21, 2014, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.61(18)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare Corporation).
10.62(18)†	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).
10.63(6)†	Commercialization Transition Agreement, dated as of February 12, 2006, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare S.A. and Baxter Healthcare Corporation).
12.1	Computation of Earnings to Fixed Charges.
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(40)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Description of Exhibit
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

* Compensatory Plan.

\# Registrant has requested confidential treatment for portions of this exhibit.

(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 Registration Statement on Form S-8, dated March 24, 1999.

(3) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-8, dated August 4, 1999.

(4) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2001.

(5) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2003.

(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, 2006.

(7) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2008.

(8) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 6, 2008.

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

(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, 2008.

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

(12) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.

(13) 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.

(14) 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.

(15) 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.

(16) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 20, 2009.

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

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

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

(20) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 30, 2010.
(21) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on November 12, 2010.
(22) 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.
(23) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 6, 2011.
(24) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2011.
(25) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2011.
(26) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2011.
(27) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Registration Statement on Form S-3/A, filed with the SEC on January 6, 2012.
(28) 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.
(29) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2012.
(30) 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, 2012.
(31) 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.
(32) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2013.
(33) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2012.
(34) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2013.
(35) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2013.
(36) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2014.
(37) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on March 21, 2014.
(38) 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.
(39) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2014.
(40) 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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Cerus Corporation

We have audited the accompanying consolidated balance sheets of Cerus Corporation as of December 31, 2014, and 2013, and 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, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cerus Corporation at December 31, 2014, and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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), Cerus Corporation's internal control over financial reporting as of December 31, 2014, 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 16, 2015 expressed an adverse opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California
March 16, 2015

CERUS CORPORATION

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

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,781	$ 29,485
Short-term investments	28,513	28,191
Accounts receivable, net of allowance of $0 at December 31, 2014 and 2013	5,493	6,125
Inventories	14,956	13,063
Prepaid expenses	1,210	848
Other current assets	1,932	442
Total current assets	74,885	78,154
Non-current assets:		
Property and equipment, net	3,781	2,189
Goodwill	1,316	1,316
Intangible assets, net	1,142	1,344
Restricted cash	508	308
Other assets	144	70
Total assets	$ 81,776	$ 83,381
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,882	$ 5,674
Accrued liabilities	8,444	9,813
Deferred revenue—current	376	181
Debt—current	0	3,366
Warrant liability	10,485	20,390
Total current liabilities	29,187	39,424
Non-current liabilities:		
Debt—non-current	9,872	0
Deferred income taxes	115	89
Other non-current liabilities	1,081	1,073
Total liabilities	40,255	40,586
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value 225,000 and 112,500 shares authorized; 80,404 and 71,859 shares issued and outstanding at December 31, 2014 and 2013, respectively	80	72
Additional paid-in capital	583,416	545,905
Accumulated other comprehensive (loss) income	(31)	7
Accumulated deficit	(541,944)	(503,189)
Total stockholders' equity	41,521	42,795
Total liabilities and stockholders' equity	$ 81,776	$ 83,381

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

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

	Year Ended December 31,		
	2014	2013	2012
Product related:			
Product revenue	$ 36,416	$ 39,657	$ 36,695
Cost of product revenue	21,188	22,602	20,616
Gross profit on product revenue	15,228	17,055	16,079
Government grants and cooperative agreements revenue	0	0	91
Operating expenses:			
Research and development	21,800	15,187	7,603
Selling, general and administrative	37,729	29,965	25,665
Amortization of intangible assets	202	202	202
Total operating expenses	59,731	45,354	33,470
Loss from operations	(44,503)	(28,299)	(17,300)
Non-operating income (expense), net:			
Gain (loss) from revaluation of warrant liability	7,708	(15,099)	2,059
Foreign exchange (loss) gain	(1,296)	533	86
Interest expense	(599)	(332)	(551)
Other income, net	130	78	31
Total non-operating income (expense), net	5,943	(14,820)	1,625
Loss before income taxes	(38,560)	(43,119)	(15,675)
Provision for income taxes	195	218	242
Net loss	$(38,755)	$(43,337)	$(15,917)
Net loss per share:			
Basic	$ (0.52)	$ (0.64)	$ (0.29)
Diluted	$ (0.61)	$ (0.64)	$ (0.33)
Weighted average shares outstanding used for calculating net loss per share:			
Basic	74,767	67,569	54,515
Diluted	76,534	67,569	55,061

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2014	2013	2012
Net loss	$(38,755)	$(43,337)	$(15,917)
Other comprehensive income (loss):			
Net unrealized gains (losses) on available-for-sale securities, net of taxes	(38)	7	0
Comprehensive loss	$(38,793)	$(43,330)	$(15,917)

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2011	3	$ 9,496	51,211	$51	$452,701	$ 0	$(443,935)	$ 18,313
Net loss	0	0	0	0	0	0	(15,917)	(15,917)
Issuance of common stock from public offering, net of expenses of $550	0	0	4,487	5	13,816	0	0	13,821
Issuance of common stock from exercise of stock options and/or warrants, and purchases from ESPP	0	0	221	0	349	0	0	349
Preferred stock conversion	(3)	(9,496)	333	0	9,496	0	0	0
Stock-based compensation	0	0	0	0	2,541	0	0	2,541
Balance at December 31, 2012	0	0	56,252	56	478,903	0	(459,852)	19,107
Net loss	0	0	0	0	0	0	(43,337)	(43,337)
Other comprehensive income	0	0	0	0	0	7	0	7
Issuance of common stock from public offering, net of expenses of $2,733	0	0	15,019	15	61,439	0	0	61,454
Issuance of common stock from exercise of stock options and/or warrants, and purchases from ESPP	0	0	588	1	2,295	0	0	2,296
Stock-based compensation	0	0	0	0	3,268	0	0	3,268
Balance at December 31, 2013	0	0	71,859	72	545,905	7	(503,189)	42,795
Net loss	0	0	0	0	0	0	(38,755)	(38,755)
Other comprehensive income	0	0	0	0	0	(38)	0	(38)
Issuance of common stock from public offering, net of expenses of $470	0	0	4,341	4	18,517	0	0	18,521
Issuance of common stock from exercise of stock options and/or warrants, and purchases from ESPP	0	0	4,204	4	13,841	0	0	13,845
Stock-based compensation	0	0	0	0	5,153	0	0	5,153
Balance at December 31, 2014	0	$ 0	80,404	$80	$583,416	$(31)	$(541,944)	$ 41,521

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2014	2013	2012
Operating activities			
Net loss	$(38,755)	$(43,337)	$(15,917)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,415	745	744
Stock-based compensation	5,153	3,268	2,541
Changes in valuation of warrant liability	(7,708)	15,099	(2,059)
Non-cash interest expense	131	(25)	20
Deferred income taxes	26	27	62
Loss on disposal of fixed assets	3	56	0
Changes in operating assets and liabilities:			
Accounts receivable	632	(1,681)	1,652
Inventories	3,033	(1,813)	(3,740)
Other assets	(1,655)	286	(1,663)
Accounts payable	(973)	(1,512)	2,506
Accrued liabilities	(1,382)	2,121	1,971
Deferred revenue	269	104	(34)
Net cash used in operating activities	(39,811)	(26,662)	(13,917)
Investing activities			
Capital expenditures	(2,106)	(663)	(81)
Purchases of investments	(25,981)	(30,146)	0
Proceeds from maturities of investments	24,915	1,631	287
Restricted cash	(175)	(14)	(1)
Net cash (used in) provided by investing activities	(3,347)	(29,192)	205
Financing activities			
Net proceeds from exercise/purchase of equity incentives and warrants	11,592	1,684	332
Net proceeds from public offering	18,488	61,425	14,226
Proceeds from debt, net of discount	9,848	3,102	1,810
Repayment of debt	(3,474)	(7,568)	(1,457)
Net cash provided by financing activities	36,454	58,643	14,911
Net (decrease) increase in cash and cash equivalents	(6,704)	2,789	1,199
Cash and cash equivalents, beginning of year	29,485	26,696	25,497
Cash and cash equivalents, end of year	$ 22,781	$ 29,485	$ 26,696
Supplemental disclosures:			
Non-cash conversion of preferred stock to common stock	$ —	$ —	$ 9,496
Cash paid for interest	$ 563	$ 294	$ 460
Cash paid for income taxes	$ 177	$ 146	$ 162
Non-cash settlement of warranty claim	$ —	$ 1,272	$ —

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2014

Note 1. Nature of Operations and Basis of Presentation

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

The Company sells its INTERCEPT platelet and plasma systems in the United States, Europe, the Commonwealth of Independent States ("CIS") countries, the Middle East and selected countries in other regions around the world. In December 2014, the U.S. Food and Drug Administration ("FDA") approved INTERCEPT platelet and plasma systems in the U.S. The Company conducts significant research, development, testing and regulatory compliance activities on its product candidates that, together with anticipated selling, general, and administrative expenses, are expected to result in substantial additional losses, and the Company may need to adjust its operating plans and programs based on the availability of cash resources. The Company's ability to achieve a profitable level of operations will depend on successfully completing development, obtaining additional regulatory approvals and achieving widespread market acceptance of its products. There can be no assurance that the Company will ever achieve a profitable level of operations.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience 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.

Reclassifications

In 2014, certain reclassifications have been made to prior period reported amounts to conform to the current period presentations. Previously the Company had presented the amortization of premium and accretion of any discount resulting from the purchase of debt securities as a component of "Interest expense" on the consolidated statements of operations. The Company has reclassified approximately $0.2 million of the amortization of premium resulting from the purchase of debt securities as a component of "Other income, net" on the consolidated statements of operations. This reclassification had no impact on net loss, total assets or total stockholders' equity.

Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 605-25, *"Revenue Recognition—Arrangements with Multiple Deliverables,"* as applicable. Revenue is recognized when (i) persuasive evidence of the arrangement exists; (ii) delivery has occurred or services have

been rendered; (iii) pricing is fixed or determinable; and (iv) collectibility is reasonably assured. The Company's main sources of revenues for the years ended December 31, 2014, 2013 and 2012, were product revenue from sales of the INTERCEPT Blood System for platelets and plasma ("platelet and plasma systems").

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company's INTERCEPT Blood System products, the Company uses a binding purchase order and signed sales contract as evidence of an arrangement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because the Company has no vendor specific objective evidence or third party evidence for its systems due to the Company's variability in its pricing across the regions into which it sells its products, the allocation of revenue is based on best estimated selling price for the systems sold. The objective of best estimated selling price is to determine the price at which the Company would transact a sale, had the product been sold on a stand-alone basis. The Company determines best estimated selling price for its systems by considering multiple factors, including, but not limited to, features and functionality of the system, geographies, type of customer, and market conditions. The Company regularly reviews best estimated selling price.

At December 31, 2014 and 2013, the Company had $0.4 million and $0.2 million, respectively, of short-term deferred revenue on its consolidated balance sheets related to future performance obligations. At December 31, 2014 and 2013, the Company had $0.1 million and $0, respectively, of long-term deferred revenue included in "Other non-current liabilities" on it consolidated balance sheets related to future performance obligations. Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *"Accounting for Shipping and Handling Fees and Costs."* Value-added-taxes ("VAT") that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such VAT from product revenue.

Revenue related to the cost reimbursement provisions under development contracts or United States government grants was recognized as the costs on the projects were incurred. The Company received certain United States government grants and contracts that support research in defined research projects. These grants generally provided for reimbursement of approved costs incurred as defined in the various grants. There were no such government grants in 2014 or 2013 and none are expected in the foreseeable future.

Research and Development Expenses

In accordance with ASC Topic 730, *"Accounting for Research and Development Expenses,"* research and development expenses are charged to expense when incurred, including cost incurred under each grant that has been awarded to the Company by the United States government or development contracts. Research and

development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development 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 research and development activities (see "Use of Estimates" above) affects the amounts of research and development expenses recorded and revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

Cash Equivalents

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

Investments

Investments with original maturities of greater than three months primarily include corporate debt and U.S. government agency securities designated as available-for-sale and classified as short-term investments, in accordance with ASC Topic 320, "*Accounting for Certain Investments in Debt and Equity Securities*". Available-for-sale securities are carried at estimated fair value. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities were recorded in "Net unrealized losses on available-for-sale securities, net of taxes" on the Company's consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale investments were recorded in "Other income, net" on the Company's consolidated statements of operations. The cost of securities sold was based on the specific identification method. 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 marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. Other-than-temporary declines in market value, if any, are recorded in "Other income, net" on the Company's consolidated statements of operations.

Restricted Cash

The Company holds a certificate of deposit with a domestic bank for any potential decommissioning resulting from the Company's possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded in "Restricted cash" on the Company's condensed consolidated balance sheets. The Company also has 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, short-term investments and accounts receivable.

Pursuant to the Company's investment policy, substantially all of the Company's cash, cash equivalents and short-term investments are maintained at a major financial institution 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. The Company has not experienced any losses in its investments and believes it is not exposed to any significant risk.

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

The Company had one customer and two customers that accounted for more than 10% of the Company's outstanding trade receivables at December 31, 2014 and 2013, respectively. These customers cumulatively represented approximately 36% and 48% of the Company's outstanding trade receivables at December 31, 2014 and 2013, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At December 31, 2014 and 2013, inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, UVA illumination devices ("illuminators"), and certain replacement parts for the illuminators. Platelet and plasma systems' disposable kits generally have a two-year life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured over a protracted length of time before being sold to, and ultimately incorporated and assembled by Fresenius Kabi Deutschland GmbH or Fresenius, Inc. (with its affiliates, "Fresenius") into the finished INTERCEPT disposable kits. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for the Company's production cycle for inventory to exceed twelve months. Instead, the Company uses its best judgment to factor in lead times for the production of its work-in-process and finished units to meet the Company's forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At December 31, 2014 and 2013, the Company classified its work-in-process inventory as a current asset on its consolidated balance sheets based on its evaluation that the work-in-process inventory would be sold to Fresenius for finished disposable kit production within each respective subsequent twelve-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or market value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in "Cost of product revenue" on the Company's consolidated statements of operations. At December 31, 2014, and 2013, the Company had $0.1 million and $0.4 million, respectively, recorded for obsolete, expiring or unsalable product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, 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.

Capitalization of Software Costs

The Company capitalizes certain significant costs incurred in the acquisition and development of software for internal use, including the costs of the software, materials, and consultants during the application development stage. Costs incurred prior to the application development stage, costs incurred once the application is substantially complete and ready for its intended use, and other costs not qualifying for capitalization, including training and maintenance costs, are charged to expense as incurred. At December 31, 2014, and 2013, the Company capitalized costs related to its enterprise resource planning software system of $1.8 million and zero, respectively. The capitalized costs associated with the enterprise resource planning system are being amortized over the estimated useful life of five years.

Costs incurred in connection with the development of software products for sale are accounted for in accordance with the ASC 985—*Costs of Software to Be Sold, Leased or Marketed*. Costs incurred prior to the establishment of technological feasibility are charged to research and development expense. Software development costs are capitalized after a product is determined to be technologically feasible and is in the process of being developed for market.

Goodwill and Intangible Assets, net

Intangible assets, net, which include a license for the right to commercialize the INTERCEPT Blood System in Asia, are subject to ratable amortization over the estimated useful life of ten years. The amortization of the Company's intangible assets, net, is recorded in "Amortization of intangible assets" on the Company's consolidated statements of operations. Goodwill is not amortized but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Such impairment analysis is performed on August 31 of each fiscal year, or more frequently if indicators of impairment exist. The test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative two-step process to test goodwill for impairment; otherwise, goodwill is not considered impaired and no further testing is warranted. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative two-step process; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The first step of the two-step process compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates in one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired and, therefore, the second step of

the impairment test is unnecessary. The second step of the two-step process, which is used to measure the amount of impairment loss, compares the implied fair value of each reporting unit's goodwill, based on the present value of future cash flows, with the respective carrying amount of that goodwill. 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.

The Company performs an impairment test on its intangible assets, in accordance ASC Topic 360-10, *"Property, Plant and Equipment,"* if certain events or changes in circumstances occur which indicate that the carrying amounts of its intangible assets may not be recoverable. If the intangible assets are not recoverable, an impairment loss would be recognized by the Company based on the excess amount of the carrying value of the intangible assets over its fair value. For further details regarding the impairment analysis, reference is made to the section below under "Long-lived Assets." See Note 7 for further information regarding the Company's impairment analysis and the valuation of goodwill and intangible assets, net.

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. The Company did not recognize impairment charges related to its long-lived assets during the years ended December 31, 2014, 2013 or 2012.

Foreign Currency Remeasurement

The functional currency of the Company's foreign subsidiary is the United States dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in United States dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in United States dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company's consolidated statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718,*"Compensation—Stock Compensation."* Stock-based compensation expense is measured at the grant-date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

For stock-based awards issued to non-employees, the Company follows ASC Topic 505-50, *"Equity Based Payment to Non-Employees"* and considers the measurement date at which the fair value of the stock-based award is measured to be the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee's performance is complete. The Company

recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee stock-based awards in its consolidated statements of operations.

See Note 13 for further information regarding the Company's stock-based compensation assumptions and expenses.

Warrant Liability

In August 2009, and November 2010, the Company issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively. The material terms of the warrants were identical under each issuance except for the exercise price, date issued and expiration date. In August 2014, all of the outstanding August 2009 warrants were exercised in full. The Company classifies warrants outstanding on the reporting date as a liability on its consolidated balance sheets as the warrants contain certain material terms which require the Company to purchase the warrants for cash in an amount equal to the value of the unexercised portion of the warrants in connection with certain change of control transactions. In addition, the Company may also be required to pay cash to a warrant holder under certain circumstances if the Company is unable to timely deliver the shares acquired upon warrant exercise to such holder.

The fair value of outstanding warrants is calculated using the Black-Scholes model and was adjusted accordingly at December 31, 2014. Prior to December 31, 2014, the Company calculated the fair value of these warrants using a combination of the Black-Scholes model and/or binomial-lattice option-pricing model.

Changes resulting from the revaluation of warrants to fair value are recorded in "Gain (loss) from revaluation of warrant liability" on the consolidated statements of operations. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from a liability to stockholders' equity on the Company's consolidated balance sheets and no further adjustment to the fair value would be made in subsequent periods.

See Note 12 for further information regarding the Company's valuation of warrant liability.

Income Taxes

The Company accounts for income taxes using the asset and liability approach in accordance with ASC Topic 740 *"Accounting for Income Taxes."* Under this method, 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. ASC Topic 740 requires derecognition of 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 as described in ASC Topic 740 is not an appropriate substitute for the derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. The Company had no unrecognized tax benefits as of December 31, 2014 and 2013. The Company continues to carry a full valuation allowance on all of its deferred tax assets. 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.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options, employee stock purchase plan rights, warrants and restricted stock units, which are calculated using the treasury stock method, and convertible preferred stock, which is calculated using the if-converted method. Diluted net loss per share also gives effect to potential adjustments to the numerator for gains resulting from the revaluation of warrants to fair value for the period, even if the Company is in a net loss position if the effect would result in more dilution.

Diluted net loss per common share used the same weighted average number of common shares outstanding for the year ended December 31, 2013, as calculated for the basic net loss per common share as the inclusion of any potential dilutive securities would be anti-dilutive. Certain potential dilutive securities were excluded from the dilution calculation for the years ended December 31, 2014 and 2012, as their inclusion would have been anti-dilutive.

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, 2014, 2013 and 2012 (in thousands, except per share amounts):

	Year Ended December 31,		
	2014	2013	2012
Numerator for Basic and Diluted:			
Net loss used for basic calculation	$(38,755)	$(43,337)	$(15,917)
Effect of revaluation of warrant liability	(7,708)	0	(2,059)
Adjusted net loss used for dilution calculation	$(46,463)	$(43,337)	$(17,976)
Denominator:			
Basic weighted average number of shares outstanding	74,767	67,569	54,515
Effect of dilutive potential shares	1,767	0	546
Diluted weighted average number of shares outstanding	76,534	67,569	55,061
Net loss per share:			
Basic	$ (0.52)	$ (0.64)	$ (0.29)
Diluted	$ (0.61)	$ (0.64)	$ (0.33)

The table below presents shares underlying stock options, employee stock purchase plan rights, warrants, restricted stock units and/or convertible preferred stock 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 were excluded from the calculation due to their anti-dilutive effect for the years ended December 31, 2014, 2013 and 2012 (shares in thousands):

	Year Ended December 31,		
	2014	2013	2012
Weighted average number of anti-dilutive potential shares	11,722	16,370	8,716

Guarantee and Indemnification Arrangements

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

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at December 31, 2014 or 2013.

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 and warrant liability. 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 available-for-sale securities related to corporate debt and United States government agency securities. 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, which include its warrant liability. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

See Notes 3 and 12 for further information regarding the Company's valuation on financial instruments.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional

disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU's effective date for the Company will be the first quarter of fiscal year 2017, using one of two retrospective application methods. Early adoption is not permitted. The Company has not selected a transition method and is currently assessing the potential effects of this ASU on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its consolidated financial statements.

Note 3. Fair Value on Financial Instruments

The Company determined the fair value of an asset or liability based on the assumptions that market participants would use 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, 2014, the Company's primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and United States 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, 2014 (in thousands):

	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[1]	$ 3,912	$3,912	$ 0	$ 0
Corporate debt securities[2]	26,088	0	26,088	0
United States government agency securities[2]	3,426	0	3,426	0
Total financial assets	$33,426	$3,912	$29,514	$ 0
Warrant liability[3]	$10,485	$ 0	$ 0	$10,485
Total financial liabilities	$10,485	$ 0	$ 0	$10,485

(1) Included in cash and cash equivalents on the Company's consolidated balances sheets.

(2) Included in short-term investments on the Company's consolidated balance sheets, except for approximately $1.0 million of corporate debt securities that are included in cash and cash equivalents on the Company's consolidated balance sheets.

(3) Included in current liabilities on the Company's consolidated balance sheets.

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2013 (in thousands):

	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[1]	$ 8,650	$8,650	$ 0	$ 0
Corporate debt securities[2]	23,173	0	23,173	0
United States government agency securities[2]	5,018	0	5,018	0
Total financial assets	$36,841	$8,650	$28,191	$ 0
Warrant liability[3]	$20,390	$ 0	$ 0	$20,390
Total financial liabilities	$20,390	$ 0	$ 0	$20,390

(1) Included in cash and cash equivalents on the Company's consolidated balances sheets.

(2) Included in short-term investments on the Company's consolidated balance sheets.

(3) Included in current liabilities on the Company's consolidated balance sheets.

A reconciliation of the beginning and ending balances for warrant liability using significant unobservable inputs (Level 3) from December 31, 2012 to December 31, 2014, was as follows (in thousands):

Balance at December 31, 2012	$ 5,903
Increase in fair value of warrants	15,099
Settlement of warrants exercised	(612)
Balance at December 31, 2013	20,390
Decrease in fair value of warrants	(7,708)
Settlement of warrants exercised	(2,197)
Balance at December 31, 2014	$10,485

See Notes 1 and 12 for further information regarding the Company's valuation techniques and unobservable inputs for the warrant liability using significant unobservable inputs (Level 3).

The Company did not have any transfers among fair value measurement levels during the years ended December 31, 2014 and 2013.

Note 4. Available-for-sale Securities

The following is a summary of available-for-sale securities at December 31, 2014 (in thousands):

	December 31, 2014		
	Amortized Cost	Gross Unrealized Loss	Fair Value
Money market funds	$ 3,912	$ 0	$ 3,912
United States government agency securities	3,427	(1)	3,426
Corporate debt securties	26,118	(30)	26,088
Total available-for-sale securities	$33,457	($ 31)	$33,426

The following is a summary of available-for-sale securities at December 31, 2013 (in thousands):

	December 31, 2013		
	Amortized Cost	Gross Unrealized (Loss) Gain	Fair Value
Money market funds	$ 8,650	$ 0	$ 8,650
United States government agency securities	5,019	(1)	5,018
Corporate debt securties	23,165	8	23,173
Total available-for-sale securities	$36,834	$ 7	$36,841

Available-for-sale securities at December 31, 2014 and 2013, consisted of the following by original contractual maturity (in thousands):

	December 31, 2014		December 31, 2013	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$27,752	$27,727	$30,700	$30,701
Greater than one year and less than five years	5,705	5,699	6,134	6,140
Total available-for-sale securities	$33,457	$33,426	$36,834	$36,841

As of December 31, 2014, the Company considered the declines in market value of its marketable securities investment portfolio to be temporary in nature and did not consider any of its investments other-than-temporarily impaired. 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 other-than-temporary impairment, 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. During the years ended December 31, 2014, 2013, and 2012, the Company did not recognize any other-than-temporary impairment loss.

The Company recorded minimal gross realized gains from the sale or maturity of available-for-sale investments during the year ended December 31, 2014, and did not record any gross realized gains from the sale or maturity of available-for-sale investments during the years ended December 31, 2013 and 2012. The Company recorded insignificant gross realized losses from the sale of available-for-sale investments during the year ended December 31, 2013, and did not record any gross realized losses during the years ended December 31, 2014 and 2012. The Company did not record losses on investments experiencing an other-than-temporary decline in fair value during the years ended December 31, 2014, 2013, and 2012.

Note 5. Inventories

Inventories at December 31, 2014 and 2013, consisted of the following (in thousands):

	December 31,	
	2014	2013
Work-in-process	$ 2,222	$ 4,863
Finished goods	12,734	8,200
Total inventories	$14,956	$13,063

Note 6. Property and Equipment, net

Property and equipment, net at December 31, 2014 and 2013, consisted of the following (in thousands):

	December 31,	
	2014	2013
Leasehold improvements	$ 5,638	$ 5,628
Machinery and equipment	1,351	1,751
Demonstration equipment	123	100
Office furniture	783	763
Computer equipment	663	651
Computer software	2,913	1,083
Consigned demonstration equipment	980	642
Construction-in-progress	150	155
Total property and equipment, gross	12,601	10,773
Accumulated depreciation and amortization	(8,820)	(8,584)
Total property and equipment, net	$ 3,781	$ 2,189

Depreciation and amortization expense related to property and equipment, net was $0.7 million, $0.4 million and $0.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Note 7. Goodwill and Intangible Assets, net

Goodwill

During the year ended December 31, 2014, the Company did not dispose of or recognize additional goodwill. On August 31, 2014, the Company performed its impairment test of goodwill. As described in Note 2 above, the Company applied the enterprise approach by reviewing the quoted market capitalization of the Company as reported on the Nasdaq Global Market to calculate the fair value. In addition, the Company considered its future forecasted results, the economic environment and overall market conditions. As a result of the Company's assessment that its fair value of the reporting unit exceeded its carrying amount, the Company determined that goodwill was not impaired.

Intangible Assets, net

The following is a summary of intangible assets, net at December 31, 2014 (in thousands):

	December 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license—INTERCEPT Asia	$2,017	$(875)	$1,142
Total intangible assets	$2,017	$(875)	$1,142

The following is a summary of intangible assets, net at December 31, 2013 (in thousands):

	December 31, 2013		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license—INTERCEPT Asia	$2,017	$(673)	$1,344
Total intangible assets	$2,017	$(673)	$1,344

During the years ended December 31, 2014, 2013 and 2012, there were no impairment charges recognized related to the Company's intangible assets.

At December 31, 2014, the expected annual amortization expense of the intangible assets, net is $0.2 million beginning with the year ending December 31, 2015, and each subsequent year thereafter through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Note 8. Long-Term Investments

In connection with the agreements to license the immunotherapy technologies to Aduro Biotech ("Aduro") in 2009, the Company received preferred shares of Aduro, a privately held company. Pursuant to these license agreements, the Company is eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. For the years ended December 31, 2014, 2013 or 2012, the Company has not received any royalty payments from Aduro pursuant to this agreement. As of December 31, 2014, the Company's ownership in Aduro was less than 1% on a fully diluted basis. Since receiving preferred stock in Aduro, the Company has carried its investment in Aduro at zero in its consolidated balance sheets.

Note 9. Accrued Liabilities

Accrued liabilities at December 31, 2014 and 2013, consisted of the following (in thousands):

	December 31,	
	2014	2013
Accrued compensation and related costs	$3,951	$2,527
Accrued professional services	2,123	2,722
Accrued inventory costs	870	3,553
Accrued customer costs	385	59
Accrued insurance premiums	264	226
Other accrued expenses	851	726
Total accrued liabilities	$8,444	$9,813

Note 10. Debt

Debt at December 31, 2014, consisted of the following (in thousands):

	December 31, 2014		
	Principal	Unamortized Discount	Net Carrying Value
Loan and Security Agreement	$10,000	$(128)	$9,872
Less: debt—current	0	0	0
Debt—non-current	$10,000	$(128)	$9,872

Principal and interest payments on debt at December 31, 2014, are expected to be as follows*:

Year ended December 31,	Principal	Interest	Total
2015	$ —	$ 695	$ 695
2016	2,614	613	3,227
2017	2,802	425	3,227
2018	3,003	224	3,227
2019	1,581	733	2,314
Total	$10,000	$2,690	$12,690

* Unless interest only period extends to December 31, 2016, as described below.

Loan and Security Agreement

On June 30, 2014, the Company entered into a five year loan and security agreement with Oxford Finance LLC (the "Term Loan Agreement") to borrow up to $30.0 million in term loans in three equal tranches (the "Term Loans"). On June 30, 2014, the Company received $10.0 million from the first tranche ("Term Loan A"). The second tranche of $10.0 million ("Term Loan B") was contingent upon the approval, by the U.S. Food and Drug Administration ("FDA") of the Company's premarket approval application for either the plasma or platelet system (the "PMA Approval"), which occurred in December 2014. The availability of Term Loan B expires on June 15, 2015. The third tranche of $10.0 million ("Term Loan C") will be available from July 1, 2015 through December 31, 2015, contingent upon the Company achieving trailing six months' revenue at a specified threshold (the "Revenue Event"). Term Loan A bears an interest rate of 6.95%. Term Loan B and Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. LIBOR rate in effect three business days prior to the applicable Term Loan funding date. All of the Term Loans mature on June 1, 2019. The Company is required to make interest only payments through December 2015 followed by forty-two months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than November 30, 2015, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. The Company is also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. The costs associated with the final payment are recognized as interest expense over the life of the Term Loans. The Company may prepay at any time the Term Loans subject to declining prepayment fees over the term of the Term Loan Agreement. The Company paid the lender a $0.2 million commitment fee related to the Term Loan Agreement which has been recorded as a discount on the Term Loans and will be amortized to interest expense using the effective interest method over the life of the Term Loans. In addition, the Company

paid $0.1 million of the lender legal fees, which are capitalized on the Company's condensed consolidated balance sheets and will be recognized using the effective interest method over the life of the Term Loans. The Company pledged all current and future assets, excluding its intellectual property and 35% of the Company's investment in its subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. The Term Loan Agreement contains certain nonfinancial covenants, with which the Company was in compliance at December 31, 2014.

Amended Credit Agreement

The Company entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, with Comerica Bank (collectively, the "Amended Credit Agreement"). The Amended Credit Agreement provided for a formula-based revolving line of credit ("RLOC") of up to $7.0 million and a $5.0 million term loan. At December 31, 2013, the Company had $3.4 million outstanding under the RLOC, which was repaid in May 2014. In April 2013, the Company repaid in full the outstanding balance of the $5.0 million term loan along with all accrued interest and a scheduled final payment fee of $0.05 million, all totaling an aggregate amount of $4.2 million. The Amended Credit Agreement expired in June 2014.

Note 11. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment 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 2019, with certain of the leases providing for renewal options, provisions for adjusting future lease payments, which is based on the consumer price index and the right to terminate the lease early. In June 2013 the Company entered into a new lease for additional space in Concord. The lease has a two-year initial term with four (4) two-year options for the Company to renew, the first of which the Company exercised in March 2015. The Company's leased facilities qualify as operating leases under ASC Topic 840, *"Leases"* and as such, are not included on its consolidated balance sheets.

Future minimum non-cancelable lease payments under operating leases as of December 31, 2014, are as follows (in thousands):

Year ended December 31,	
2015	$ 891
2016	163
2017	93
2018	25
2019 and thereafter	0
Total minimum non-cancellable lease payments	$1,172

Rent expense for office facilities was $0.8 million, $0.7 million and $0.6 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Financed Leasehold Improvements

In 2010, the Company financed $1.1 million of leasehold improvements. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the respective leases. If the Company exercises its right to early terminate the original Concord, California lease, which may occur at any time hereafter, the Company would be required to repay for any remaining portion of the landlord financed leasehold improvements at such time. At December 31, 2014, the Company had an outstanding liability of $0.6 million related to these leasehold improvements, of which $0.1 million was reflected in "Accrued liabilities" and $0.5 million was reflected in "Other non-current liabilities" on the Company's consolidated balance sheets.

Purchase Commitments

The Company is party to agreements with certain providers for certain components of INTERCEPT Blood System which the Company purchases from third party manufacturers. Certain of these agreements require minimum purchase commitments from the Company. The Company has paid $6.8 million, $6.5 million and $7.2 million for goods under agreements which are subject to minimum purchase commitments during the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, the Company has future minimum purchase commitments under these agreements of $8.5 million for the year ending December 31, 2015, and approximately $2.3 million for the year ending December 31, 2016.

In June 2014, the Company terminated its distribution agreement with one of its distributors in certain countries and entered into an agreement to provide for specific post-termination obligations (the "Transition Agreement"). The Transition Agreement expired September 30, 2014. The Company is required to pay this former distributor a fee of €10 per disposable kit for platelet systems sold by the Company to any customer in certain countries commencing with the termination of the agreement through April 1, 2018, subject to a maximum payment of €3 million. During the year ended December 31, 2014, the Company accrued approximately $0.1 million associated with this fee. As this former distributor will remain as a customer in other countries, in accordance with ASC Topic 605-50 *"Customer Payments and Incentives"* any fees paid to the former distributor related to INTERCEPT disposable kits will be offset against the revenue associated with the sale of INTERCEPT disposable kits in those territories.

Note 12. Stockholders' Equity

On June 12, 2014, the Company filed a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation with the Secretary of the State of Delaware to increase the number of authorized shares of the Company's common stock, par value $0.001 per share, from 112,500,000 shares to 225,000,000 shares. The amendment was approved by the Company's stockholders at the Company's 2014 Annual Meeting of Stockholders held on June 11, 2014.

Common Stock and Associated Warrant Liability

In August 2009, the Company issued warrants to purchase 2.4 million shares of common stock, exercisable at an exercise price of $2.90 per share ("2009 Warrants"). In August 2014, all outstanding 2009 Warrants were exercised in full and accordingly were no longer outstanding at December 31, 2014.

In November 2010, the Company issued warrants to purchase 3.7 million shares of common stock, exercisable at an exercise price of $3.20 per share. The warrants issued in November 2010 ("2010 Warrants") became exercisable on May 15, 2011, and are exercisable for a period of five years from the issue date.

The fair value of the 2009 Warrants and 2010 Warrants was recorded on the consolidated balance sheets as a liability pursuant to ASC Topic 480-10 *"Distinguishing Liabilities from Equity"* and are adjusted to fair value at each financial reporting date thereafter until the earlier of exercise, expiration or modification to remove the provisions which require the warrants to be treated as a liability, at which time, these warrants would be reclassified into stockholders' equity. The Company classified the 2009 Warrants and 2010 Warrants as a liability as these warrants contain certain provisions that, under certain circumstances, which may be out of the Company's control, could require the Company to pay cash to settle the exercise of the warrants or may require the Company to redeem the warrants.

The fair value of the warrants outstanding at December 31, 2014 and 2013, consisted of the following (in thousands):

	December 31,	
	2014	2013
2009 Warrants	$ —	$ 8,542
2010 Warrants	10,485	11,848
Total warrant liability	$10,485	$20,390

The fair value of the Company's warrants was based on option valuation model and using the following assumptions at December 31, 2014 and 2013:

	December 31, 2014	December 31, 2013
2009 Warrants:		
Expected term (in years)	—	0.65
Estimated volatility	—	45%
Risk-free interest rate	—	0.10%
Expected dividend yield	—	0%

	December 31, 2014	December 31, 2013
2010 Warrants:		
Expected term (in years)	0.86	1.86
Estimated volatility	55%	41%
Risk-free interest rate	0.25%	0.38%
Expected dividend yield	0%	0%

The Company recognizes non-cash loss and gains in "Gain (loss) from revaluation of warrant liability" on the consolidated statements of operations due to the changes in fair value of the warrants. Significant changes to the Company's market price for its common stock will impact the implied and/or historical volatility used to fair value the warrants. Any significant increases in the Company's stock price will likely create an increase to the fair value of the warrant liability. Similarly, any significant decreases in the Company's stock price will likely

create a decrease to the fair value of the warrant liability. During the years ended December 31, 2014, 2013 and 2012, Warrants to purchase 2.6 million, 0.2 million and 0.005 million shares of common stock, respectively were exercised. At December 31, 2014, the Company had 2010 Warrants outstanding to purchase an aggregate 3.3 million shares of common stock.

Sales Agreement

On March 21, 2014, the Company entered into Amendment No. 1 to the Controlled Equity Offering℠ Sales Agreement, dated August 31, 2012 (as amended, the "Amended Cantor Agreement") with Cantor Fitzgerald & Co. ("Cantor") that provides for the issuance and sale of shares of its common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to $70.0 million through Cantor. Under the Amended Cantor Agreement, Cantor also acts as the Company's sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by the Company pursuant to the Amended Cantor Agreement are deemed an "at-the-market" offering and are registered under the Securities Act of 1933, as amended. During the year ended December 31, 2014 and 2013, approximately, 4.3 million and 5.4 million shares, respectively, of the Company's common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of $18.6 million and $23.5 million, respectively. At December 31, 2014, the Company had approximately $22.5 million of common stock available to be sold under the Amended Cantor Agreement.

Stockholder Rights Plan

In October 2009, the Company's Board of Directors adopted an amendment to its 1999 stockholder rights plan, commonly referred to as a "poison pill," to reduce the exercise price, extend the expiration date and revise certain definitions under the plan. The stockholder rights plan is intended to deter hostile or coercive attempts to acquire the Company. The stockholder rights plan enables stockholders to acquire shares of the Company's common stock, or the common stock of an acquirer, at a substantial discount to the public market price should any person or group acquire more than 15% of the Company's common stock without the approval of the Board of Directors under certain circumstances. The Company has designated 250,000 shares of Series C Junior Participating preferred stock for issuance in connection with the stockholder rights plan.

Note 13. Stock-Based Compensation

Employee Stock Plans

Employee Stock Purchase Plan

The Company maintains an Employee Stock Purchase Plan (the "Purchase Plan"), which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. Under the Purchase Plan eligible employee participants may purchase ordinary shares at a discount of 15% through payroll deductions. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. The Purchase Plan is authorized to issue an aggregate of 1,320,500 shares. At December 31, 2014, the Company had 387,349 shares available for future issuance.

2008 Equity Incentive Plan

The Company also maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. On June 6, 2012 and June 12, 2013, the stockholders approved amendments to the 2008 Plan (collectively the "Amended 2008 Plan") such that the Amended 2008 Plan has reserved for issuance an amount not to exceed 19,540,940 shares. Awards under the Amended 2008 Plan generally have a maximum term of 10 years from the date of the award. The Amended 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant and will generally vest over four years. Performance-based stock or cash awards granted under the Amended 2008 Plan are limited to either 500,000 shares of common stock or $1.0 million per recipient per calendar year. The attainment of any performance-based awards granted shall be conclusively determined by a committee designated by the Company's Board of Directors. At December 31, 2014, no performance-based stock options were outstanding.

1996 Equity Incentive Plan, 1998 Non-Officer Stock Option Plan, and 1999 Equity Incentive Plan

The Company continues to have equity awards outstanding under its previous stock plans: 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan (collectively, the "Prior Plans") and 1996 Equity Incentive Plan (the "1996 Plan"). Equity awards issued under the Prior Plans and the 1996 Plan continues to adhere to the terms of those respective stock plans and no further options may be granted under those previous plans. However, at June 2, 2008, any shares that remained available for future grants under the Prior Plans became available for issuance under the 2008 Plan.

At December 31, 2014, the Company had an aggregate of approximately 17.1 million shares of its common stock subject to outstanding options or remaining available for future issuance under the Amended 2008 Plan, the Prior Plans and the 1996 Plan, of which approximately 11.3 million shares were subject to outstanding options, and approximately 5.8 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options.

Activity under the Company's equity incentive plans related to stock options is set forth below (in thousands except weighted average exercise price):

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balances at December 31, 2013	10,405	$3.46
Granted	2,783	5.90
Forfeited	(233)	4.31
Expired	(114)	8.64
Exercised	(1,518)	2.44
Balances at December 31, 2014	11,323	4.13

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2014, was as follows (in thousands except weighted average exercise price and contractual term):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances at December 31, 2014				
Stock options outstanding	11,323	$4.13	6.8	$25,517
Stock options vested and expected to vest	10,920	$4.08	6.7	$25,174
Stock options exercisable	7,006	$3.70	5.7	$19,324

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

The total intrinsic value of options exercised for the years ended December 31, 2014, 2013 and 2012, was $3.8 million, $0.6 million and $0.3 million, respectively.

Restricted Stock Units

The Company has previously granted restricted stock units primarily to its senior management in accordance with the Amended 2008 Plan. Subject to each grantee's continued employment, the restricted stock units generally vested in three annual installments from the date of grant and were generally issuable at the end of the three-year vesting term. The fair value of restricted stock units which vested during the years ended December 31, 2013 and 2012, were both $0.05 million. As of December 31, 2013, all previously granted restricted stock units were fully vested.

Stock-based Compensation Expense

Stock-based compensation expense recognized on the Company's consolidated statements of operations for the years ended December 31, 2014, 2013 and 2012, was as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Stock-based compensation expense by caption:			
Research and development	$ 998	$ 482	$ 554
Selling, general and administrative	4,155	2,786	1,987
Total stock-based compensation expense	$5,153	$3,268	$2,541

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 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, 2014, 2013 and 2012. The Company has also not recorded any stock-based compensation associated with performance-based stock options during the years ended December 31, 2014, 2013 and 2012.

As of December 31, 2014, the Company expects to recognize the remaining unamortized stock-based compensation expense of $9.1 million related to non-vested stock options, net of estimated forfeitures, over an estimated remaining weighted average period of 2.4 years.

Valuation Assumptions for Stock-based Compensation

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

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

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

The weighted average assumptions used to value the Company's stock-based awards for the years ended December 31, 2014, 2013 and 2012, was as follows:

	Year Ended December 31,		
	2014	2013	2012
Stock Options:			
Expected term (in years)	5.71	5.59	5.54
Estimated volatility	61%	60%	67%
Risk-free interest rate	1.73%	0.87%	1.03%
Expected dividend yield	0%	0%	0%
Employee Stock Purchase Plan Rights:			
Expected term (in years)	0.76	0.50	0.50
Estimated volatility	52%	39%	101%
Risk-free interest rate	0.10%	0.10%	0.14%
Expected dividend yield	0%	0%	0%

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2014, 2013 and 2012, was $3.28 per share, $2.03 per share and $2.13 per share, respectively. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2014, 2013 and 2012, was $1.42 per share, $1.18 per share and $1.43 per share, respectively.

Note 14. 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 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. The Company has not contributed to the 401(k) Plan during the years ended December 31, 2014, 2013 and 2012.

Note 15. Development and License Agreements

Agreements with Fresenius

The Company has certain agreements with Fresenius which require the Company to pay royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. During the years ended December 31, 2014, 2013 and 2012, the Company made royalty payments to Fresenius of $2.5 million, $3.0 million and $2.7 million, respectively. At both December 31, 2014 and December 31, 2013, the Company owed Fresenius $0.7 million, respectively, for royalties.

Until 2014, the Company and Fresenius operated under a supply agreement (the "Original Supply Agreement") for the manufacture of the Company's platelet and plasma systems. Under the Original Supply Agreement, the Company paid Fresenius a set price per kit, which was established annually, plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead was to be paid or refunded if actual manufacturing volumes were lower or higher than the estimated production volumes.

In November 2013, the Company amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014 (the "2013 Amendment"). Under the 2013 Amendment, Fresenius is obligated to sell, and the Company is obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, the Company is able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provides for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. In addition, the 2013 Amendment requires the Company to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of the Company's proprietary inactivation compounds and adsorption media from the Company at fixed prices. The Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying unaudited condensed consolidated balance sheets until such time as the Company purchases finished disposable kits using those components. The term of the 2013 Amendment extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in the Company's case. The Company and Fresenius each have normal and customary termination rights, including termination for material breach.

The Company made payments to Fresenius of $19.1 million, $15.0 million and $12.2 million relating to the manufacturing of the Company products during the years ended December 31, 2014, 2013 and 2012, respectively. At December 31, 2014 and December 31, 2013, the Company owed Fresenius $5.1 million and $4.3 million, respectively, for INTERCEPT disposable kits manufactured. At December 31, 2014 and 2013, amounts due from Fresenius were $1.3 million and zero, respectively.

Note 16. Income Taxes

U.S and foreign components of consolidated loss before income taxes for the years ended December 2014, 2013 and 2012, was as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Loss before income taxes:			
U.S.	$(38,928)	$(44,035)	$(16,360)
Foreign	368	916	685
Loss before income taxes	$(38,560)	$(43,119)	$(15,675)

The provision for income taxes for the years ended December 2014, 2013 and 2012, was as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Provision for income taxes:			
Current:			
Foreign	$168	$191	$180
Federal	0	0	0
State	1	0	0
Total Current	169	191	180
Deferred:			
Foreign	0	0	0
Federal	22	21	48
State	4	6	14
Total Deferred	26	27	62
Provision for income taxes	$195	$218	$242

The difference between the provision for income taxes and the amount computed by applying the federal statutory income tax rate to loss before taxes for the years ended December 31, 2014, 2013 and 2012, was as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Federal statutory tax	$(13,110)	$(14,661)	$(5,329)
Stock-based compensation	(8)	(10)	99
Lobbying expenses	33	107	51
Warrants	(3,367)	4,926	(706)
Foreign rate differential	43	(121)	(53)
Expiration of federal net operating losses and credits—tax effected	0	0	4,352
Change in valuation allowance	16,576	9,955	1,809
Other	28	22	19
Provision for income taxes	$ 195	$ 218	$ 242

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. The significant components of the Company's deferred tax assets at December 31, 2014 and 2013, were as follows (in thousands):

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$ 151,100	$ 142,500
Research and development credit carryforwards	33,800	32,100
Capitalized research and development	15,500	12,300
Deferred compensation	5,800	4,900
Capital loss carryforwards	3,700	3,900
Other	3,200	3,300
Total deferred tax assets	213,100	199,000
Valuation allowance	(213,100)	(199,000)
Net deferred tax assets	0	0
Deferred tax liabilities:		
Amortization of goodwill	115	89
Total deferred tax liabilities	$ 115	$ 89

The valuation allowance increased by $14.1 million for the year ended December 31, 2014, compared to the increase of $8.5 million and a decrease of $0.8 million for the years ended December 31, 2013 and 2012, 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 full 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, expected near-term future losses and the absence of taxable income in prior carryback years. The Company expects to maintain a full valuation allowance until circumstances change.

Undistributed earnings of the Company's foreign subsidiary, Cerus Europe B.V., amounted to approximately $4.6 million at December 31, 2014. The earnings are considered to be permanently reinvested and accordingly, no deferred U.S. income taxes have been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to U.S. income taxes. The unrecognized deferred tax liability for unrepatriated earnings at December 31, 2014, was approximately $1.7 million. In the event all foreign undistributed earnings were remitted to the U.S., any incremental tax liability would be fully offset by the Company's domestic net operating loss.

For the year ended December 31, 2014, the Company reported pretax net losses of $38.6 million on its consolidated statement of operations and calculated taxable losses for both federal and state taxes. The difference between reported net loss and taxable loss are due to temporary differences between book accounting and the respective tax laws.

At December 31, 2014, the Company had federal and state net operating loss carryforwards of approximately $416 million and $255 million, respectively. The net operating loss carryforwards for federal and state expire at various dates beginning in 2015 through 2034. The Company's net operating losses do not include $2.2 million related to windfall tax deductions associated with stock based compensation. The stock based compensation windfall deductions, if utilized, would serve to reduce any income taxes payable.

At December 31, 2014, the Company had federal research and development credit carryforwards of approximately $22.5 million that expire in various years between 2018 and 2034. The state research and development credits are approximately $17.1 million as of December 31, 2014, have an indefinite carryover period.

The utilization of net operating loss carryforwards, as well as research and development credit carryforwards, is limited by current tax regulations. These net operating loss carryforwards, as well as research and development credit carryforwards, will be utilized in future periods if sufficient income is generated. The Company believes it more likely than not that its tax positions would be recognized upon review by a taxing authority having full knowledge of all relevant information. The Company's ability to utilize certain loss carryforwards and certain research credit carryforwards are subject to limitations pursuant to the ownership change rules in accordance with Section 382 of the Internal Revenue Code of 1986 and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. The Company had no unrecognized tax benefits as of December 31, 2014 and 2013. The Company's tax years 2010 through 2013 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

Note 17. Segment, Customer and Geographic Information

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

The Company's operations outside of the U.S. include a wholly-owned subsidiary headquartered in Europe. The Company's operations in the United States of America are responsible for the research and development 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, all of which operate in a country outside of the United States, during the years ended December 31, 2014, 2013 and 2012 (in percentages):

	Year Ended December 31,		
	2014	2013	2012
Etablissement Francais du Sang	25%	17%	20%
Grifols	*	18%	19%
Delrus Inc.	*	*	12%

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

Revenues by geographical location was based on the location of the customer, in the case of product revenues, and in the location of the collaboration partner, in the case of non-product revenues, during the years ended December 31, 2014, 2013 and 2012 and was as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Product Revenue:			
France	$ 9,184	$ 7,030	$ 7,321
Spain and Portugal	2,776	7,033	7,061
CIS	6,636	8,220	8,016
Belgium	4,456	3,971	4,016
Switzerland	3,784	4,078	3,866
Other countries	9,580	9,325	6,415
Total product revenue	36,416	39,657	36,695
Government grants and cooperative agreements:			
United States	0	0	91
Total government grants and cooperative agreements	0	0	91
Total revenue	$36,416	$39,657	$36,786

Long-lived assets by geographical location, which consist of property and equipment, net and intangible assets, net, at December 31, 2014 and 2013, were as follows (in thousands):

	December 31,	
	2014	2013
United States	$4,624	$3,088
Europe & other	299	445
Total long-lived assets	$4,923	$3,533

Note 18. Quarterly Financial Information (Unaudited)

The following tables summarize the Company's quarterly financial information for the years ended December 31, 2014 and 2013 (in thousands except per share amounts):

	Three Months Ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Product revenue	$7,866	$ 8,601	$ 10,362	$ 9,587
Gross profit on product revenue	3,709	3,849	4,673	2,997
Net loss	$ (225)	$(7,589)	$(10,759)	$(20,182)
Net loss per common share:				
Basic	$ (0.00)	$ (0.10)	$ (0.14)	$ (0.26)
Diluted	$ (0.12)	$ (0.16)	$ (0.16)	$ (0.26)

	Three Months Ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Product revenue	$ 9,733	$10,150	$ 10,542	$ 9,232
Gross profit on product revenue	4,643	4,403	3,716	4,293
Net loss	$(10,252)	$ (6,724)	$(20,501)	$(5,860)
Net loss per common share:				
Basic	$ (0.17)	$ (0.10)	$ (0.29)	$ (0.08)
Diluted	$ (0.17)	$ (0.10)	$ (0.29)	$ (0.10)

Note 19. Subsequent Events (Unaudited)

In January 2015, the Company issued 14,636,363 shares of its common stock, par value $0.001 per share, in an underwritten public offering. The price to the public in the offering was $5.50 per share. The net proceeds from this offering were approximately $75.7 million, net of underwriting discounts and other issuance costs of $5.1 million.

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, in the City of Concord, State of California, on the 16th day of March, 2015.

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 true and lawful attorney-in-fact and agent, each acting alone, with full power of substitution and resubstitution, for him and in his 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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ WILLIAM M. GREENMAN **William M. Greenman**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 16, 2015
/s/ KEVIN D. GREEN **Kevin D. Green**	Vice President, Finance and Chief Financial Officer *(Principal Financial Officer)*	March 16, 2015
/s/ DANIEL. N. SWISHER, JR. **Daniel N. Swisher, Jr.**	Chairman of the Board of Directors	March 16, 2015
/s/ TIMOTHY B. ANDERSON **Timothy B. Anderson**	Director	March 16, 2015
/s/ LAURENCE M. CORASH, M.D. **Laurence M. Corash, M.D.**	Director	March 16, 2015
/s/ BRUCE C. COZADD **Bruce C. Cozadd**	Director	March 16, 2015
/s/ GAIL SCHULZE **Gail Schulze**	Director	March 16, 2015
/s/ FRANK WITNEY **Frank Witney, Ph.D.**	Director	March 16, 2015

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
2.1(20)†	Asset Purchase and Redemption Agreement by and between Cerus Corporation and BioOne Corporation, dated as of August 24, 2010.
3.1(31)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(31)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(31)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4(38)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(9)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(15)	Rights Agreement, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
4.3(17)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
4.4(16)	Form of 2009 Warrant to Purchase Common Stock.
4.5(21)	Form of 2010 Warrant to Purchase Common Stock.
	Supply and/or Manufacturing Agreements
10.1(7)†	Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.
10.2(39)†	Amended and Restated Supply Agreement, dated April 21, 2014, by and between Cerus Corporation and Purolite Corporation.
10.3(7)†	Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus Corporation and Porex Corporation.
10.4(33)†	First Amendment to Supply and Manufacturing Agreement, dated November 28, 2012, by and between Cerus Corporation and Porex Corporation.
10.5#	Amendment #2 to Supply and Manufacturing Agreement, dated December 23, 2014, by and between Cerus Corporation and Porex Corporation.
10.6(35)†	Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Fenwal, Inc.).
10.7(35)†	Amendment No. 1 to the Amended and Restated Manufacturing and Supply Agreement, dated November 22, 2013, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.8(11)†	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.9(25)†	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.

Exhibit Number	Description of Exhibit
10.10(34)†	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
	Loan and Security Agreements
10.11(25)†	Loan and Security Agreement, dated as of September 30, 2011, by and between Cerus Corporation and Comerica Bank.
10.12(29)†	First Amendment to Loan and Security Agreement, dated as of December 13, 2011, by and between Cerus Corporation and Comerica Bank.
10.13(29)	Second Amendment to Loan and Security Agreement, dated as of June 30, 2012, by and between Cerus Corporation and Comerica Bank.
10.14(38)†	Loan and Security Agreement, dated as of June 30, 2014, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
	Real Estate Lease Agreements
10.15(4)	Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.
10.16(10)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.17(18)	Letter to California Development, Inc. exercising option to extend the lease term from the Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.18(35)	Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
	Employment Agreements or Offer Letters
10.19(22)*	Employment Letter, by and between Cerus corporation and William M. Greenman, dated May 12, 2011.
10.20(33)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.21(35)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.22(19)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.23(15)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.24(26)*	Employment Agreement for Caspar Hogeboom, dated March 6, 2006.
10.25(26)*	Promotion Letter for Caspar Hogeboom, dated December 11, 2009 and executed on September 21, 2010.
10.26(26)*	Addendum to Employment Agreement for Caspar Hogeboom, dated February 17, 2011.
10.27(26)*	Healthcare Contribution Letter for Caspar Hogeboom, dated December 18, 2007.
10.28(26)*	Home Telephone and Internet Expenses Letter for Caspar Hogeboom, dated January 11, 2012.
10.29(36)*	Equity Change in Control Agreement with Caspar Hogeboom, dated March 7, 2014.

Exhibit Number	Description of Exhibit
10.30(33)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.31(35)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
	Stock Plans and Related Forms
10.32(1)*	1996 Equity Incentive Plan.
10.33(1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.34(1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.35(1)*	1996 Employee Stock Purchase Plan.
10.36(29)*	Employee Stock Purchase Plan, as amended, effective June 6, 2012.
10.37(2)*	1998 Non-Officer Stock Option Plan.
10.38(3)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.39(5)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.40(8)*	2008 Equity Incentive Plan, approved by stockholders June 2, 2008.
10.41(24)*	2008 Equity Incentive Plan, as amended, reapproved by stockholders June 1, 2011.
10.42(32)*	2008 Equity Incentive Plan, as amended, effective June 12, 2013.
10.43(28)*	Form of Option Agreement for employees under the 2008 Equity Incentive Plan, as amended.
10.44(28)*	Form of Option Agreement for non-employee directors under the 2008 Equity Incentive Plan, as amended.
10.45(28)*	Form of Restricted Stock Unit Agreement under the 2008 Equity Incentive Plan, as amended.
	Other Compensatory Plans or Agreements
10.46(33)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.47(12)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.48(14)*	Form of Severance Benefits Agreement.
10.49(36)*	Amended and Restated Non-Employee Director Compensation Policy.
10.50(35)*	International Bonus Plan for 2013.
10.51	International Bonus Plan.
10.52(36)	2013 and 2014 Executive Officer Compensation Arrangements.
	Other Material Agreements
10.53(23)	At-The-Market-Issuance Sales Agreement, dated June 3, 2011, by and between Cerus Corporation and MLV & Co. LLC.
10.54(27)	Amendment to At-The-Market-Issuance Sales Agreement, dated January 4, 2012, by and between Cerus Corporation and MLV & Co. LLC.
10.55(30)	Amendment No. 2 to At-The-Market-Issuance Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and MLV & Co. LLC.

Exhibit Number	Description of Exhibit
10.56(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.57(13)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.58(16)	Form of Subscription Agreement.
10.59(30)	Controlled Equity Offering℠ Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.60(37)	Amendment No 1. to Controlled Equity Offering℠ Sales Agreement, dated March 21, 2014, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.61(18)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare Corporation).
10.62(18)†	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).
10.63(6)†	Commercialization Transition Agreement, dated as of February 12, 2006, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare S.A. and Baxter Healthcare Corporation).
12.1	Computation of Earnings to Fixed Charges.
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(40)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

† Certain portions of this exhibit are subject to a confidential treatment order.
* Compensatory Plan.
# Registrant has requested confidential treatment for portions of this exhibit.
(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 Registration Statement on Form S-8, dated March 24, 1999.
(3) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-8, dated August 4, 1999.
(4) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2001.
(5) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2003.
(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, 2006.
(7) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2008.
(8) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 6, 2008.
(9) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 19, 2008.
(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, 2008.
(11) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2008.
(12) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
(13) 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.
(14) 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.
(15) 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.
(16) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 20, 2009.
(17) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on October 30, 2009.
(18) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2009.
(19) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on March 8, 2010.
(20) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 30, 2010.
(21) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on November 12, 2010.
(22) 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.
(23) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 6, 2011.
(24) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2011.
(25) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2011.
(26) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2011.
(27) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Registration Statement on Form S-3/A, filed with the SEC on January 6, 2012.

(28) 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.
(29) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2012.
(30) 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, 2012.
(31) 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.
(32) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2013.
(33) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2012.
(34) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2013.
(35) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2013.
(36) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2014.
(37) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on March 21, 2014.
(38) 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.
(39) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2014.
(40) 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.

Exhibit 31.1

CERTIFICATION

I, William M. Greenman, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2015

/s/ WILLIAM M. GREENMAN

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

Exhibit 31.2

CERTIFICATION

I, Kevin D. Green, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2015

/s/ KEVIN D. GREEN

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2014, and to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 16th day of March, 2015.

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

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

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Executive Management

William "Obi" M. Greenman
President and Chief Executive Officer

Laurence M. Corash, M.D.
Senior Vice President, Chief Medical and Chief Scientific Officer

Kevin D. Green
Vice President, Finance and Chief Financial Officer

Caspar Hogeboom
President, Cerus Europe and EEMEA

Suzanne Margerum
Vice President, Manufacturing and Operations

Chrystal Menard
Chief Legal Officer and General Counsel

Carol Moore
Senior Vice President, Regulatory Affairs, Quality and Clinical

Nina Mufti
Vice President, Development

Lori L. Roll
Vice President, Administration and Corporate Secretary

Adonis Stassinopoulos
Vice President, Global Scientific Affairs and Research

Kenneth Trader
Vice President, Sales Americas

Board of Directors

Daniel N. Swisher, Jr.
Chair of the Board,
Chief Executive Officer
Sunesis Pharmaceuticals, Inc.

Timothy B. Anderson
Former Senior Vice President
Baxter International, Inc.

Laurence M. Corash, M.D.
Senior Vice President, Chief Medical and Chief Scientific Officer
Cerus Corporation

Bruce C. Cozadd
Chairman and
Chief Executive Officer
Jazz Pharmaceuticals plc

William M. Greenman
President and
Chief Executive Officer
Cerus Corporation

Gail Schulze
Former Chairman
Zosano Pharma, Inc.

Frank Witney, Ph.D.
President and Chief Executive Officer
Affymetrix, Inc.

Corporate Information

Corporate Headquarters
2550 Stanwell Drive
Concord, California 94520
Telephone: (925) 288-6000
Fax: (925) 288-6001
www.cerus.com

European Headquarters
Stationsstraat 79-D
3811 MH Amersfoort
Netherlands
Telephone: 31 33 496 0600
Fax: 31 33 496 0606

Corporate Counsel
Cooley LLP
Palo Alto, California

Patent Counsel
Morrison & Foerster LLP
Palo Alto, California

Auditors
Ernst & Young LLP
Redwood City, California

Registrar and Transfer Agent
Wells Fargo Shareowner Services
1110 Centre Pointe Curve, Suite 101
MAC N9173-010
Mendota Heights, MN 55120
Telephone: (800) 401-1957
Fax: (651) 450-4033

Annual Report on Form 10-K

A copy of the company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission is available without charge on request to:

Investor Relations Department
Cerus Corporation
2550 Stanwell Drive
Concord, California 94520
Telephone: (925) 288-6000

Stock Information
The Company's common stock traded on the NASDAQ Global Market under the symbol: CERS

Annual Meeting of Stockholders
9:00 a.m., June 10, 2015
at Cerus Corporation
2550 Stanwell Drive
Concord, California 94520

Forward-looking Statement

This annual report includes forward looking statements regarding Cerus' expectations regarding future product demand and revenue growth and the impact of FDA approval on that growth; Cerus' expectations for its U.S. commercialization efforts, including blood center implementation and the effect on blood center logistics; expectations for resumed sales growth in Europe, including revenue inflection points and new customers; the planned CE mark submission for and approval of the INTERCEPT Red Blood Cell system and the timing thereof; the potential commercial launch of the INTERCEPT Red Blood Cell system and the timing thereof; potential expanded label claims for the INTERCEPT plasma and platelet systems in the U.S. These forward looking statements involve risks and uncertainties. Actual results could differ materially from these forward-looking statements as a result of certain factors, including without limitation, risks associated with the commercialization and market acceptance of, and customer demand for, the INTERCEPT Blood System, including the risk that Cerus may not resume revenue growth in future periods; risks associated with Cerus' lack of commercialization experience in the United States and its ability to develop and maintain an effective and qualified U.S.-based commercial organization, as well as the resulting uncertainty of its ability to achieve market acceptance of and otherwise successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States; the uncertain and time-consuming development and regulatory process, including the risks (a) that Cerus may be unable to complete the additional development and other activities necessary to support the planned CE Mark submission for the INTERCEPT Red Blood Cell system in a timely manner or at all, and may otherwise be unable to obtain any regulatory approvals for the INTERCEPT Red Blood Cell system, (b) that Cerus may be unable to comply with the FDA's post-approval requirements for the INTERCEPT platelet and plasma systems, which could result in a loss of U.S. marketing approval for the INTERCEPT platelet and plasma systems and (c) related to Cerus' ability to expand the label claims for THE INTERCEPT platelet and plasma systems in the U.S. and elsewhere, which will require additional regulatory approvals; Cerus' reliance on third parties to market, sell, distribute and maintain its products; and other factors discussed in Cerus' most recent filings with the Securities and Exchange Commission, including Cerus' Annual Report on Form 10-K for the fiscal year ended December 31, 2014. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this annual report. Cerus does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

OUR MISSION

Cerus will establish INTERCEPT as the standard of care for transfused blood components globally and enable our customers to do everything in their power to deliver safe and effective blood products to patients.

At Cerus, we are proud of our unwavering focus on achieving our mission, as reflected in our core values:

- The patient is our ultimate concern. We intend to make INTERCEPT the standard of care for blood safety globally.

- We will be a dependable partner for all blood services to allow them to achieve their important mission, concentrating on ensuring the quality, supply, and operational efficiency of our products. No other company will know blood center operations better, nor provide better service.

- We operate as one team and resolve to attract and retain the best people in the business. We operate in multiple cultures and geographies and work in a coordinated, mutually supportive fashion.

- Integrity, perseverance, scientific rigor, and urgency are core to who we are.

CERUS
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