

CERUS CORP  
Form 10-K  
March 09, 2016  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2015

OR

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from to

Commission file number 000-21937

**CERUS CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of

incorporation or organization)  
2550 Stanwell Dr.

Concord, California  
(Address of principal executive offices)

68-0262011  
(I.R.S. Employer

Identification No.)

94520  
(Zip Code)

(925) 288-6000

(Registrant's telephone number, including area code)

## Edgar Filing: CERUS CORP - Form 10-K

### 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 \$422 million. (1)

As of February 26, 2016, there were 99,360,744 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 2016 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, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of \$5.19 per share on June 30, 2015. Excludes 15.5 million shares of the registrant's common stock held by executive officers, directors and stockholders that the registrant has concluded were affiliates at June 30, 2015.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	17
Item 1B. <u>Unresolved Staff Comments</u>	51
Item 2. <u>Properties</u>	51
Item 3. <u>Legal Proceedings</u>	51
Item 4. <u>Mine Safety Disclosures</u>	51
<b>PART II</b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	52
Item 6. <u>Selected Financial Data</u>	54
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	55
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	72
Item 8. <u>Financial Statements and Supplementary Data</u>	73
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	73
Item 9A. <u>Controls and Procedures</u>	73
Item 9B. <u>Other Information</u>	75
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	76
Item 11. <u>Executive Compensation</u>	76
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	76
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	76
Item 14. <u>Principal Accountant Fees and Services</u>	76
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	77
<b><u>SIGNATURES</u></b>	118

---

**Table of Contents**

**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;*

*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; our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;*

*the ability of our products to inactivate the emerging viruses and other pathogens that we may target in the future;*

*our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; 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 the rate of customer adoption in the U.S. and our ability to achieve market acceptance of our products in the U.S. and international markets, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products or for product*

*extensions or additional claims for our products, our ability to obtain reimbursement approval for our products, our ability to complete the development and testing of additional configurations or redesigns of our products, our need for additional financing, the impacts of regulation of*

**Table of Contents**

*our products by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fresenius Kabi AG and third parties to manufacture certain components of the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete our red blood cell system's commercial design, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, legal proceedings, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002, and other factors discussed below and under the caption Risk Factors, in Item 1A of this Annual Report on Form 10-K. We discuss many of these risks in this Annual Report on Form 10-K in greater detail in the section titled Risk Factors under Part I, Item 1A below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K completely. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise any forward-looking statements to reflect new information or future events, even if new information becomes available in the future. You should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.*

**Item 1. Business**  
**Overview**

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

Our INTERCEPT Blood System is for use with 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 but not limited to U.S. Food and Drug Administration, or FDA, approval in the United States of America ( U.S. ) and Class III CE marks in the European Union and other jurisdictions that recognize CE mark approval, and are being marketed and sold in a number of countries around the world, including the U.S.; certain countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East, and Latin America and selected countries in other regions of the world. We sell both the platelet and plasma systems using our direct sales force and through distributors. 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. In late 2014 and early 2015, we 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 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 successfully commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products and product candidates, which, together with anticipated increased selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

**Table of Contents**

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***

The following table identifies our products, product candidates and product development activities and their current status:

<b>Product or Product Candidate Under Development</b>	<b>Product or Development Status</b>
INTERCEPT Blood System Platelets	Commercialized in the U.S. and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world
INTERCEPT Blood System Plasma	Commercialized in the U.S. and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world
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. <i>in vitro</i> studies planned

***INTERCEPT Blood System for Platelets and Plasma***

The platelet system and plasma system are designed to inactivate blood-borne pathogens in platelets and plasma donated for transfusion. Both systems received CE mark approval in Europe and are currently marketed and sold in a number of countries around the world including the U.S., Europe, the CIS, the Middle East and selected countries in other regions of the world. Separate approvals for use of INTERCEPT-treated platelet and plasma products have been obtained in France and Switzerland. In Germany and Austria, where approvals must be obtained by individual blood centers for use of INTERCEPT-treated platelets and plasma, several centers have obtained such approvals for use of INTERCEPT-treated platelets and one center has obtained such approval for use of INTERCEPT-treated plasma. Many countries outside of Europe accept the CE mark and have varying additional administrative or regulatory processes that must be completed before the platelet system or plasma system can be made commercially available. In general, these processes do not require additional clinical trials. Regardless, some potential customers may desire to conduct their own clinical studies before adopting the platelet system or plasma system.

## Table of Contents

The FDA has 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 haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT treated platelets. The first patient enrolled in that study in December 2015. The FDA has also approved the plasma system for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

Although we are commercializing the plasma and platelet systems in the U.S. and have announced customer contracts for the sale of the INTERCEPT Blood System for platelets and plasma, our commercial activities for 2016 in the U.S. will continue to be focused on supporting initial customer adoption and implementation. Prior to broader customer adoption in the U.S., 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. Until those licenses are obtained, U.S. blood centers will be limited to sales to hospital customers within the state in which the INTERCEPT-treated platelets or plasma are processed. 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 further delay customer adoption in the U.S. In addition, in order to address the entire market in the U.S., we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. For example, in the U.S., we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses, or triple doses. 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 U.S. are collected by apheresis, which is part of our FDA-approved label for the platelet system, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. 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 premarket application, or PMA, supplement. In this regard, we submitted a PMA supplement to seek approval of an expanded label claim to support platelets suspended in 100% plasma in the second half of 2015 and we anticipate an FDA decision on the submission by the end of the first quarter of 2016. The remainder of 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.

We have been performing 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 been performing a separate, expanded use IDE, using INTERCEPT to treat platelet donations in areas of the U.S. that had experienced outbreaks of the chikungunya and dengue viruses. Both of these studies are on-going and are expected to be completed within the next year.

### *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



---

## Table of Contents

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 successfully 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 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. 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 the European Union, we may need to generate additional safety data from commercial use and/or achieve a successful outcome in the ongoing chronic anemia Phase III clinical trial for our red blood cell system in order 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 U.S., we successfully completed a Phase II recovery and lifespan study and we will likely need to undertake additional development activities, including Phase III clinical trials, before we would be able to potentially obtain approval for INTERCEPT-treated RBCs in the U.S. 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 U.S. can be found under Item 1A Risk Factors of this Annual Report on Form 10-K, under the risk factor titled *Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country's regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue in that country. Our investigational red blood cell system requires extensive additional testing and development.*

---

## **Table of Contents**

Information regarding our revenues for the years ended December 31, 2015, 2014 and 2013 can be found in *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations*, and *Financial Statement Schedules Financial Statements* of this Annual Report on Form 10-K.

### ***INTERCEPT Blood System Technology***

Both our platelet system and plasma system employ the same technology. Platelet or plasma components collected from blood donors are transferred into plastic INTERCEPT disposable kits and are mixed with our proprietary compound, amotosalen, a small molecule compound that has an affinity for nucleic acid.

The disposable kits are then placed in an illumination device, or illuminator, where the mixture is exposed to ultra-violet A, or UVA, light. If pathogens such as viruses, bacteria or parasites, as well as leukocytes, or white cells, are present in the platelet or plasma components, the energy from the UVA light causes the amotosalen to bond with the nucleic acid. Since platelets and plasma do not rely on nucleic acid for therapeutic efficacy, the INTERCEPT Blood System is designed to preserve the therapeutic function of the platelet and plasma components when used in human transfusions.

The ability of amotosalen to form both cross-links between strands of nucleic acid and links to single nucleic acid strands results in a strong chemical bond between the amotosalen and the nucleic acid of the pathogens. The presence of these bonds is designed to prevent replication of the nucleic acid within pathogens, effectively inactivating the pathogens. A high level of inactivation has been demonstrated in a broad range of pathogens studied by us and others in laboratory testing. For instance, INTERCEPT has demonstrated inactivation of a number of single stranded nucleic acid-based viruses such as HIV, hepatitis B, hepatitis C (using a model virus), West Nile, chikungunya and certain influenza viruses.

Following the inactivation process, residual amotosalen and by-products are reduced by more than 99% through use of a compound adsorption device, which is an integrated component of the disposable kit. We have performed extensive toxicology testing on the residual amotosalen and its by-products and good safety margins have been demonstrated. Any remaining amotosalen which may be transfused, should any exist, is rapidly excreted by humans.

Leukocytes, also known as white blood cells, are typically present in platelet and plasma components collected for transfusion and can cause adverse transfusion reactions as well as an often fatal disease called graft-versus host disease. Leukocytes, like pathogens, rely on nucleic acid for replication and cellular function. The INTERCEPT Blood System, with its combination of the amotosalen and UVA light, is designed to inactivate leukocytes in the same manner it inactivates pathogens.

Like the platelet and plasma systems, the red blood cell system is designed to prevent pathogen replication by using a small molecule additive compound to form bonds with nucleic acid in pathogens that may be present in donated red blood cell collections. The red blood cell system is designed to preserve the therapeutic qualities of the red blood cells, which, like platelets and plasma, do not rely on nucleic acid for their therapeutic efficacy. The red blood cell system uses another of our proprietary compounds, amustaline. Unlike the platelet and plasma systems, the chemical bonds from amustaline are not triggered by UVA light, but instead, by the pH level of the red blood cell components. After mixture with the red blood cell components in plastic disposable kits and resulting nucleic-acid bonding, amustaline is designed to rapidly break down into a form that is no longer chemically reactive with nucleic acid. As with the platelet and plasma systems, a high level of inactivation in a broad range of pathogens has been demonstrated with the red blood cell system in the clinical setting. We plan on conducting additional pathogen-inactivation studies of the red blood cell system, broadening our understanding of the pathogens the system may be able to inactivate.

By treating blood components with INTERCEPT within a day of collection, the inactivation of bacteria prevents bacterial growth that could create increased risk of inflammatory response or dangerous levels of endotoxins.

---

## **Table of Contents**

Extensive clinical testing has been done on platelet and plasma products treated with the INTERCEPT Blood System, as well as post-marketing haemovigilance studies of the treated blood products in routine use.

We believe that, due to their mechanisms of action, the platelet system, plasma system, and red blood cell system will potentially inactivate blood-borne pathogens that have not yet been tested with our systems, including emerging and future threats to the blood supply. We do not claim, however, that our INTERCEPT Blood System will inactivate all pathogens, including prions, and our inactivation claims are limited to those contained in our product specifications. There can also be no assurance that INTERCEPT will inactivate even those pathogens where claims exist, in every instance or under every processing condition.

### **Investment in Aduro Biotech**

In connection with the agreements to license the immunotherapy technologies to Aduro Biotech Inc., or Aduro, in 2009, we received shares of preferred stock of Aduro, a privately held company at that time. Pursuant to these license agreements, we were eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. For the years ended December 31, 2015, 2014 or 2013, we have not received any royalty payments from Aduro pursuant to these license agreements. We historically accounted for the investment under the cost method of accounting with a net carrying value of zero. In April 2015, Aduro's common stock began trading on the NASDAQ Global Select Market, under the symbol ADRO. At the time of Aduro's initial public offering, our preferred shares in Aduro converted to 396,700 shares of common stock, and the fair value of the our investment became readily determinable and, as a result became a marketable equity security. Therefore, we no longer account for the investment in Aduro under the cost basis method of accounting. We now reflect the investment in Aduro as an available-for-sale security included as an investment in marketable equity securities on our consolidated balance sheet (Note 4) and will adjust the carrying value of this investment to fair value each quarterly reporting period, with changes in fair value recorded within other comprehensive income (loss), net of tax. William Greenman, our President and Chief Executive Officer, is a member of the Board of Directors of Aduro in his individual capacity and does not represent our 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 Kabi AG, or 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 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 we are currently in the process of identifying potential alternate manufacturers. In October 2015, we amended and restated our manufacturing and supply agreement with Fresenius with the new terms effective July 1, 2015. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase finished disposable kits for the platelet, plasma and red blood cell systems from Fresenius for both clinical and commercial use. The amended and restated agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are initially fixed and decline at specified annual production levels. The amended and restated agreement also contemplates that we and Fresenius will jointly fund and collaborate on certain specified initiatives focused on new product development or enhancements, potential implementation of automation, installation of new equipment, capacity expansion and cost reduction. We are required to make contributions toward those joint collaboration projects in certain specified installment amounts. In addition, we will make a one-time, lump sum payment, or the Milestone Payment, to Fresenius at the earlier of achievement of certain production volumes or a specified mutually agreed date. Under the amended and restated agreement, we are no longer required to make royalty payments to Fresenius for the sale of products after June 30, 2015. The term of the amended and restated manufacturing and supply agreement with Fresenius extends through July 1,

## **Table of Contents**

2025, and will automatically renew for successive additional two year periods unless terminated by either party upon two years prior written notice, in the case of the initial term, or one year prior written notice, in the case of any renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach.

Components of compound adsorption devices used in platelet and plasma disposable kits are manufactured by Porex Corporation, or Porex. Under our supply agreement with Porex, we are obligated to meet certain annual purchase order requirements. The term of our 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. 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. Our supply agreement with Purolite 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.

We operate with an amended manufacturing and supply agreement with Ash Stevens, Inc., or Ash Stevens, for the synthesis of amotosalen, the inactivation compound used in our platelet and plasma systems. Under this amended agreement, we are 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 original term of the amended manufacturing and supply agreement with Ash Stevens extended through December 31, 2015, and has automatically renewed for two years and will continue to automatically renew for successive two year periods, unless terminated by either party upon providing at least one year prior written notice, in our case, or at least two years prior written notice, in the case of Ash Stevens. Neither party has delivered notice of its intent to terminate the agreement.

We and our contract manufacturers, including Fresenius and NOVA, purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound adsorption devices and UVA illuminators from a limited number of suppliers. Some of 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. For example, we understand that certain plastics used to make INTERCEPT disposable kits will only be available for a finite period of time. As a result, we and our manufacturers have identified alternate plastics but will need to qualify and validate those plastics before we can utilize them in commercial manufacturing.

## **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

---

**Table of Contents**

represents the largest single portion of the blood collection market in the United States. While we believe adoption of the INTERCEPT Blood System will afford the American Red Cross with many benefits, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make, if any, under our multi-year commercial agreement that we and the American Red Cross entered into in February 2016. 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 one blood center has received such approval for 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 December 2015, we entered into a new two-year framework contract with the EFS to supply platelet and plasma disposable kits. The structure of this contract differs from our previous contract with EFS and we are currently in the process of negotiating a sub-contract to the framework contract which will define prices and volumes. We cannot provide any assurance that terms, including the pricing or committed volumes, if any, of the new sub-contract will be equivalent or superior to the terms under our prior contract. If the final commercial terms of the sub-contract are less favorable than the terms under our prior contract, our financial results may be adversely impacted.

In England, decisions on product adoption are centralized in the National Blood Service, or NHSBT, which collects, tests, processes and supplies blood products to hospitals in England and North Wales. The National Blood Service has implemented and used bacterial detection for platelets for the past several years instead of pathogen inactivation. More recently, the National Blood Service has implemented the INTERCEPT Blood System for platelets in one of its centers for validation of the technology. In July 2015, the National Blood Service issued a public tender to solicit bids for both pathogen inactivation and bacterial detection, to which we responded. In December 2015, the National Blood Service announced that it had terminated the potential tender for pathogen inactivation. We do not know when, if ever, the NHSBT will consider adoption of a product for pathogen reduction, including INTERCEPT.

In Japan, the Japanese Red Cross controls a significant majority of blood centers and exerts a high degree of influence on the adoption and use of blood safety measures 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 are currently under development but 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,

---

**Table of Contents**

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 economic legislation in certain countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In the United States, 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. In October 2015, the Centers for Medicare & Medicaid Services published a separate reimbursement code and premium pricing for pathogen-reduced platelet and plasma components under the Healthcare Common 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. Selected areas where we have entered into geographically exclusive distribution agreements include but are not limited to certain countries in the CIS, Italy, the Middle East, Latin America, South Africa and Southeast Asia, as well as the People's Republic of China. Our success in these regions is dependent on our ability to support our distributors and our distributor's ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements account for a significant amount of our revenues. As such, declining performance or the outright termination or loss of certain distributor relationships could harm our existing business, may impact our growth potential, and could result in higher operating costs for us. As our distributors play a critical role in our commercialization efforts, we evaluate their performance on an ongoing basis. As we continue to evaluate our distributors, we may take further actions in the future which may have an impact on our operating results. 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 felt were capable of improved performance relative to their predecessors as well as transitioned some of these territories to a Cerus direct sales effort, which we believed would provide us with better visibility into and control of sales execution. As a result of these changes, we experienced a decrease in the volume of INTERCEPT disposable kit sales for the impacted territories as those distribution partners sold through their disposable kit inventory. In addition, the new distributors and our own direct sales force continue to require some time to develop the market with the same proficiency as previous distributors. We cannot provide assurance that they will be successful in achieving the same level of operations or proficiency as our previous distributors. 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.

---

## **Table of Contents**

### **Competition**

Our products face a wide variety of competition from entities competing directly with alternative pathogen reducing technologies for platelets and/or plasma, as well as from entities developing and selling diagnostic screening products to detect and prevent contaminated products from being transfused, and from process and procedural decisions involving blood banking operations including but not limited to shortened shelf-life of blood components. Many of our competitors have mature, well-established products or have other products which are sold to blood centers and many have more commercial resources than we do. In addition, competitors may choose to seek a lower class of approval than our products, which may be easier and less costly for them to maintain and may be perceived as sufficient by the marketplace. We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen reduction methods that are either on the market or in development. The INTERCEPT Blood System is designed for use in blood centers, which allows for integration with current blood collection, processing and storage procedures. Certain competing products currently on the market, such as solvent detergent-treated plasma, use centralized processing that takes blood products away from the blood center in order to be treated at a central facility before being shipped back out to the blood centers or hospitals for ultimate transfusion, which may result in higher costs.

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

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.

---

## **Table of Contents**

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

### **Patents, Licenses and Proprietary Rights**

Our commercial success will depend in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2015, we owned approximately 12 issued or allowed U.S. patents and approximately 87 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2016 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 2018 and 2024. Due to the complexity of our products, we believe it is the protection afforded to our products by the portfolio of intellectual property rights that best protect our proprietary system rather than any one particular patent or trade secret. Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S.

We are aware of a U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we 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 we have not experienced purchasing patterns from our customers based on seasonal trends, we do not expect seasonality to have a material effect on our business, although purchasing patterns and inventory levels can fluctuate.

### **Inventory Requirements and Product Return Rights**

Our platelet and plasma disposable kits have received regulatory approval for two-year shelf lives. Illuminators and replacement parts do not have regulated expiration dates. We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our consolidated balance sheet, may potentially take over one year to complete production before being utilized in finished disposable kits. In 2014, 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



**Table of Contents**

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,		
	2015	2014	2013
Etablissement Francais du Sang	23%	25%	17%
Grifols	*	*	18%

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

To date, we have not experienced collection difficulties from these customers. For additional details about these customers for the years ended December 31, 2015, 2014 and 2013, 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 *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 \$25.6 million, \$21.8 million and \$15.2 million for the years ended December 31, 2015, 2014 and 2013, respectively. As we look ahead, we anticipate that the regulatory submission processes amendments to our PMA applications for the platelet system in the United States, will require continued investment in research and development activities, as will our ongoing clinical, development and CMC work for our red blood cell system. In addition, we plan to continue spending on new product development and enhancements to our illumination

---

## **Table of Contents**

device which may increase research and development expenses. See Note 2 in the Notes to Consolidated Financial Statements under *Financial Statement Schedules Financial Statements* of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for the years ended December 31, 2015, 2014 and 2013.

### **Government Regulation**

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

Our European investigational plan has been based on the INTERCEPT Blood System being categorized as Class III drug/device combination under the 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



## **Table of Contents**

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 redesigned the illuminator used in the platelet and plasma systems. We also understand that we will have to qualify and validate certain new plastics in the platelet and plasma systems. We will need to seek regulatory approval of the redesigned illuminator and plastics. Should we be 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 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 the center within the FDA principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our blood safety products, CBER also regulates the blood collection centers and would

---

## **Table of Contents**

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.*

---

## **Table of Contents**

### **Employees**

As of December 31, 2015, we had 176 employees, 48 of whom were engaged in research and development and 128 in selling, general and administrative activities. Of the 128 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](http://www.cerus.com); however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission.

### **Financial Information**

Our financial information including our consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of stockholders' equity, consolidated statements of cash flows, and the related footnotes thereto, can be found under *Financial Statement Schedules* in Part IV of this Annual Report on Form 10-K.

### **Item 1A. Risk Factors**

*Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this 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 effect on our business, financial condition, results of operations and growth prospects.*

We have invested a significant portion of our efforts and financial resources on the development of the INTERCEPT Blood System for platelets 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. In December 2014, we received U.S. regulatory approval of the INTERCEPT Blood System for platelets and plasma, with certain restrictions regarding usage 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. Based on our experience in foreign jurisdictions, potential customers in the United States may first choose to validate our technology or conduct experience studies of the INTERCEPT Blood System, among other activities, prior to purchasing or deciding whether to adopt the INTERCEPT Blood System for commercial use, which may never occur. In addition, potential customers must obtain site-specific licenses from the Center for Biologics Evaluation and Research, or 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

## **Table of Contents**

System to those customers for the portion of their business involved in interstate commerce. Until those licenses are obtained, U.S. blood centers will be limited to sales to hospital customers within the state in which the INTERCEPT-treated platelets or plasma are processed. 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 further delay 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, support and maintain a qualified U.S.-based commercial organization and field sales force;

expand the labeled indications of use for the INTERCEPT Blood System and/or design, develop and test new product configurations;

comply with requirements established by the FDA, including post-marketing requirements and label restrictions;

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;

the amount available for reimbursement pursuant to codes we have obtained under the Healthcare Common Procure Coding System, or HCPCS, and pricing for outpatient use of INTERCEPT-treated blood components;

## Edgar Filing: CERUS CORP - Form 10-K

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, effective and economical from the broad constituencies involved in the healthcare system.



---

## **Table of Contents**

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, or the perception of 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 customers that attempt to optimize collection practices in order to produce the highest volume of transfusable units with those collections may view adoption of INTERCEPT as detrimental to their processing yield and therefore revenue potential. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called corrected count increment ) and may be more effective than transfusion of INTERCEPT-treated platelets. Although certain other studies demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, prospective customers may choose not to adopt our platelet system due to considerations relating to corrected count increment, efficacy or other factors.

The INTERCEPT Blood System does not inactivate all known pathogens, and the inability of the INTERCEPT Blood System to inactivate certain pathogens may limit its market adoption. For example, our products have not been demonstrated to be effective in the reduction of certain non-lipid-enveloped viruses, including hepatitis A and E viruses, 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 been shown to be effective in reducing bacterial spores once formed. In addition, our products do not inactivate prions since prions do not contain nucleic acid. While transmission of prions has not been a major problem in blood transfusions, and we are not aware of any competing products that inactivate prions, the inability to inactivate prions may limit market adoption of our products. 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. Should INTERCEPT-treated components contain detectable levels of pathogens after

---

**Table of Contents**

treatment, the efficacy of INTERCEPT may be called into question, whether or not any remaining pathogens are the result of INTERCEPT's efficacy or other factors. Such uncertainties may limit the market adoption of our products.

We have been operating 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 a 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, and hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination 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 data management application software for their operations before they would consider adopting INTERCEPT. Such software development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Developing, maintaining and supporting software can be time consuming, costly and may require resources and skill sets that we do not possess. Failure to do so may limit market adoption in geographies where we commercialize the INTERCEPT Blood System, including the 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,

---

**Table of Contents**

some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, including in the United States for in-patient treatment, commercial use of our products is not yet subject to reimbursement by governmental or commercial third party payors for health care services and may never be subject to specific reimbursement. In the United States, we only recently obtained HCPCS reimbursement codes for INTERCEPT treated platelets and plasma in the outpatient setting. The costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third party payors, including under the new HCPCS codes, the costs and expenses related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. 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. Moreover, the market for pathogen reduction systems in the United States is highly concentrated and dominated by a small number of blood collection organizations. In the United States, the American Red Cross represents the largest single portion of the blood collection market. While we entered into a multi-year commercial agreement with the American Red Cross in February 2016, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make, if any, under our agreement. Conversely, given the large relative size of the American Red Cross, should they deploy the technology rapidly, our resources may be inadequate to fulfill the American Red Cross's and other customers' demands, which could result in a loss of revenues or customer contracts, or both. 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 December 2015, we entered into a new two-year framework agreement with the Établissement Français du Sang, or the EFS, to supply platelet and plasma disposable kits. The structure of this contract differs from our previous contract with EFS and we are currently in the process of negotiating a sub-contract to the framework agreement which will define prices and volumes. We cannot provide any assurance that the terms, including the pricing or committed volumes, if any, of the new sub-contract will be equivalent or superior to the terms under our prior contract. If the final commercial terms of the sub-contract are less favorable than the terms under our prior contract, our financial results may be adversely impacted.

Decisions on product adoption in England are centralized with the National Blood Service, or NHSBT, which has implemented bacterial detection testing for platelets instead of pathogen reduction. In September, 2015, we submitted a proposal to the NHSBT for the treatment of platelets using the INTERCEPT platelet system. We also understand that a separate tender process for bacterial detection testing was issued at the same time. In December

---

**Table of Contents**

2015, the NHSBT announced that it had terminated the potential tender for pathogen inactivation. We do not know when, if ever, the NHSBT will consider adoption of a product for pathogen inactivation, including INTERCEPT.

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 are currently under development but 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 cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems have been approved in the United States only since December 2014 and are not approved in many countries around the world. The red blood cell system is in the development stage and may never emerge from the development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, or to compete favorably with other blood safety interventions or other pathogen reduction technologies, which may reduce or altogether eliminate 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 new product development, enhancements to existing products, planning, enrolling and completing our required post-approval study and the ongoing 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. These costs could be substantial and could extend the period during which we expect to operate at a loss, particularly if we experience any difficulties or delays in completing the activities.

In 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 that could have a negative impact on our profit margins.

***Adverse market and economic conditions may exacerbate certain risks affecting our business.***

Sales of our products are dependent on purchasing decisions of and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including the sovereign debt crisis in certain countries in Europe, disruptions due to political instability, economies and currencies largely effected by declining commodity prices or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for the INTERCEPT Blood System. In addition, there have been concerns for the overall stability and suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European

## Table of Contents

Union, such as the United Kingdom, 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 and other CIS countries. Low worldwide oil prices and the current political conflict stemming from tensions in the Ukraine have significantly devalued the Russian Ruble and other CIS currencies and may continue to have a negative impact on the Russian and other CIS countries' economies, particularly if sanctions continue to be levied against Russia or are strengthened from those currently in place from either the European Union, United States or both. While our agreement with our Russian and other CIS distributors calls for sales, invoicing and collections to be denominated in Euros, if significant sanctions continue or are strengthened, if 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 or other CIS currencies may further weaken or remain weak, and our business in Russia and other CIS countries may be negatively impacted. Similarly, low worldwide oil prices and current political conflicts may negatively impact potential future sales of our products in the Middle East and other oil producing exporters.

***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.

---

**Table of Contents**

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 or if the FDA requires us to collect and provide more data to support a label expansion request to include platelets suspended in 100% plasma, market acceptance of our products may be delayed or negatively impacted and our growth prospects would be delayed or materially and adversely affected.

*Clinical and Preclinical*

Clinical trials are particularly expensive and have a high risk of failure. Any of our trials may fail or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we will begin or complete clinical trials on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board, ministry of health or 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

---

**Table of Contents**

development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay or preclude regulatory approval and commercialization. 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, or if we obtain approval for expanded label claims for the platelet system or plasma system, the FDA may require one or more post-approval clinical 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, Singapore and elsewhere may require, among other requirements, that our products be widely adopted commercially in Europe and the United States, or may delay approval decisions until our products are more widely adopted. In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the 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. Final development of the red blood cell system and completion of CMC activities may never occur 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, growth prospects and potential future market adoption of any of our products, including the red blood cell system. Many of the factors described above that can contribute to the failure or delay of a clinical trial could impact the trials we conduct for our red blood cell system. Even if we are successful in earlier clinical trials, the results of those early trials may not be predictive of results obtained in



---

**Table of Contents**

later and larger clinical trials of the red blood cell system or the results of routine use if we are able to commercialize the red blood cell system. In those cases, the FDA or foreign regulatory agencies may require 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, inefficient use of our resources and could distract personnel from other activities. 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 chronic anemia trial. Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. In a subsequent Phase 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, respectively. We successfully completed the acute anemia Phase III clinical trial, 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 chronic anemia 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 chronic anemia or any potential future clinical trials using our modified process.

We will likely need to successfully conduct and complete a license enabling Phase III clinical trial in the U.S. before the FDA 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 complete development and CMC activities to support an anticipated CE mark submission planned for the second half of 2016, such activities, 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 cannot predict when we would receive regulatory approval of our red blood cell system, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in the European Union, we may need to generate additional safety data from commercial use and/or

---

**Table of Contents**

achieve a successful outcome in the ongoing chronic anemia Phase III clinical trial for our red blood cell system in order to achieve broad market acceptance. Failure to enroll sufficient patients and generate a body of data in chronic patients in a clinical or commercial setting may delay regulatory approval, commercialization or market adoption. 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. In addition, we will likely need to undertake additional development activities, including Phase III clinical trials, prior to receiving potential regulatory approvals in the United States, which 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 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 blood center customers may object to working with a potent chemical, like amustaline, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system. If the red blood cell system were to face such objections from potential customers, we may choose to pay for capital assets, specialized equipment or personnel for the blood center, which would have a negative impact on any potential contribution margin from red blood cell system sales.

*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 within the Europe in France, Switzerland, Germany and Austria. We or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals due to changes in regulatory law, our inability to maintain compliance with regulations or other factors.

In 2006, we obtained a CE mark approval (extended in 2011) from European Union regulators for our plasma system and are in the process of filing a renewal for the approval in accordance with the five year renewal schedule. We or our customers have received approval for the sale and/or use INTERCEPT-treated plasma within Europe 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.

---

**Table of Contents**

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 have conducted and are conducting additional *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In this regard, we submitted a PMA supplement to the FDA to seek approval of an expanded label claim to support platelets suspended in 100% plasma. We have received questions from the FDA regarding our PMA supplement to support platelets suspended in 100% plasma. If our responses to the FDA's questions prove unsatisfactory, we may have to resubmit the PMA supplement which would cause a significant and possibly long-term approval delay. 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. Successful enrollment and completion of this study requires that we develop sufficient INTERCEPT production capabilities with U.S. blood center customers. Delays in delivering INTERCEPT systems to blood centers that can supply INTERCEPT-treated platelets to hospitals involved in the study may lead to increased costs to us and may jeopardize our ability to complete the study in a timeframe acceptable to the FDA. In addition, we must identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers. If we are unable to complete this study, in a timely manner or at all, 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 system. 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.

The execution and completion our ongoing IDE studies will continue to 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 cGMP and current 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

---

## Table of Contents

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.

Should a regulatory agency question a reported adverse event, we may not be able to rule out product failure as the cause, whether or not product failure is the cause of the reported adverse event. If a regulatory agency suspects or discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory agency may impose restrictions on use of that product, including requiring withdrawal of the product from the market. Our failure to comply with applicable regulatory requirements could result in enforcement action by regulatory agencies, which may include any of the following sanctions:

adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, recall or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;

refusal to grant export or import approval for our products;

withdrawing marketing approvals that have already been granted, resulting in prohibitions on sales of our products; and

criminal prosecution.

Any of these actions, in combination or alone, could prevent us from selling our products and harm our business. In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing or changing regulatory requirements may significantly and adversely affect our ability to successfully commercialize and generate additional 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 cGMP regulations or otherwise fail to maintain FDA approval, we may be required to identify an alternate supplier for our products or components.



---

## **Table of Contents**

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 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 have redesigned the

## Edgar Filing: CERUS CORP - Form 10-K

illuminators used in the platelet and plasma systems, and we will need to receive approval of this redesign from the FDA. In addition, in order to address the entire market in the United States, we will need to obtain approval for additional configurations of the platelet system, including making the

**Table of Contents**

platelet system compatible with platelets suspended in 100% plasma, triple dose collections and random donor platelets. We have conducted and are conducting additional *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In this regard, we submitted a PMA supplement to the FDA to seek approval of an expanded label claim to support platelets suspended in 100% plasma. We have responded to questions from the FDA regarding our PMA supplement to support platelets suspended in 100% plasma. If our responses to the FDA's questions prove unsatisfactory, we may have to resubmit the PMA supplement which would cause a significant and possibly long-term approval delay. 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 U.S., Latin and South America and Asia are based out of our headquarters in Concord, California with certain support from our European headquarters in the Netherlands, with certain individuals servicing Latin and South America and Asia, domiciled outside of the United States. Our commercial organization focused on the U.S. market has limited resources and is relatively inexperienced, and as a result, has limited to no experience selling and marketing our platelet and plasma systems. Given the large relative size of the American Red Cross, should they deploy INTERCEPT rapidly under our commercial agreement, our resources may be inadequate to fulfill the American Red Cross's and other customers' demands, which could result in a loss of revenues or customer contracts, or both. We will need to maintain and may need to increase our competence and size in a number of functions, including sales, 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



---

**Table of Contents**

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. Periodically, we transition certain territories to new distribution partners or our direct sales force where we believe we can improve performance relative to the distributor. Because new distribution partners or our direct sales force may have limited experience marketing and selling our products in certain territories, or at all, we cannot be certain that they will perform better than the predecessor distributor. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. Termination, loss of exclusivity or transitioning from these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us or new distributors which may be difficult to do in a timely manner, or at all. We expect that our product 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. In addition, terminated distributors may own illuminators placed at customer sites and may require us to repurchase those devices or require end-user customers to purchase new devices from us. These factors may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense 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.

---

**Table of Contents**

*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, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our 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. Even if we are able to achieve market acceptance in the United States or newly commercialized markets, we may provide initial adoption incentives which may negatively impact our reported sales. As a company, we have no prior experience in commercializing any products in the United States and we will need to attract, retain, train and support sales, marketing and scientific affairs personnel and other commercial talent. For example, we will need to retain our medical science liaisons team, 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 and employment market for MSLs is highly competitive. As such, we will need to commit significant additional management and other resources in order to maintain our MSL team and grow and sustain 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 October 2015, we amended and restated our manufacturing and supply agreement with Fresenius. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase finished disposable kits for the platelet, plasma and red blood cell kits from Fresenius with certain exceptions permitted. The initial term of the amended agreement extends through July 1, 2025, and is automatically renewed thereafter for additional two year renewal terms, subject to termination by either party upon (i) two years written notice prior to the expiration of the initial term or (ii) one year written notice prior to the expiration of any renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business. Disruptions to our supply chain as a result of any potential ensuing protests, strikes or other work-stoppages would be detrimental to our business and operating results. While we and Fresenius recently entered into the amended agreement, 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.

---

**Table of Contents**

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

Our manufacturing and supply agreement with Ash Stevens currently extends through December 31, 2017, 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 are party to a development agreement with another manufacturer for the development of compound adsorption devices. Although we are actively seeking to develop alternative manufacturers and components, commercially viable alternatives are likely at least a year away. 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 manufactures our illuminators, currently extends through September 2016 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 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. In addition, suppliers that our contract manufacturers source components and raw materials from may cease production of or providing those components to our contract manufacturers. For example, we understand that certain plastics used to make INTERCEPT disposable kits will only be available for a finite period of time. As a result, we and our manufacturers have identified alternate plastics but will need to qualify and validate those plastics before we can utilize them in commercial manufacturing. 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. 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

---

**Table of Contents**

or sign up new customers may be negatively impacted. Due to the obsolescence of certain parts, we have redesigned the illuminators used in the platelet and plasma systems, and we will need to receive approval of this redesign from the FDA. 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. Software development is inherently risky and may be time consuming and costly.

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 suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms more favorable to us than those that we currently have with our manufacturers. Many of the existing agreements we have with suppliers contain provisions that we have been operating under for an extended period of time, including pricing. Should we enter into agreements or amend agreements with any manufacturer with less favorable terms, including pricing, our results of operations may be impacted, our recourse against such manufacturers may be limited, and the quality of our products may be impacted.

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In 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 production cycles which could lead to inefficient use of cash or may impair our ability to supply customers with product.

---

**Table of Contents**

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or may not accurately forecast demand ourselves for the INTERCEPT Blood System. Further, certain customers require, and potential future customers may require, product with a minimum shelf life. As a result, we may need to manufacture sufficient product to meet that forecasted demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. 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 mitigate supply disruptions. Certain customers may require product with a minimum shelf life remaining prior to shipment. If customers requiring minimum shelf-lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf-lives which may lead to increased write-offs and inefficient use of our cash. Should we chose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs 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;

---

**Table of Contents**

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 foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the European Union member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission, or EC, to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, a recent judgment of the European Court of Justice that invalidated the EC decision on the United States safe harbor has increased uncertainty around the adequacy of these legal mechanisms. This means that it will no longer be possible to transfer personal data from the EU to entities in the United States that rely on safe harbor certification as a legal basis for the transfer of such data. In addition, data protection authorities from the different EU member states may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. If we fail to comply with applicable data privacy laws, or if the legal mechanisms we rely upon to allow for the transfer of personal data from the EEA or Switzerland to the United States (or other countries not considered by the EC to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business

---

**Table of Contents**

could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. Further, a proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration. The proposed EU Data Protection Regulation, if adopted, is expected to introduce new data protection requirements and substantial fines for breaches of the data protection rules. When the draft EU Data Protection Regulation is adopted, it may increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

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. Section 6002 of the Affordable Care Act known as the

---

## **Table of Contents**

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. 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 or other third party agents. We have limited knowledge and control over the business practices of our distributors and agents, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition.

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

***Legislative 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 eligible entities that manufacture or import medical devices offered for sale in the United States;



---

## **Table of Contents**

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 collection device manufacturers may need to modify device collection parameters or software before a prospective customer could use INTERCEPT. Failure to comply by these manufacturers may limit the potential market for our products. 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

**Table of Contents**

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 addition, many blood centers may view pooled random donor platelets treated with INTERCEPT as an economically optimal approach. 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. We have conducted and are conducting additional *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In this regard, we submitted a PMA supplement to the FDA to seek approval of an expanded label claim to support platelets suspended in 100% plasma. We have responded to questions from the FDA regarding our PMA supplement to support platelets suspended in 100% plasma. If our responses to the FDA's questions prove unsatisfactory, we may have to resubmit the PMA supplement which would cause a significant and possibly long-term approval delay. Our failure to obtain FDA and foreign regulatory approvals of any new configurations could significantly limit revenues from sales of the platelet system. In addition, given that there is some loss of platelets using our product, blood centers may need to increase collection volumes in order to use our product and maintain an adequate concentration for a triple therapeutic dose. In any event, delays in receipt or failure to receive approval could reduce our sales and negatively impact our profitability potential and future growth prospects. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma systems. In addition, 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 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.

---

## **Table of Contents**

*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 reducing 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 further understand that Terumo BCT developed a pathogen reduction system for whole blood and has recently completed a clinical trial of its whole blood system in Ghana, receiving a class II CE mark. Terumo's products 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.

In addition, we understand that Octapharma received approval to sell fresh frozen plasma in France. Octapharma's entry into the French market may pose a competitive threat to other pathogen reduced plasmas, including INTERCEPT and may in turn limit the potential market available to us in France.

---

## **Table of Contents**

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 or was a result of a potential defect or lack of efficacy of our products. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. In addition, should personnel at clinical study sites or ultimately, potential customers, be harmed by amustaline, or believe they have been or could be harmed by amustaline, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. Amustaline is considered a potent chemical and is the active compound of our red blood cell system.

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

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

---

## **Table of Contents**

***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, commitments to fund projects with Fresenius, costs to develop different configurations of existing products and new products, including our

---

**Table of Contents**

illuminator, costs associated with planning, enrolling and completing ongoing studies, 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 for 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 on 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, 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 the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products and may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

***Covenants in our 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 revenue to meet the condition required in order to access the final loan available under the agreement and may also 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 \$20.0 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

---

**Table of Contents**

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, 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 could adversely affect our liquidity. Before we would consider accessing the final \$10.0 million under the loan and security agreement, if available, 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. For example, our President of Cerus Europe B.V. and we have entered into a separation agreement. While we have identified and hired an interim general manager as a replacement, we cannot be certain that the new general manager will be able to learn our business timely or at all or successfully

---

**Table of Contents**

maintain or grow our commercial business in Europe, the Middle East or African markets. 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 that we are dependent on is located in France and may have employees that are members of unions or represented by a works council as required by law. These more stringent labor and employment laws to the extent that they are applicable, coupled with the requirement to consult with the relevant unions or works councils, could increase our operational costs with respect to our own employees and could result in passed through operational costs by our manufacturing partner. If the increased operational costs become significant, our business, financial condition and results of operations could be adversely impacted.

***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 enterprise resource planning system, or ERP System, is extremely complex and impacts a significant number of our business processes. Should we experience unforeseen difficulties with our 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 of the Internal



**Table of Contents**

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 exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we 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 between 2018 and 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products, including in connection with our planned commercialization of the platelet and plasma systems in the 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.

---

## **Table of Contents**

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 sold outside of the United States 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 and other currencies we transact in, our revenues and expenses denominated in Euros or other foreign currencies are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility. As our commercial operations grow globally, our operations are exposed to more currencies and as a result our exposure to foreign exchange risk will grow.

***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

---

**Table of Contents**

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. Although we have been able to successfully remediate those internal control deficiencies, 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

**Table of Contents**

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 acquirer and/or deter such third party from acquiring us.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate headquarters, which includes our principal executive offices, is located in Concord, California. 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, 2015.

Location	Square Footage	Lease Expiration Date	Primary Functions
Concord, CA, United States	36,029	November 2019	Administrative and research
Concord, CA, United States	21,440	July 2017	Sales, administrative, marketing and technical support
Amersfoort, Netherlands	7,300	January 2018	Sales and administrative

**Item 3. Legal Proceedings**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Table of Contents****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:

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2015:</b>		
First Quarter	\$ 7.03	\$ 3.95
Second Quarter	5.70	3.82
Third Quarter	5.87	4.29
Fourth Quarter	6.60	4.27
<b>Year Ended December 31, 2014:</b>		
First Quarter	\$ 8.00	\$ 4.76
Second Quarter	5.19	3.74
Third Quarter	4.36	3.48
Fourth Quarter	6.93	3.60

On February 26, 2016, the last reported sale price of our common stock on the Nasdaq Global Market was \$5.08 per share. On February 26, 2016, we had approximately 138 holders of record of our common stock.

*Dividends*

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

**Table of Contents****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, 2010, and tracked the performance through December 31, 2015, for (i) our common stock, (ii) the NASDAQ Biotechnology Index, (iii) the NYSE ARCA Biotechnology 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**

	<b>December 31,</b>					
	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
Cerus Corporation	\$ 100.00	\$ 113.82	\$ 128.46	\$ 262.20	\$ 253.66	\$ 256.91
NASDAQ Biotech Index	100.00	111.81	147.48	244.24	327.52	364.93
NYSE ARCA Biotech Index	100.00	84.11	119.22	179.59	265.03	293.92
NASDAQ	100.00	98.20	113.82	157.44	178.53	188.75

- (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.

**Table of Contents****Item 6. Selected Financial Data**

The following table summarizes certain selected financial data for the five years ended December 31, 2015, 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.

(in thousands, except per share amounts)	Year Ended December 31,				
	2015	2014	2013	2012	2011
<b>Consolidated Statements of Operations Data:</b>					
Product related:					
Revenue	\$ 34,223	\$ 36,416	\$ 39,657	\$ 36,695	\$ 30,602
Cost of revenue	23,464	21,188	22,602	20,616	18,535
Gross profit	10,759	15,228	17,055	16,079	12,067
Government grants and cooperative agreements revenue				91	2,442
Loss from operations	(61,075)	(44,503)	(28,299)	(17,300)	(15,924)
Net loss	(55,868)	(38,755)	(43,337)	(15,917)	(16,982)
Net loss per share:					
Basic	\$ (0.58)	\$ (0.52)	\$ (0.64)	\$ (0.29)	\$ (0.35)
Diluted	\$ (0.61)	\$ (0.61)	\$ (0.64)	\$ (0.33)	\$ (0.35)
Weighted average shares outstanding used for calculating loss per share:					
Basic	96,068	74,767	67,569	54,515	48,050
Diluted	96,905	76,534	67,569	55,061	48,050

(in thousands)	December 31,				
	2015	2014	2013	2012	2011
<b>Consolidated Balance Sheets Data:</b>					
Cash, cash equivalents, short-term investments and investment in marketable equity securities	\$ 107,879	\$ 51,294	\$ 57,676	\$ 26,696	\$ 25,784
Working capital	108,544	45,698	38,730	18,383	18,625
Total assets	139,470	81,776	83,381	48,919	45,367
Long-term obligations	22,810	11,068	1,162	4,199	5,940
Total stockholders' equity	94,765	41,521	42,795	19,107	18,313

---

**Table of Contents****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, 2015. Operating results for the year ended December 31, 2015 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.

In December 2014, we received approval of our premarket applications, or PMAs, from the United States Food and Drug Administration, or FDA, for the platelet system and the plasma system. The platelet system is approved in the United States 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. The plasma system is approved in the United States for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

We have ongoing studies 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 another ongoing study under an expanded use IDE, to use INTERCEPT to treat platelet donations in areas of the U.S. that have had outbreaks of the chikungunya and dengue viruses. Both of these studies are ongoing and are expected to be completed within the next year.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development and has not been commercialized anywhere in the world. We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients. Although we plan to undertake additional development and chemistry, manufacturing and control, or CMC, activities to support an anticipated CE mark submission for the red blood cell system in 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 in the next twelve months, 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, we may need to generate additional safety data from commercial use and/or achieve a successful outcome in the ongoing chronic anemia Phase III clinical trial for our red blood cell system in order 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



---

**Table of Contents**

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. Successful completion 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 experience delays in testing, conducting trials or obtaining 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, commitments to fund projects with Fresenius, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval 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 for 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 on 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, 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 the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional

## **Table of Contents**

randomized controlled clinical trials for existing or new products and may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Although we have begun the combined commercial launch of the plasma and platelet systems in the United States and have announced customer contracts for the sale of the INTERCEPT Blood System for platelets and plasma, our commercial activities for 2016 in the United States will continue to 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 Commonwealth of Independent States, or 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 products and product candidates, which, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

### **Aduro Biotech**

We hold an investment in Aduro Biotech Inc., or Aduro, common stock totaling 396,700 shares. Aduro trades on the NASDAQ Global Select Market, under the symbol `ADRO`. As of December 31, 2015, the fair value of Aduro's common stock was \$28.14 per share. We account for the investment in Aduro as an available-for-sale security on our consolidated balance sheet and adjust the carrying value of this investment to fair value each quarterly reporting period with changes in fair value recorded within other comprehensive income (loss), net of tax. Prior to Aduro's IPO in April 2015, we held the investment in Aduro at zero on our consolidated balance sheet.

### **Fresenius**

Through June 30, 2015, we paid 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 varied by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Fresenius 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.

In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014, which we refer to as the 2013 Agreement. Under the 2013 Agreement, Fresenius was obligated to sell, and we were 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 was purchased from Fresenius, we were able to purchase additional quantities of disposable kits from other third-party manufacturers. The amended terms also provided for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. In addition, the 2013 Agreement required us to purchase additional specified annual volumes of sets if and when an additional Fresenius manufacturing site was identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius was also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices.

---

**Table of Contents**

In October 2015, we entered into a ten year Amended and Restated Manufacturing and Supply Agreement, or the 2015 Agreement, with Fresenius, which amended and restated the 2013 Agreement. Under the 2015 Agreement, Fresenius continues to be obligated to sell and we are obligated to purchase finished disposable kits for our platelet, plasma and red blood cell systems. The 2015 Agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are initially fixed and decline at specified annual production levels, and are subject to certain adjustments after the initial pricing term.

Under the 2015 Agreement, we are no longer required to make royalty payments to Fresenius for the sale of products after June 30, 2015. Under the 2013 Agreement and 2015 Agreement, we maintain the amounts due from the components sold to Fresenius as a current asset on our accompanying consolidated balance sheets until such time as we purchase finished disposable kits using those components. The 2015 Agreement also requires us to make certain payments totaling 8.6 million ( Manufacturing and Development Payments ) to Fresenius in 2016 and on December 31st of the earlier of (a) the year of achievement of certain production volumes or (b) 2022. Because these payments represent unconditional payment obligations, we recognize its liability for these payments at their net present value. The Manufacturing and Development Payments liability is accreted through interest expense based on the estimated timing of its ultimate settlement. As of December 31, 2015, we had accrued \$7.8 million ( 7.2 million) related to the Manufacturing and Development Payments.

The Manufacturing and Development Payments will be made to support certain projects Fresenius will perform on behalf of us related to research and development activities and manufacturing efficiency activities. We allocated \$4.8 million to research and development activities and \$2.4 million to manufacturing efficiency activities based on their market value. The prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company is expensed over the period which such activities occur. The manufacturing efficiency asset is expensed on a straight line basis over the life of the 2015 Agreement.

The initial term of the 2015 Agreement extends through July 1, 2025 (the Initial Term ) and is automatically renewed thereafter for additional two year terms (each, a Renewal Term ), subject to termination by either party upon (i) two years written notice prior to the expiration of the Initial Term or (ii) one year written notice prior to the expiration of any Renewal Term. Under 2015 Agreement we shall have the right, but not the obligation, to purchase certain assets and assume certain liabilities from Fresenius.

While we and Fresenius recently entered into the 2015 Agreement, in the event that Fresenius refuses or is unable to continue operating under the 2015 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. Like most regulated manufacturing processes, our ability to produce our products is dependent on our or Fresenius ability to source components and raw materials which may at times be in short demand or obsolete. In such cases, we and/or Fresenius may need to source, qualify and obtain approval for replacement materials or components which would likely prove to be disruptive and consume capital resources sooner than we anticipate.

---

## **Table of Contents**

### **Equity and Debt Agreements**

#### *Cantor*

On March 21, 2014, we entered into Amendment No. 1 to the Controlled Equity Offering<sup>SM</sup> 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 our 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 years ended December 31, 2015 and 2014, approximately, zero and 4.3 million shares, respectively, of our common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of zero and \$18.6 million, respectively. At December 31, 2015, we had approximately \$22.5 million of common stock registered to be sold under the Amended Cantor Agreement, subject to the continued effectiveness of our current shelf registration statement or an effective replacement registration statement.

#### *Debt Agreement*

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. On June 15, 2015, we received \$10.0 million from the second tranche, or Term Loan B. On September 29, 2015, the Term Loan Agreement was amended to extend (i) the period in which the third tranche can be drawn and (ii) the interest-only period for all advances under the Term Loan Agreement. As amended, the third tranche of \$10.0 million, or Term Loan C, would be available, subject to our achievement of consolidated trailing six months revenue at a specified threshold, or the Revenue Event, from the date on which the Revenue Event is achieved, to the earlier of (i) June 30, 2016, and (ii) 60 days after the Revenue Event is achieved. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. Term Loan C would 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 Term Loan C funding date. All of the Term Loans mature on June 1, 2019. Following the amendment to Term Loan Agreement, we are required to make interest only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than May 31, 2016, 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, 2015. For additional discussion on the Term Loan Agreement, see Commitments and Off-Balance Sheet Arrangements Debt.

### **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

---

## **Table of Contents**

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, or 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 or signed sales contract as evidence of a written agreement. We sell our platelet and plasma systems directly to blood banks, hospitals, universities, 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. 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, 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 our platelet and plasma systems by considering multiple factors.

Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs*. Taxes that we invoice to our customers and remit to governments are recorded on a net basis, which excludes such tax 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, 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 2015 Agreement 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. The amended terms also provided for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. 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.

**Table of Contents**

Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or net realizable 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. 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 revenue* on our consolidated statements of operations.

**Accrued liabilities** 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, 2015, we performed our annual review of goodwill as described above and determined that goodwill was not impaired during the year ended December 31, 2015. We will continue to monitor events and changes in circumstances that could indicate carrying amounts of our intangible

---

## Table of Contents

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, 2015, 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 and November 2015, all outstanding warrants issued in August 2009 and November 2010, respectively, were exercised in full. The fair value of these outstanding warrants was calculated using a combination of 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. For the period ended December 31, 2014, the fair value of the outstanding warrants was classified as a liability on our consolidated balance sheet as the warrants contained certain material terms which required 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. As of December 31, 2015, no warrants were issued or outstanding.

Prior to the exercise of the warrants in 2015, the fair value of the outstanding warrants was calculated using a combination of 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.

**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

**Table of Contents**

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 U.S. federal and California for all tax years through 2015 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

**Results of Operations****Years Ended December 31, 2015, 2014 and 2013****Revenue**

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
Revenue	\$ 34,223	\$ 36,416	\$ 39,657	(6)%	(8)%

Revenue decreased by \$2.2 million during the year ended December 31, 2015, compared to the year ended December 31, 2014. The primary driver for the decline in reported revenue was the weakening of the average Euro relative to our reporting currency, the U.S. dollar, of approximately 16% during the year ended December 31, 2015, compared to the year ended December 31, 2014. During the periods presented, most of our revenue was invoiced and transacted in Euros with reported revenue in U.S. dollars. The decrease in revenue during 2015 was partially offset by a higher unit sales volume of our disposable platelet and plasma system kits of 15%.

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 a weaker 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 of disposable kits to end-user customers in the territory contributing to the year-over-year reduction in demand for disposable kits by approximately 5%.

We anticipate 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 and newly accessible geographies. However, continued deterioration in the Euro relative to the U.S. dollar and continued general declines in the economic climate in Russia and the CIS markets would continue to adversely impact product revenue. As a result of these and other factors, the historical results may not be indicative of INTERCEPT Blood System revenue in the future. In addition, if the final commercial terms of our sub-contract with Établissement Français du Sang are less favorable than the terms under our prior contract, our financial results may be adversely impacted.

**Cost of Revenue**

Our cost of revenue consists of the cost of the INTERCEPT Blood System inventory sold; provisions for obsolete, slow-moving and unsaleable product; certain order fulfillment costs, to the extent applicable, costs for idle facilities, and, prior to July 1, 2015, royalties payable to Fresenius for product sales. Inventory is accounted for on a first-in, first-out basis.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
Cost of revenue	\$ 23,464	\$ 21,188	\$ 22,602	11%	(6)%



**Table of Contents**

Cost of revenue increased by \$2.3 million during the year ended December 31, 2015, compared to the year ended December 31, 2014. The increase was primarily the result of higher unit sales volume and increase of \$1.8 million in obsolescence and manufacturing charges, partially offset by inventory produced during periods of more favorable foreign currency exchange rates. Similar to our revenues, during the periods presented, a significant majority of our product was sourced from vendors transacting in Euros and reported by us in U.S. dollars. Per unit cost of product sold declined by 11.4% during the year ended December 31, 2015 compared to 2014.

Cost of 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 manufacturing and supply 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.

Our gross margin on sales was 31% during the year ended December 31, 2015, compared to 42% during the year ended December 31, 2014. The decrease in gross margins on sales, compared to the year ended December 31, 2014, was primarily due to the deterioration in the Euro relative to the U.S. dollar on current period revenues and increased obsolescence and manufacturing charges, partially offset by the impact on cost of revenues which were recorded at more favorable foreign exchange rates in effect at the time the inventory was purchased. In addition, increased period charges for outdated product also resulted in the overall decreases in gross margins during the year ended December 31, 2015, compared to the year ended December 31, 2014.

Our gross margin on product sales was 42% during the year ended December 31, 2014, compared to 43% during the year ended December 31, 2013. 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.

Changes in our gross margins are affected by various factors, including the exchange rate of the Euro relative to the U.S. dollar, manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which product is sold. 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, or delays in manufacturing products. In addition, we may face competition which may limit our ability to maintain existing selling prices for our products which in turn would negatively affect our reported gross margins. 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 2015.

**Research and Development Expenses**

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

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
Research and development	\$ 25,643	\$ 21,800	\$ 15,187	18%	44%

**Table of Contents**

Research and development expenses increased by \$3.8 million during the year ended December 31, 2015, compared to the year ended December 31, 2014, primarily due to increased costs associated with pursuing potential label claim extensions for the platelet system in the U.S., conducting our IDE studies, development of a new generation of our illuminator, and development activities for our red blood cell program. Research and development expenses increased by \$6.6 million during the year ended December 31, 2014, compared to the year ended December 31, 2013, 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.

We expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval study for the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., and completing 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. 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, internal control, legal, facility and infrastructure related expenses, and insurance premiums.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
Selling, general and administrative	\$ 45,989	\$ 37,729	\$ 29,965	22%	26%

Selling, general, and administrative expenses increased by \$8.3 million during the year ended December 31, 2015, compared to the year ended December 31, 2014, primarily due to increased spending related to activities associated with the U.S. launch of our plasma and platelet products which increased over the course of 2015 and to a lesser extent, increases in back-office support functions. 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 2014 costs incurred for preparatory activities for the U.S. launch of our plasma and platelet systems, and to a lesser extent, higher workforce costs.

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 and marketing personnel, as well as medical science liaisons to educate hospital personnel and physicians on our products.

**Table of Contents****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 are reviewed for impairment at each reporting period.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
Amortization of intangible assets	\$ 202	\$ 202	\$ 202	%	%

Amortization of intangible assets remained flat during the year ended December 31, 2015, compared to the years ended December 31, 2014 and 2013, 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, 2015, 2014 and 2013.

We expect 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, and other non-operating gains and losses, including interest earned from our short-term investment portfolio.

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
Gain (loss) from revaluation of warrant liability	\$ 3,566	\$ 7,708	\$ (15,099)	(54)%	151%
Foreign exchange (loss) gain	(396)	(1,296)	533	69%	(343)%
Interest expense	(1,705)	(599)	(332)	185%	80%
Other income, net	71	130	78	(45)%	67%
<b>Total non-operating income (expense), net</b>	<b>\$ 1,536</b>	<b>\$ 5,943</b>	<b>\$ (14,820)</b>	<b>(74)%</b>	<b>140%</b>

**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 and November of 2015, all of the outstanding August 2009 and November 2010 warrants, respectively, were exercised. The fair value of the outstanding warrants, which used the Black-Scholes model, was classified as a liability on our consolidated balance sheet and was adjusted at each subsequent reporting period, until such time the warrants were exercised. Upon exercise, the fair value of the warrants was reclassified from liabilities to stockholders' equity.

We recorded a non-cash gain from the revaluation of the warrant liability of \$3.6 million for the year ended December 31, 2015, compared to a non-cash gain of \$7.7 million for the year ended December 31, 2014. 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 \$22.8 million increased from a non-cash loss of \$15.1 million during the year ended December 31, 2014, compared to the year ended December 31, 2013, primarily due to the change in our underlying stock price compared to the strike price of the warrants. As of December 31, 2015, we had no remaining outstanding warrants.

**Foreign exchange gain (loss)**

Foreign exchange loss decreased to \$0.4 million during the year ended December 31, 2015, compared to a loss of \$1.3 million during the year ended December 31, 2014, primarily attributable to stabilization of foreign currency



**Table of Contents**

variations between the Euro and U.S. dollar, our functional currency, in 2015 as compared to the Euro and U.S. dollar exchange rates in 2014. For the year ended December 31, 2014, compared to the year ended December 31, 2013, we experienced foreign exchange charges of \$1.8 million due to unfavorable foreign currency variations period over period between the Euro and U.S. dollar.

*Interest expense*

Interest expense increased by \$1.1 million for the year ended December 31, 2015, compared to the year ended December 31, 2014, primarily due to larger outstanding debt balance under our Term Loan Agreement (see Debt section below), resulting from the drawdown of Term Loan B of \$10.0 million in June 2015. 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, which commenced on June 30, 2014, compared to the credit facility that was outstanding in the prior periods.

*Other income, net*

Other income, net remained consistent during the year ended December 31, 2015, compared to the years ended December 31, 2014 and 2013.

*Provision for Income Taxes*

(in thousands, except percentages)	Year Ended December 31,			% Change	
	2015	2014	2013	2015 to 2014	2014 to 2013
(Benefit) provision for income taxes	\$ (3,671)	\$ 195	\$ 218	(1,983)%	(11)%

For the year ended December 31, 2015, we recorded a tax benefit of \$3.7 million, which is the result of changes in the fair value of our investments, primarily shares of Aduro. The tax benefit is partially offset by the tax provision recorded in other comprehensive income which is also associated with the increased value of our Aduro investment. Provision for income taxes for the years ended December 31, 2014 and 2013 primarily consisted 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. Due to our history of cumulative operating losses, management has concluded that, after considering all the available objective evidence, it is not likely that all our net deferred tax assets will be realized. Accordingly, all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of December 31, 2015.

**Liquidity and Capital Resources**

In recent years, our sources of capital have primarily consisted of public issuance of common stock, debt instruments, and to a lesser extent, contribution from product sales.

At December 31, 2015, we had cash and cash equivalents of \$71.0 million, compared to \$22.8 million at December 31, 2014. Our cash equivalents consist of money market instruments. In addition, we had \$36.9 million of short-term investments and investments in marketable equity securities at December 31, 2015, and \$28.5 million at December 31, 2014. We also had total indebtedness under our Term Loan Agreement of approximately \$19.9 million at December 31, 2015 and \$9.9 million at December 31, 2014.

*Operating Activities*

Net cash used in operating activities was \$51.1 million for the year ended December 31, 2015, compared to \$39.8 million during the year ended December 31, 2014. The increase in net cash used in operating activities was

---

**Table of Contents**

primarily related to the level of cash spent for development activities for our red blood cell program, support of our expanded use IDE for treatment of platelets, and selling and administrative expenses related to the U.S. commercial launch of our platelet and plasma systems. Also contributing to this increase in net cash used in operating activities were changes in working capital resulting from a decrease in our accounts payable due to the accelerated timing of payments, coupled with an increase in accounts receivable during the year ended December 31, 2015, as compared to the corresponding period in 2014.

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.

*Investing Activities*

Net cash provided in investing activities was \$1.4 million for the year ended December 31, 2015, compared to \$3.3 million of net cash used during the year ended December 31, 2014. The change was primarily the result of maturities of short term investments in excess of purchases of short term investments, and fewer capital expenditures in 2015.

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.

*Financing Activities*

Net cash provided by financing activities was \$98.0 million during the year ended December 31, 2015, compared to \$36.5 million during the year ended December 31, 2014. The increase in net cash provided by financing activities was primarily due to the proceeds received from our January 2015 public offering of common stock. The net proceeds from this offering were approximately \$75.3 million, net of underwriting discounts and other issuance costs. Net cash provided from financing activities was further increased by our drawdown of Term Loan B of \$10.0 million in June 2015. This was partially offset by the lack of issuances of our common stock pursuant to the Amended Cantor Agreement during the year ended December 31, 2015.

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, and, to a lesser extent, fewer sales of our common stock pursuant to the Amended Cantor Agreement during the year ended December 31, 2014 compared to the prior year. The overall decrease was partially offset by increased proceeds from the exercise of warrants and stock options and increased borrowings in 2014.

*Working Capital*

Working capital increased to \$108.5 million at December 31, 2015, from \$45.7 million at December 31, 2014, primarily due to funds received from the January 2015 public offering, our drawdown of Term Loan B of \$10.0

---

**Table of Contents**

million in June 2015, and the valuation of our equity investment in Aduro common stock resulting from Aduro's initial public offering in April 2015, coupled with a decrease in our warrant liability. These increases were partially offset by cash used in operations during 2015. 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.

*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, commitments to fund projects with Fresenius, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies and the post-approval 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 for 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 on 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, 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 the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or

**Table of Contents**

commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products and may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

*Other Information*

On March 2014, we entered into 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 million through Cantor as our sales agent. There were no sales under the Amended Cantor Agreement during the year ended December 31, 2015. 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, 2015, we had approximately \$22.5 million of common stock registered 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 million of common stock, preferred stock, warrants, and/or debt securities, less amounts sold under the Amended Cantor Agreement following the effectiveness of the shelf registration statement and less the \$80.5 million of common stock sold in our January 2015 public offering.

**Commitments and Off-Balance Sheet Arrangements***Off-balance sheet arrangements*

We did not have any off-balance sheet arrangements as of December 31, 2015 or 2014.

*Contractual Commitments*

The following summarizes our contractual commitments at December 31, 2015:

(in thousands)	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Minimum purchase requirements	\$ 9,048	\$ 8,354	\$ 694	\$	\$
Manufacturing and development obligations	9,379	3,381	5,998		
Debt	24,323	4,402	14,817	5,104	
Operating leases	3,490	1,111	1,745	634	
Other commitments	1,519	1,084	303	132	
Total contractual obligations	\$ 47,759	\$ 18,332	\$ 23,557	\$ 5,870	\$

*Minimum purchase requirements*

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

*Manufacturing and development obligations*

On October 19, 2015, we entered into the 2015 Agreement with Fresenius. The 2015 Agreement calls for payments of \$3.4 million ( 3.1 million) to be made in 2016, and a payment of \$6.0 million ( 5.5 million) on December 31 of the year in which certain production volumes are achieved, or December 31, 2022, whichever occurs first. We expect to achieve the production threshold in 2018.



---

**Table of Contents***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. The operating leases expire at various dates through 2020, 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. Our leased facilities 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. At December 31, 2015, we had an outstanding liability of \$0.5 million related to these leasehold improvements. Also included in other commitments are payments for termination and consulting fees, to be paid in 2016 and 2017.

*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. On June 15, 2015, we received \$10.0 million from Term Loan B. On September 29, 2015, the Term Loan Agreement was amended to extend the period in which the third tranche can be drawn and the interest-only period for all advances under the Term Loan Agreement. As amended, the third tranche of \$10.0 million, Term Loan C, would be available, subject to our achievement of the Revenue Event, from the date on which the Revenue Event is achieved, to the earlier of (i) June 30, 2016, and (ii) 60 days after the Revenue Event is achieved. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. 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 Term Loan C funding date. All of the Term Loans mature on June 1, 2019. Following the amendment, we are required to make interest-only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than May 31, 2016, 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. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at December 31, 2015. 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. 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 we may not be able to meet.

**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

**Table of Contents**

money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our marketable equity securities consist of our investment in Aduro and are classified as Level 1 in the fair value hierarchy, as quoted price in active markets is readily available. 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, 2015, 2014 and 2013. Adverse global economic conditions have had, and may continue to have, a negative impact on the market values of potential investments.

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

At December 31, 2015, we held cash, cash equivalents, short-term investments and investments in marketable equity securities of \$107.9 million. We do not believe our exposure to interest rate risk to be material given we held cash in interest-bearing accounts with financial institutions and the short-term nature of our investment portfolio consisted of highly liquid money market instruments and corporate debt and U.S. government agency securities with short-term maturities. The weighted average interest rates of our cash and cash equivalents at December 31, 2015 were 0.07%.

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 \$0.1 million, if we were able to draw down 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 Euro. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems. These inventory purchases and operating expenses are generally paid in Euro and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of non-operating income (expense), net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. An unfavorable 10% change

---

## **Table of Contents**

in foreign currency exchange rates for our cash, accounts receivable, accounts payable and accrued liabilities that are denominated in foreign currencies at December 31, 2015, would have negatively impacted our annual financial results by \$0.3 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.

### **Equity Market Risk**

Our investment in marketable equity securities consists of our investment in Aduro common stock. Aduro's common stock trades on the NASDAQ Global Select Market under the symbol ADRO. At December 31, 2015, the fair value of our investment in Aduro was \$11.2 million. This investment is subject to the underlying volatility of Aduro's common stock price and each \$1 change in the price per share of Aduro's common stock will change the fair value of our investment by \$0.4 million.

### **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***

We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2015.

#### ***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, and our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, that these controls and procedures were effective at the reasonable assurance level.

#### ***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) under the Securities Exchange Act, as amended. 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 in the United States of America.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial

---

**Table of Contents**

reporting as of December 31, 2015. Management based its assessment on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) in Internal Control Integrated Framework. Based on this evaluation, our management concluded that as of December 31, 2015, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their attestation report, which is included below.

***Remediation of Previously Reported Material Weaknesses***

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. In connection with our preparation of our financial statements for the year ended December 31, 2014, and our assessment of the effectiveness of our internal control over financial reporting, we determined that material weaknesses existed in our internal control over financial reporting at December 31, 2014 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 response to the material weaknesses described above, during the year ended December 31, 2015, we implemented the following changes to remediate those material weaknesses:

we modified and expanded our internal control over financial reporting to include a review of capitalization of inventory cost adjustments to ensure such adjustments are based on the most recent inventory purchasing activity, including the appropriate historical foreign exchange rates at the time inventory was purchased, and to ensure that product sold during any reporting period is recorded under appropriate first-in first-out historical foreign exchange rates;

we modified and expanded our internal control over financial reporting to ensure timely and accurate identification of accruals and adjustments to accruals based on information received during and after period-end; and

we enhanced our management review controls used to monitor payments made after period-end and to ensure such payments are recorded in the period to which they relate.

Based on the measures taken and implemented, management has tested the newly-implemented control activities and found them to be effective and has concluded that the material weaknesses described above had been remediated as of December 31, 2015.

***Changes in Internal Control over Financial Reporting***

Except as described above under Remediation of Previously Reported Material Weaknesses, there were no changes in our internal control over financial reporting which occurred during our fiscal quarter ended December 31, 2015, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Cerus Corporation

We have audited Cerus Corporation's internal control over financial reporting as of December 31, 2015, 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.

In our opinion, Cerus Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

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 December 31, 2015 and 2014, 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, 2015, of Cerus Corporation and our report dated March 9, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 9, 2016

**Item 9B. Other Information**

None.

**Table of Contents**

**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 2016 annual meeting of stockholders, or the Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

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

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

*Code of Ethics*

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

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

**Item 11. *Executive Compensation***

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

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

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

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

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

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

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

**Table of Contents****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.*

	<b>Page</b>
<u>Report of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</u>	83
<u>Consolidated Balance Sheets as of December 31, 2015 and 2014</u>	84
<u>Consolidated Statements of Operations for the three years ended December 31, 2015</u>	85
<u>Consolidated Statements of Comprehensive Loss for the three years ended December 31, 2015</u>	86
<u>Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2015</u>	87
<u>Consolidated Statements of Cash Flows for the three years ended December 31, 2015</u>	88
<u>Notes to Consolidated Financial Statements</u>	89

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

(b) *Exhibits.*

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1(22)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(22)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(22)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4(28)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(8)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(14)	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(15)	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).
	<b><i>Supply and/or Manufacturing Agreements</i></b>
10.1(7)	Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.
10.2(29)	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(23)	First Amendment to Supply and Manufacturing Agreement, dated November 28, 2012, by and between Cerus Corporation and Porex Corporation.





**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.5(30)	Amendment #2 to Supply and Manufacturing Agreement, dated December 23, 2014, by and between Cerus Corporation and Porex Corporation.
10.6#	Amended and Restated Manufacturing and Supply Agreement, dated October 19, 2015, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.7(10)	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.8(19)	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.9(24)	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
	<b><i>Loan and Security Agreements</i></b>
10.10(28)	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.
10.11	First Amendment to Loan and Security Agreement, dated January 30, 2015, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
10.12 (33)	Second Amendment to Loan and Security Agreement, dated September 29, 2015, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
	<b><i>Real Estate Lease Agreements</i></b>
10.13(4)	Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.
10.14(9)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.15(16)	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.
10.16(25)	Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
10.17(31)	Letter, dated March 13, 2015 to Cuff Property Management exercising option to extend the lease term under the Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
	<b><i>Employment Agreements or Offer Letters</i></b>
10.18(18)*	Employment Letter, by and between Cerus corporation and William M. Greenman, dated May 12, 2011.
10.19(23)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.20(25)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.21(17)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.22(14)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.23(26)*	Equity Change in Control Agreement with Caspar Hogeboom, dated March 7, 2014.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.24(23)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.25(25)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
10.26(33)*	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPath, dated May 12, 2015.
10.27*	Settlement Agreement, by and between Cerus Europe B.V. and Caspar Hogeboom, dated December 23, 2015.
10.28*	Consulting Agreement, by and between Cerus Corporation and Caspar Hogeboom, dated December 23, 2015
<b><i>Stock Plans and Related Forms</i></b>	
10.29(1)*	1996 Equity Incentive Plan.
10.30(1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.31(1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.32(32)*	Amended and Restated 1996 Employee Stock Purchase Plan, effective June 10, 2015.
10.33(2)*	1998 Non-Officer Stock Option Plan.
10.34(3)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.35(5)*	1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.
10.36(32)*	Amended and Restated 2008 Equity Incentive Plan, effective June 10, 2015.
10.37(20)*	Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.
10.38(20)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.
10.39(20)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
<b><i>Other Compensatory Plans or Agreements</i></b>	
10.40(23)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.41(11)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.42(13)*	Form of Severance Benefits Agreement.
10.43(26)*	Amended and Restated Non-Employee Director Compensation Policy.
10.44(31)*	2014 and 2015 Executive Officer Compensation Arrangements.
<b><i>Other Material Agreements</i></b>	
10.45(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.46(12)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.47(21)	Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.48(27)	Amendment No 1. to Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated March 21, 2014, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.49(16)	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).
10.50(16)	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).
10.51(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(34)	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.

**Table of Contents**

- (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 19, 2008.
- (9) 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.
- (10) 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.
- (11) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
- (12) 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.
- (13) 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.
- (14) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.
- (15) 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.
- (16) Incorporated by reference to the like-described exhibit to the Registrant s Annual Report on Form 10-K, for the year ended December 31, 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 March 8, 2010.
- (18) 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.
- (19) 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.
- (20) 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.
- (21) 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.
- (22) 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.
- (23) 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.
- (24) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended September 30, 2013.
- (25) 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.
- (26) 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.
- (27) 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.
- (28) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2014.
- (29) 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.
- (30) Incorporated by reference to the like-described exhibit to Registrant s Annual Report on Form 10-K, for the year ended December 31, 2014.
- (31) Incorporated by reference to the like-described exhibit to Registrant s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2015.
- (32) Incorporated by reference to the like-described exhibit to Registrant s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2015.
- (33) Incorporated by reference to the like-described exhibit to Registrant s Quarterly Report on Form 10-Q, for the quarter ended September 30, 2015.

**Table of Contents**

- (34) 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.

**Table of Contents**

**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, 2015, and 2014, 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, 2015. 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, 2015, and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, 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 9, 2016 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California

March 9, 2016

**Table of Contents****CERUS CORPORATION****CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

	December 31,	
	2015	2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 71,018	\$ 22,781
Short-term investments	25,698	28,513
Investment in marketable equity securities	11,163	
Accounts receivable	5,794	5,493
Inventories	10,812	14,956
Prepaid expenses	1,166	1,210
Other current assets	4,788	1,932
Total current assets	130,439	74,885
Non-current assets:		
Property and equipment, net	3,549	3,781
Goodwill	1,316	1,316
Intangible assets, net	940	1,142
Restricted cash	612	508
Other assets	2,614	144
Total assets	\$ 139,470	\$ 81,776
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,217	\$ 9,882
Accrued liabilities	9,853	8,444
Manufacturing and development obligations - current	3,282	
Debt - current	2,989	
Deferred revenue - current	554	376
Warrant liability		10,485
Total current liabilities	21,895	29,187
Non-current liabilities:		
Debt - non-current	16,883	9,872
Deferred income taxes	122	115
Manufacturing and development obligations - non-current	4,542	
Other non-current liabilities	1,263	1,081
Total liabilities	44,705	40,255
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, issuable in series; zero shares issued and outstanding at December 31, 2015 and 2014, respectively		
Common stock, \$0.001 par value; 225,000 shares authorized; 99,095 and 80,404 shares issued and outstanding at December 31, 2015 and 2014, respectively	99	80
Additional paid-in capital	685,189	583,416
Accumulated other comprehensive income (loss)	7,289	(31)

Edgar Filing: CERUS CORP - Form 10-K

Accumulated deficit	(597,812)	(541,944)
Total stockholders' equity	94,765	41,521
Total liabilities and stockholders' equity	\$ 139,470	\$ 81,776

See accompanying Notes to Consolidated Financial Statements.



**Table of Contents****CERUS CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share amounts)

	Year Ended December 31,		
	2015	2014	2013
Revenue	\$ 34,223	\$ 36,416	\$ 39,657
Cost of revenue	23,464	21,188	22,602
Gross profit	10,759	15,228	17,055
Operating expenses:			
Research and development	25,643	21,800	15,187
Selling, general and administrative	45,989	37,729	29,965
Amortization of intangible assets	202	202	202
Total operating expenses	71,834	59,731	45,354
Loss from operations	(61,075)	(44,503)	(28,299)
Non-operating income (expense), net:			
Gain (loss) from revaluation of warrant liability	3,566	7,708	(15,099)
Foreign exchange (loss) gain	(396)	(1,296)	533
Interest expense	(1,705)	(599)	(332)
Other income, net	71	130	78
Total non-operating income (expense), net	1,536	5,943	(14,820)
Loss before income taxes	(59,539)	(38,560)	(43,119)
(Benefit) provision for income taxes	(3,671)	195	218
Net loss	\$ (55,868)	\$ (38,755)	\$ (43,337)
Net loss per share:			
Basic	\$ (0.58)	\$ (0.52)	\$ (0.64)
Diluted	\$ (0.61)	\$ (0.61)	\$ (0.64)
Weighted average shares outstanding used for calculating net loss per share:			
Basic	96,068	74,767	67,569
Diluted	96,905	76,534	67,569

See accompanying Notes to Consolidated Financial Statements.

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

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (55,868)	\$ (38,755)	\$ (43,337)
Other comprehensive income (loss):			
Unrealized gains (losses) on available-for-sale investments, net of tax effect of \$3,825, zero and zero for 2015, 2014, and 2013, respectively	7,320	(38)	7
Comprehensive loss	\$ (48,548)	\$ (38,793)	\$ (43,330)

See accompanying Notes to Consolidated Financial Statements.

**Table of Contents****CERUS CORPORATION****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
Balance at December 31, 2012	56,252	\$ 56	\$ 478,903	\$	\$ (459,852)	\$ 19,107
Net loss					(43,337)	(43,337)
Other comprehensive income				7		7
Issuance of common stock from public offering, net of offering costs	15,019	15	61,439			61,454
Issuance of common stock from exercise of stock options and warrants, and purchases from ESPP	588	1	2,295			2,296
Stock-based compensation			3,268			3,268
Balance at December 31, 2013	71,859	72	545,905	7	(503,189)	42,795
Net loss					(38,755)	(38,755)
Other comprehensive income				(38)		(38)
Issuance of common stock from public offering, net of offering costs	4,341	4	18,517			18,521
Issuance of common stock from exercise of stock options and warrants, and purchases from ESPP	4,204	4	13,841			13,845
Stock-based compensation			5,153			5,153
Balance at December 31, 2014	80,404	80	583,416	(31)	(541,944)	41,521
Net loss					(55,868)	(55,868)
Other comprehensive income				7,320		7,320
Issuance of common stock from public offering, net of offering costs	14,636	15	75,361			75,376
Issuance of common stock from exercise of stock options and warrants, and purchases from ESPP	4,055	4	19,682			19,686
Stock-based compensation			6,730			6,730
Balance at December 31, 2015	99,095	\$ 99	\$ 685,189	\$ 7,289	\$ (597,812)	\$ 94,765

See accompanying Notes to Consolidated Financial Statements.

**Table of Contents****CERUS CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Year Ended December 31,		
	2015	2014	2013
<b>Operating activities</b>			
Net loss	\$ (55,868)	\$ (38,755)	\$ (43,337)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,699	1,415	745
Stock-based compensation	6,730	5,153	3,268
Changes in valuation of warrant liability	(3,566)	(7,708)	15,099
Non-cash interest expense (income)	508	131	(25)
Non-cash deferred manufacturing and development expense	434		
Deferred income taxes	7	26	27
Loss on disposal of fixed assets		3	56
Tax benefit from other unrealized gain on available-for-sale securities	(3,825)		
Changes in operating assets and liabilities:			
Accounts receivable	(301)	632	(1,681)
Inventories	3,991	3,033	(1,813)
Other assets	1,379	(1,655)	286
Accounts payable	(3,866)	(973)	(1,512)
Accrued liabilities	1,359	(1,382)	2,121
Deferred revenue	190	269	104
<b>Net cash used in operating activities</b>	<b>(51,129)</b>	<b>(39,811)</b>	<b>(26,662)</b>
<b>Investing activities</b>			
Capital expenditures	(722)	(2,106)	(663)
Purchases of investments	(90,407)	(25,981)	(30,146)
Proceeds from maturities of investments	92,645	24,915	1,631
Restricted cash	(104)	(175)	(14)
<b>Net cash provided by (used in) investing activities</b>	<b>1,412</b>	<b>(3,347)</b>	<b>(29,192)</b>
<b>Financing activities</b>			
Net proceeds from exercise/purchase of equity incentives and warrants	12,767	11,592	1,684
Net proceeds from public offering	75,300	18,488	61,425
Proceeds from debt, net of discount	10,000	9,848	3,102
Repayment of debt	(113)	(3,474)	(7,568)
<b>Net cash provided by financing activities</b>	<b>97,954</b>	<b>36,454</b>	<b>58,643</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>48,237</b>	<b>(6,704)</b>	<b>2,789</b>
Cash and cash equivalents, beginning of year	22,781	29,485	26,696
<b>Cash and cash equivalents, end of year</b>	<b>\$ 71,018</b>	<b>\$ 22,781</b>	<b>\$ 29,485</b>
<b>Supplemental disclosures:</b>			
Cash paid for interest	\$ 1,087	\$ 563	\$ 294
Cash paid for income taxes	\$ 153	\$ 177	\$ 146
Non-cash settlement of warranty claim	\$	\$	\$ 1,272

Edgar Filing: CERUS CORP - Form 10-K

Unpaid manufacturing and development obligation	\$ 7,051	\$	\$
---	----------	----	----

See accompanying Notes to Consolidated Financial Statements.

---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2015**

**Note 1. Nature of Operations and Basis of Presentation**

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

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

**Note 2. Summary of Significant Accounting Policies**

**Principles of Consolidation**

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

**Use of Estimates**

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

**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) collectability is reasonably assured. The Company's main sources of revenues for the years ended December 31, 2015, 2014 and 2013, 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 or 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

---

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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. The Company regularly reviews best estimated selling price. At December 31, 2015 and 2014, the Company had \$0.6 million and \$0.4 million, respectively, of short-term deferred revenue on its consolidated balance sheets related to future performance obligations. At each of December 31, 2015 and 2014, the Company had \$0.1 million of long-term deferred revenue included in Other non-current liabilities on its consolidated balance sheets related to future performance obligations. Freight costs charged to customers are recorded as a component of revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

**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 U.S. government or development contracts. Research and development expenses include salaries and related expenses for scientific and regulatory personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of 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. 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, U.S. government agency securities and marketable equity securities of Aduro Biotech, Inc. (Aduro), are designated

---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**December 31, 2015**

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 Other assets 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. At December 31, 2015, the fair value of the Company's marketable equity securities of Aduro is subject to the underlying volatility of Aduro's stock price. At December 31, 2015, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents.

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

The Company had three customers and one customer that accounted for more than 10% of the Company's outstanding trade receivables at December 31, 2015 and 2014, respectively. These customers cumulatively represented approximately 49% and 36% of the Company's outstanding trade receivables at December 31, 2015 and 2014, respectively. To date, the Company has not experienced collection difficulties from these customers.



---

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015****Inventories**

At December 31, 2015 and 2014, 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 their affiliates, Fresenius ) into the finished INTERCEPT disposable kits. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production 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, 2015 and 2014, 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 net realizable value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of revenue on the Company's consolidated statements of operations. At December 31, 2015, and 2014, the Company had \$1.8 million and \$0.1 million, respectively, recorded for potential obsolete, expiring or unsalable product.

**Property and Equipment, net**

Property and equipment is comprised of furniture, equipment, 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. During the years ended December 31, 2015, and 2014, the Company capitalized costs related to its enterprise resource planning software system of zero and

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

\$1.8 million, respectively. At December 31, 2015 and 2014, the Company had \$1.3 million and \$1.6 million of capitalized cost related to its enterprise resource planning system, respectively. The capitalized costs associated with the enterprise resource planning system are being amortized over the estimated useful life of five years.

**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 original 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

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**December 31, 2015**

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, 2015, 2014 or 2013.

**Foreign Currency Remeasurement**

The functional currency of the Company's foreign subsidiary is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using historical exchange rates. 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 its 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. In November 2015, all of the outstanding November 2010 warrants were exercised in full. The Company classified warrants outstanding on the reporting date as a liability on its consolidated balance sheets as the warrants contained certain material terms which required 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.

The fair value of outstanding warrants was calculated using the Black-Scholes model and was adjusted accordingly at reporting dates since 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.

---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**December 31, 2015**

Changes resulting from the revaluation of warrants to fair value were recorded in Gain (loss) from revaluation of warrant liability on the consolidated statements of operations. Upon the exercise of the warrants, the fair value of the warrants was reclassified from a liability to stockholders' equity on the Company's consolidated balance sheets.

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

**Income Taxes**

The Company accounts for income taxes using an 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 derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's U.S. federal and California tax years through 2015 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a full valuation allowance on all of its net deferred tax assets, except for its indefinite lived intangibles.

**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.

Certain potential dilutive securities were excluded from the dilution calculation for the years ended December 31, 2015 and 2014, as their inclusion would have been anti-dilutive. 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.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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, 2015, 2014 and 2013 (in thousands, except per share amounts):

	Year Ended December 31,		
	2015	2014	2013
<b>Numerator for Basic and Diluted:</b>			
Net loss used for basic calculation	\$ (55,868)	\$ (38,755)	\$ (43,337)
Effect of revaluation of warrant liability	(3,566)	(7,708)	
Adjusted net loss used for dilution calculation	\$ (59,434)	\$ (46,463)	\$ (43,337)
<b>Denominator:</b>			
Basic weighted average number of shares outstanding	96,068	74,767	67,569
Effect of dilutive potential shares	837	1,767	
Diluted weighted average number of shares outstanding	96,905	76,534	67,569
<b>Net loss per share:</b>			
Basic	\$ (0.58)	\$ (0.52)	\$ (0.64)
Diluted	\$ (0.61)	\$ (0.61)	\$ (0.64)

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, 2015, 2014 and 2013 (shares in thousands):

	Year Ended December 31,		
	2015	2014	2013
<b>Weighted average number of anti-dilutive potential shares</b>			
Outstanding options	13,681	11,722	10,296
Warrants			6,074
Total	13,681	11,722	16,370

**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.

## Edgar Filing: CERUS CORP - Form 10-K

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

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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, 2015 or 2014.

**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 U.S. 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. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606), Deferral of the Effective Date*, which defers by one year the effective date of ASU No. 2014-09 to annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). The ASU's effective date for the Company will be the first quarter of fiscal year 2018, using one of two retrospective application methods. 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

---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**December 31, 2015**

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 adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30), Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330), Simplifying the Measurement of Inventory*, which simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value. Net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This ASU will be effective for the Company in fiscal year 2017. Early adoption is permitted. The Company has early adopted this ASU in 2015 prospectively and it did not have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*, which requires all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. This ASU may be adopted either prospectively or retrospectively. This ASU will be effective for the Company in fiscal year 2017. Early adoption is permitted. The Company has early adopted this ASU in 2015 prospectively and it did not have a material impact on the Company's consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments-Overall (Subtopic 825-10)*, which requires all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee). The amendments also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, this ASU eliminates the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities and the requirement for to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public business entities. This ASU will be effective for the Company in fiscal year 2018. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which, for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. This ASU will be effective for the Company in fiscal year 2019. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its consolidated financial statements and anticipates the new guidance will significantly impact its consolidated financial statements.



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015****Note 3. Fair Value on Financial Instruments**

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

Level 1: Quoted prices in active markets for identical instruments

Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)

Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

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

To estimate the fair value of Level 2 debt securities as of December 31, 2015, the Company's primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2015 (in thousands):

			<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
	<b>Balance sheet classification</b>	<b>Total</b>			
Money market funds	Cash and cash equivalents	\$ 59,302	\$ 59,302	\$	\$
Corporate debt securities	Short-term investments	25,698		25,698	
Marketable equity securities	Marketable equity securities	11,163	11,163		
Total financial assets		\$ 96,163	\$ 70,465	\$ 25,698	\$

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2014 (in thousands):

	<b>Balance sheet classification</b>	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Money market funds	Cash and cash equivalents	\$ 3,912	\$ 3,912	\$	\$
Corporate debt securities	Short-term investments	26,088		26,088	
United States government agency securities	Short-term investments	3,426		3,426	
Total financial assets		\$ 33,426	\$ 3,912	\$ 29,514	\$
Warrant liability	Warrant liability	\$ 10,485	\$	\$	\$ 10,485
Total financial liabilities		\$ 10,485	\$	\$	\$ 10,485

A reconciliation of the beginning and ending balances for the warrant liability using significant unobservable inputs (Level 3) from December 31, 2013 to December 31, 2015, was as follows (in thousands):

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
Decrease in fair value of warrants	(3,566)
Settlement of warrants exercised	(6,919)
Balance at December 31, 2015	\$

See Notes 2 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, 2015 and 2014.

**Note 4. Available-for-sale Securities**

The following is a summary of available-for-sale securities at December 31, 2015 (in thousands):

Edgar Filing: CERUS CORP - Form 10-K

		December 31, 2015	
	Amortized Cost	Gross Unrealized Gain (Loss)	Fair Value
Money market funds	\$ 59,302	\$	\$ 59,302
Corporate debt securities	25,747	(49)	25,698
Marketable equity securities		11,163	11,163
Total available-for-sale securities	\$ 85,049	\$ 11,114	\$ 96,163

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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	\$	\$ 3,912
United States government agency securities	3,427	(1)	3,426
Corporate debt securities	26,118	(30)	26,088
Total available-for-sale securities	\$ 33,457	\$ (31)	\$ 33,426

Available-for-sale securities at December 31, 2015 and 2014, consisted of the following by contractual maturity (in thousands):

	December 31, 2015		December 31, 2014	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	\$ 85,049	\$ 85,000	\$ 27,752	\$ 27,727
Marketable equity securities		11,163		
Greater than one year and less than five years			5,705	5,699
Total available-for-sale securities	\$ 85,049	\$ 96,163	\$ 33,457	\$ 33,426

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

	Less than 12 Months		December 31, 2015 12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Money market funds	\$	\$	\$	\$	\$	\$
Corporate debt securities	20,170	(46)	5,528	(3)	25,698	(49)
Marketable equity securities						
Total available-for-sale securities	\$ 20,170	\$ (46)	\$ 5,528	\$ (3)	\$ 25,698	\$ (49)

	Less than 12 Months		December 31, 2014 12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss

Edgar Filing: CERUS CORP - Form 10-K

Money market funds	\$	\$	\$	\$	\$	\$
United States government agency securities	3,426	(1)			3,426	(1)
Corporate debt securities	22,169	(30)			22,169	(30)
Total available-for-sale securities	\$ 25,595	\$ (31)	\$	\$	\$ 25,595	\$ (31)

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

As of December 31, 2015, 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, 2015, 2014, and 2013, the Company did not recognize any other-than-temporary impairment loss. The Company has no current requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held.

The Company recorded minimal gross realized gains from the sale or maturity of available-for-sale investments during the years ended December 31, 2015 and 2014, and did not record any gross realized gains from the sale or maturity of available-for-sale investments during the year ended December 31, 2013. 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, 2015 and 2014. The Company did not record losses on investments experiencing an other-than-temporary decline in fair value during the years ended December 31, 2015, 2014, and 2013.

**Note 5. Inventories**

Inventories at December 31, 2015 and 2014, consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
Work-in-process	\$ 3,187	\$ 2,222
Finished goods	7,625	12,734
<b>Total inventories</b>	<b>\$ 10,812</b>	<b>\$ 14,956</b>

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015****Note 6. Property and Equipment, net**

Property and equipment, net at December 31, 2015 and 2014, consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
Leasehold improvements	\$ 5,678	\$ 5,638
Machinery and equipment	1,603	1,351
Demonstration equipment	145	123
Furniture and fixtures	794	783
Computer equipment	591	663
Computer software	2,935	2,913
Consigned equipment	1,010	980
Construction-in-progress	219	150
<b>Total property and equipment, gross</b>	<b>12,975</b>	<b>12,601</b>
Accumulated depreciation and amortization	(9,426)	(8,820)
<b>Total property and equipment, net</b>	<b>\$ 3,549</b>	<b>\$ 3,781</b>

Depreciation and amortization expense related to property and equipment, net was \$1.1 million, \$0.7 million and \$0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

**Note 7. Goodwill and Intangible Assets, net***Goodwill*

During the year ended December 31, 2015, the Company did not dispose of or recognize additional goodwill. On August 31, 2015, 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, 2015 (in thousands):

	<b>Gross Carrying Amount</b>	<b>December 31, 2015 Accumulated Amortization</b>	<b>Net Carrying Amount</b>
<b>Acquisition-related intangible assets:</b>			
Reacquired license INTERCEPT Asia	\$ 2,017	\$ (1,077)	\$ 940

Edgar Filing: CERUS CORP - Form 10-K

Total intangible assets	\$ 2,017	\$ (1,077)	\$ 940
-------------------------	----------	------------	--------



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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

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

During the years ended December 31, 2015, 2014 and 2013, there were no impairment charges recognized related to the Company's intangible assets.

At December 31, 2015, the expected annual amortization expense of the intangible assets, net is \$0.2 million beginning with the year ending December 31, 2016, 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. Marketable Equity Investments**

In connection with the agreements to license the immunotherapy technologies to Aduro in 2009, the Company received preferred shares of Aduro, a privately held company at the time the Company received such shares. Pursuant to these license agreements, the Company was eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. For the years ended December 31, 2015, 2014 and 2013, the Company has not received any royalty payments from Aduro pursuant to this agreement. The Company historically accounted for the investment under the cost method of accounting with a net carrying value of zero. In April 2015, Aduro's common stock began trading on the NASDAQ Global Select Market, under the symbol ADRO. At the time of Aduro's initial public offering (IPO), the Company's preferred shares in Aduro converted to 396,700 shares of common stock, and the fair value of the Company's investment became readily determinable and, as a result became a marketable equity security. Therefore, the Company no longer accounts for the investment in Aduro under the cost basis of accounting. The Company now reflects the investment in Aduro as an available-for-sale security included in investment in marketable equity securities on the Company's consolidated balance sheet (Note 4) and will adjust the carrying value of this investment to fair value each quarterly reporting period, with changes in fair value recorded within other comprehensive income (loss), net of tax.

**Note 9. Accrued Liabilities**

Accrued liabilities at December 31, 2015 and 2014, consisted of the following (in thousands):

	December 31,	
	2015	2014
Accrued compensation and related costs	\$ 5,198	\$ 3,951
Accrued professional services	2,337	2,123
Accrued inventory costs	73	870
Accrued customer costs	987	385
Accrued insurance premiums	438	264
Other accrued expenses	820	851

Total accrued liabilities	\$ 9,853	\$ 8,444
---------------------------	----------	----------

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015****Note 10. Debt**

Debt at December 31, 2015, consisted of the following (in thousands):

	Principal	December 31, 2015 Unamortized Discount	Net Carrying Value
Loan and Security Agreement	\$ 20,000	\$ (128)	\$ 19,872
Less: debt current	(3,050)	61	(2,989)
<b>Debt non-current</b>	<b>\$ 16,950</b>	<b>\$ (67)</b>	<b>\$ 16,883</b>

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

	Principal	December 31, 2014 Unamortized Discount	Total
Loan and Security Agreement	\$ 10,000	\$ (128)	\$ 9,872
Less: debt current			
<b>Debt non-current</b>	<b>\$ 10,000</b>	<b>\$ (128)</b>	<b>\$ 9,872</b>

Principal and interest payments on debt at December 31, 2015, are expected to be as follows\*:

Year ended December 31,	Principal	Interest	Total
2016	3,050	1,352	4,402
2017	6,428	980	7,408
2018	6,892	517	7,409
2019	3,630	1,474	5,104
<b>Total</b>	<b>\$ 20,000</b>	<b>\$ 4,323</b>	<b>\$ 24,323</b>

\* 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 drawn on June 15, 2015. On September 29, 2015, the

## Edgar Filing: CERUS CORP - Form 10-K

Term Loan Agreement was amended to extend (i) the period in which the third tranche of \$10.0 million ( Term Loan C ) can be drawn and (ii) the interest-only period for all advances under the Term Loan Agreement. The Company determined that the Term Loan Agreement Amendment resulted in a modification. As a result, the Term Loan will continue to be accounted for by using the effective interest method, with a new effective interest rate based on revised cash flows calculated on a prospective basis upon the execution of the amendment to the Term Loan Agreement. As amended, Term Loan C will be available, subject to the Company achieving consolidated trailing six months revenue at a specified threshold (the Revenue Event ), from the date of the achievement of the Revenue Event, to the earlier of (i) June 30, 2016, and (ii) 60 days after the Revenue Event is achieved. Term Loan A bears an interest rate of 6.95%. Term Loan B bears an interest rate of 7.01%. Term Loan

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

C would 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 Term Loan C funding date. All of the Term Loans mature on June 1, 2019. The Company is required to make interest only payments through June 2016, followed by thirty-six months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than May 31, 2016, 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. At December 31, 2015 and 2014, the Company accrued approximately \$0.5 million and \$0.1 million interest expense associated with the final payment in Other non-current liabilities on the Company's Consolidated Balance Sheets. 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, and \$0.1 million of the lender legal fees 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. 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, 2015.

**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 2020, with certain of the leases providing for renewal options, provisions for adjusting future lease payments based on the consumer price index, and the right to terminate the lease early. The Company'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, 2015, are as follows (in thousands):

<b>Year ended December 31,</b>	
2016	\$ 1,111
2017	1,016
2018	729
2019	620
2020	14
Total minimum non-cancellable lease payments	\$ 3,490

Rent expense for office facilities was \$0.8 million, \$0.8 million and \$0.7 million for the years ended December 31, 2015, 2014 and 2013, respectively.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015***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. At December 31, 2015, the Company had an outstanding liability of \$0.5 million related to these leasehold improvements, of which \$0.1 million was reflected in *Accrued liabilities* and \$0.4 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 \$7.7 million, \$6.8 million and \$6.5 million for goods under agreements which are subject to minimum purchase commitments during the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, the Company has future minimum purchase commitments under these agreements of \$8.4 million for the year ending December 31, 2016, and approximately \$0.7 million for the year ending December 31, 2017.

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, 2015, the Company paid approximately \$0.5 million (\$0.4 million) associated with this fee. As of December 31, 2015, the Company had accrued \$0.1 million (\$0.1 million) associated with this fee. As this former distributor remains 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 are offset against the revenue associated with the sale of INTERCEPT disposable kits in those territories.

**Note 12. Stockholders' Equity***Public Offering of Common Stock*

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 \$75.3 million, net of the underwriting discount and other issuance costs.

*Common Stock and Associated Warrant Liability*

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 were exercisable for a period of five years from the issue date. In 2015, all outstanding 2010 Warrants were exercised in full.

The fair value of the 2010 Warrants was recorded on the consolidated balance sheets as a liability pursuant to ASC Topic 480-10 *Distinguishing Liabilities from Equity* and were adjusted to fair value at each financial reporting date thereafter until exercise, at which time, these warrants were reclassified into stockholders' equity.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

The Company classified the 2010 Warrants as a liability as these warrants contained certain provisions that, under certain circumstances, could have been out of the Company's control and could have required the Company to pay cash to settle the exercise of the 2010 Warrants or required the Company to redeem the 2010 Warrants.

The fair value of the 2010 Warrants was based on option valuation model and using the following assumptions at December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
<b>2010 Warrants:</b>		
Expected term (in years)		0.86
Estimated volatility		55%
Risk-free interest rate		0.25%
Expected dividend yield		

The Company recorded non-cash gains or losses in Gain (loss) from revaluation of warrant liability on the consolidated statements of operations due to the changes in fair value of the 2010 Warrants. During the years ended December 31, 2015, 2014 and 2013, the 2010 Warrants to purchase 3.3 million, 2.6 million and 0.2 million shares of common stock, respectively, were exercised. At December 31, 2015, the Company had no outstanding warrants remaining.

*Sales Agreement*

On March 21, 2014, the Company entered into Amendment No. 1 to the Controlled Equity Offering<sup>SM</sup> 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 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, 2015 and 2014, zero and approximately 4.3 million shares, respectively, of the Company's common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of zero and \$18.6 million, respectively. At December 31, 2015, the Company had approximately \$22.5 million of common stock registered 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. As of December 31, 2015, no Series C Junior Participating preferred stock has been issued.

---

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015****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 shares of common stock of the Company at a purchase price equal to 85% of the lower of the fair market value per share on the start date of the offering period or the fair market value per share on the purchase date. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. The Purchase Plan was authorized to issue an aggregate of 1,320,500 shares. On June 10, 2015, the Company's stockholders approved an amendment and restatement of the Purchase Plan that increased the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 1,500,000 shares. At December 31, 2015, the Company had 1,652,972 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. On June 10, 2015, the Company's stockholders approved an amendment and restatement of the 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 5,000,000 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, 2015, no performance-based stock options were outstanding.

At December 31, 2015, the Company had an aggregate of approximately 21.5 million shares of its common stock subject to outstanding options or remaining available for future issuance under the Amended 2008 Plan, of which approximately 14.1 million shares were subject to outstanding options, and approximately 7.4 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options.



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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, 2014	11,323	\$ 4.13
Granted	3,730	4.58
Forfeited	(225)	5.12
Expired	(223)	8.55
Exercised	(486)	2.74
Balances at December 31, 2015	14,119	4.21

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2015, 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, 2015				
Stock options outstanding	14,119	\$ 4.21	6.9	\$ 30,746
Stock options vested and expected to vest	13,606	4.19	6.8	29,973
Stock options exercisable	8,693	3.81	5.7	22,754

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, 2015, 2014 and 2013, was \$1.2 million, \$3.8 million and \$0.6 million, respectively.

**Stock-based Compensation Expense**

Stock-based compensation expense recognized on the Company's consolidated statements of operations for the years ended December 31, 2015, 2014 and 2013, was as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Stock-based compensation expense by caption:			

## Edgar Filing: CERUS CORP - Form 10-K

Research and development	\$ 1,260	\$ 998	\$ 482
Selling, general and administrative	5,470	4,155	2,786
Total stock-based compensation expense	\$ 6,730	\$ 5,153	\$ 3,268

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

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

stock-based compensation costs capitalized as part of an asset during the years ended December 31, 2015, 2014 and 2013. The Company has also not recorded any stock-based compensation associated with performance-based stock options during the years ended December 31, 2015, 2014 and 2013.

As of December 31, 2015, the Company expects to recognize the remaining unamortized stock-based compensation expense of \$11.0 million related to non-vested stock options, net of estimated forfeitures, over an estimated remaining weighted average period of 2.6 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, 2015, 2014 and 2013, was as follows:

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
<b>Stock Options:</b>			
Expected term (in years)	5.66	5.71	5.59
Estimated volatility	56%	61%	60%
Risk-free interest rate	1.55%	1.73%	0.87%
Expected dividend yield	0%	0%	0%
<b>Employee Stock Purchase Plan Rights:</b>			
Expected term (in years)	0.75	0.76	0.50
Estimated volatility	53%	52%	39%
Risk-free interest rate	0.28%	0.10%	0.10%
Expected dividend yield	0%	0%	0%

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2015, 2014 and 2013, was \$2.35 per share, \$3.28 per share and \$2.03 per share, respectively. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2015, 2014 and 2013, was \$1.54 per share, \$1.42 per share and \$1.18 per share, respectively.



---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**December 31, 2015**

**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, 2015, 2014 and 2013.

**Note 15. Development and License Agreements**

**Agreements with Fresenius**

The Company had certain agreements with Fresenius which required the Company to pay royalties through June 30, 2015, on INTERCEPT Blood System product sales at royalty rates that varied 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, 2015, 2014 and 2013, the Company made royalty payments to Fresenius of \$1.9 million, \$2.5 million and \$3.0 million, respectively. At December 31, 2015 and December 31, 2014, the Company owed Fresenius zero and \$0.7 million, respectively, for royalties.

Through December 31, 2013, 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 was obligated to sell, and the Company was 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. The 2013 Amendment also provided for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. Fresenius was 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.

In October 2015, the Company entered into an Amended and Restated Manufacturing and Supply Agreement (the 2015 Agreement ) with Fresenius, which amended and restated the 2013 Amendment and Original Supply Agreement. Under the 2015 Agreement, Fresenius continues to be obligated to sell and the Company is obligated to purchase finished disposable kits for the Company s platelet and plasma systems and the Company s INTERCEPT Blood System for Red Blood Cells (the RBC Sets ) product candidate. The 2015 Agreement permits the Company to purchase platelet and plasma systems and RBC Sets from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are initially fixed and decline at specified annual production levels, and are subject to certain adjustments after the initial pricing term. Under the 2015 Agreement, the Company is no longer required to make royalty payments to Fresenius for the sale of products after June 30, 2015. Under the 2013 Agreement and 2015 Agreement, the Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying consolidated balance sheets until such time as the Company purchases finished disposable kits using those components.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

The 2015 Agreement also requires the Company to make certain payments totaling 8.6 million ( Manufacturing and Development Payments ) to Fresenius in 2016 and on December 31st of the earlier of (a) the year of achievement of certain production volumes or (b) 2022. Because these payments represent unconditional payment obligations, the Company recognized its liability for these payments at their net present value at discount rate of 9.72% based on the Company's effective borrowing rate. The Manufacturing and Development Payments liability is accreted through interest expense based on the estimated timing of its ultimate settlement. As of December 31, 2015, the Company had accrued \$7.8 million ( 7.2 million) related to the Manufacturing and Development Payments, of which \$3.3 million ( 3.0 million) was included in Manufacturing and development obligations current, and \$4.5 million ( 4.2 million) was included in Manufacturing and development obligations non-current on the Company's Consolidated Balance Sheets.

The Manufacturing and Development Payments will be made to support certain projects Fresenius will perform on behalf of the Company related to research and development activities and manufacturing efficiency activities. The Company allocated \$4.8 million to research and development activities and \$2.4 million to manufacturing efficiency activities based on their market value. The prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company is expensed over the period which such activities occur. The manufacturing efficiency asset is expensed on a straight-line basis over the life of the 2015 Agreement. As of December 31, 2015, the prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company was included in Other current assets on the Company's Consolidated Balance Sheets at \$4.1 million. As of December 31, 2015, the manufacturing efficiency asset was included in Other assets on the Company's Consolidated Balance Sheets at \$2.4 million.

The initial term of the 2015 Agreement extends through July 1, 2025 (the Initial Term) and is automatically renewed thereafter for additional two year terms (each, a Renewal Term), subject to termination by either party upon (i) two years written notice prior to the expiration of the Initial Term or (ii) one year written notice prior to the expiration of any Renewal Term. Under 2015 Agreement the Company shall have the right, but not the obligation, to purchase certain assets and assume certain liabilities from Fresenius.

The Company made payments to Fresenius of \$14.9 million, \$19.1 million and \$15.0 million relating to the manufacturing of the Company products during the years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015 and December 31, 2014, the Company owed Fresenius \$2.5 million and \$5.1 million, respectively, for INTERCEPT disposable kits manufactured. At December 31, 2015 and 2014, amounts due from Fresenius were \$0.2 million and \$1.3 million respectively.

**Note 16. Income Taxes**

U.S and foreign components of consolidated loss before income taxes for the years ended December 2015, 2014 and 2013, was as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Loss before income taxes:			
U.S.	\$ (59,897)	\$ (38,928)	\$ (44,035)
Foreign	358	368	916
Loss before income taxes	\$ (59,539)	\$ (38,560)	\$ (43,119)

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

The provision for income taxes for the years ended December 2015, 2014 and 2013, was as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Provision for income taxes:			
Current:			
Foreign	\$ 147	\$ 168	\$ 191
Federal			
State		1	
Total Current	147	169	191
Deferred:			
Foreign			
Federal	(3,750)	22	21
State	(68)	4	6
Total Deferred	(3,818)	26	27
(Benefit) provision for income taxes	\$ (3,671)	\$ 195	\$ 218

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, 2015, 2014 and 2013, was as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Federal statutory tax	\$ (20,243)	\$ (13,110)	\$ (14,661)
Warrants	(3,565)	(3,367)	4,926
Expiration of federal loss carryovers	3,337		
Change in valuation allowance	11,754	16,576	9,955
Change in state apportionment	4,085		
Other	961	96	(2)
(Benefit) provision for income taxes	\$ (3,671)	\$ 195	\$ 218

On December 31, 2015, the California Supreme Court issued a decision disallowing the use of an income apportionment method pursuant to the Multistate Tax Compact. Previously the Company had relied on lower court decisions allowing the use of this apportionment method to file its 2013 and 2014 tax returns and to determine its deferred tax balances. As the California Supreme Court decision serves as the current law as of December 31, 2015, this change has been reflected in the determination of deferred tax balances and the respective valuation allowance.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. The significant components of the Company's deferred tax assets and liabilities at December 31, 2015 and 2014, were as follows (in thousands):

	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 165,813	\$ 151,100
Research and development credit carryforwards	35,131	33,800
Capitalized research and development	17,916	15,500
Deferred compensation	5,908	5,800
Capital loss carryforwards		3,700
Other	3,911	3,200
<b>Total deferred tax assets</b>	<b>228,679</b>	<b>213,100</b>
Valuation allowance	(224,854)	(213,100)
<b>Net deferred tax assets</b>	<b>3,825</b>	
<b>Deferred tax liabilities:</b>		
Unrealized gain on investments	3,825	
Amortization of goodwill	122	115
<b>Total deferred tax liabilities</b>	<b>\$ 3,947</b>	<b>\$ 115</b>

The valuation allowance increased by \$11.8 million for the year ended December 31, 2015, compared to the increase of \$14.1 million and \$8.5 million for the years ended December 31, 2014 and 2013, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization, expected near-term future losses and the absence of taxable income in prior carryback years. The Company expects to maintain a valuation allowance until circumstances change.

Undistributed earnings of the Company's foreign subsidiary, Cerus Europe B.V., amounted to approximately \$4.8 million at December 31, 2015. 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, 2015, was approximately \$1.6 million. In the event all foreign undistributed earnings were remitted to the U.S., the Company believes any incremental tax liability would be offset by the Company's domestic net operating losses and credits.

For the year ended December 31, 2015, the Company reported pretax net losses of \$59.5 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 differences between book accounting and the respective tax laws.

At December 31, 2015, the Company had federal and state net operating loss carryforwards of approximately \$466 million and \$114 million, respectively. The net operating loss carryforwards for federal and state expire at various dates beginning in 2016 through 2035. The Company's



net operating losses do not include \$2.3 million

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

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 with a corresponding credit to additional paid in capital.

At December 31, 2015, the Company had federal research and development credit carryforwards of approximately \$23.3 million that expire in various years between 2018 and 2035. The state research and development credits are approximately \$18.0 million as of December 31, 2015, and 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, 2015 and 2014. The Company's tax years through 2015 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. There was no income tax audit activity in 2015 nor has the Company been notified by any tax agency of any planned audits.

**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 U.S. 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.

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 U.S., during the years ended December 31, 2015, 2014 and 2013 (in percentages):

	Year Ended December 31,		
	2015	2014	2013
Etablissement Francais du Sang	23%	25%	17%
Grifols	*	*	18%

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

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2015**

Revenues by geographical location was based on the location of the customer during the years ended December 31, 2015, 2014 and 2013, and was as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Revenue:			
France	\$ 7,732	\$ 9,184	\$ 7,030
Spain and Portugal	4,070	2,776	7,033
CIS	3,361	6,636	8,220
Belgium	5,728	4,456	3,971
Switzerland	2,938	3,784	4,078
Other countries	10,394	9,580	9,325
Total revenue	\$ 34,223	\$ 36,416	\$ 39,657

Long-lived assets by geographical location, which consist of property and equipment, net and intangible assets, net, at December 31, 2015 and 2014, were as follows (in thousands):

	December 31,	
	2015	2014
U.S.	\$ 4,260	\$ 4,624
Europe & other	229	299
Total long-lived assets	\$ 4,489	\$ 4,923

**Note 18. Quarterly Financial Information (Unaudited)**

The following tables summarize the Company's quarterly financial information for the years ended December 31, 2015 and 2014 (in thousands except per share amounts):

	Three Months Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenue	\$ 7,692	\$ 8,830	\$ 8,045	\$ 9,656
Gross profit	2,978	1,802	2,485	3,494
Net loss	\$ (9,460)	\$ (15,972)	\$ (15,680)	\$ (14,756)
Net loss per share:				
Basic	\$ (0.10)	\$ (0.17)	\$ (0.16)	\$ (0.15)
Diluted	\$ (0.17)	\$ (0.17)	\$ (0.17)	\$ (0.15)

Edgar Filing: CERUS CORP - Form 10-K

	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	3,709	3,849	4,673	2,997
Net loss	\$ (225)	\$ (7,589)	\$ (10,759)	\$ (20,182)
Net loss per share:				
Basic	\$ (0.00)	\$ (0.10)	\$ (0.14)	\$ (0.26)
Diluted	\$ (0.12)	\$ (0.16)	\$ (0.16)	\$ (0.26)

**Table of Contents****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 9th day of March, 2016.

**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
<i>/s/</i> WILLIAM M. GREENMAN	President, Chief Executive	March 9, 2016
<b>William M. Greenman</b>	Officer and Director <i>(Principal Executive Officer)</i>	
<i>/s/</i> KEVIN D. GREEN	Vice President, Finance and	March 9, 2016
<b>Kevin D. Green</b>	Chief Financial Officer <i>(Principal Financial Officer)</i>	
<i>/s/</i> DANIEL N. SWISHER, JR.	Chairman of the Board of Directors	March 9, 2016
<b>Daniel N. Swisher, Jr.</b>		
<i>/s/</i> TIMOTHY B. ANDERSON	Director	March 9, 2016
<b>Timothy B. Anderson</b>		
<i>/s/</i> LAURENCE M. CORASH, M.D.	Director	March 9, 2016
<b>Laurence M. Corash, M.D.</b>		
<i>/s/</i> BRUCE C. COZADD	Director	March 9, 2016
<b>Bruce C. Cozadd</b>		

Edgar Filing: CERUS CORP - Form 10-K

/s/ GAIL SCHULZE

Director

March 9, 2016

**Gail Schulze**

/s/ FRANK WITNEY

Director

March 9, 2016

**Frank Witney, PHD.**

**Table of Contents****INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1(22)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(22)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(22)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4(28)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(8)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(14)	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(15)	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).
	<b><i>Supply and/or Manufacturing Agreements</i></b>
10.1(7)	Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.
10.2(29)	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(23)	First Amendment to Supply and Manufacturing Agreement, dated November 28, 2012, by and between Cerus Corporation and Porex Corporation.
10.5(30)	Amendment #2 to Supply and Manufacturing Agreement, dated December 23, 2014, by and between Cerus Corporation and Porex Corporation.
10.6#	Amended and Restated Manufacturing and Supply Agreement, dated October 19, 2015, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.7(10)	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.8(19)	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.
10.9(24)	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
	<b><i>Loan and Security Agreements</i></b>
10.10(28)	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.
10.11	First Amendment to Loan and Security Agreement, dated January 30, 2015, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
10.12 (33)	Second Amendment to Loan and Security Agreement, dated September 29, 2015, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
<b><i>Real Estate Lease Agreements</i></b>	
10.13(4)	Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.
10.14(9)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.15(16)	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.
10.16(25)	Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
10.17(31)	Letter, dated March 13, 2015 to Cuff Property Management exercising option to extend the lease term under the Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
<b><i>Employment Agreements or Offer Letters</i></b>	
10.18(18)*	Employment Letter, by and between Cerus corporation and William M. Greenman, dated May 12, 2011.
10.19(23)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.
10.20(25)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.21(17)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.22(14)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.23(26)*	Equity Change in Control Agreement with Caspar Hogeboom, dated March 7, 2014.
10.24(23)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.25(25)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
10.26(33)*	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPATH, dated May 12, 2015.
10.27*	Settlement Agreement, by and between Cerus Europe B.V. and Caspar Hogeboom, dated December 23, 2015.
10.28*	Consulting Agreement, by and between Cerus Corporation and Caspar Hogeboom, dated December 23, 2015
<b><i>Stock Plans and Related Forms</i></b>	
10.29(1)*	1996 Equity Incentive Plan.
10.30(1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.31(1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.32(32)*	Amended and Restated 1996 Employee Stock Purchase Plan, effective June 10, 2015.
10.33(2)*	1998 Non-Officer Stock Option Plan.
10.34(3)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.35(5)*	1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.



**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.36(32)*	Amended and Restated 2008 Equity Incentive Plan, effective June 10, 2015.
10.37(20)*	Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.
10.38(20)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.
10.39(20)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
	<b><i>Other Compensatory Plans or Agreements</i></b>
10.40(23)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.41(11)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.42(13)*	Form of Severance Benefits Agreement.
10.43(26)*	Amended and Restated Non-Employee Director Compensation Policy.
10.44(31)*	2014 and 2015 Executive Officer Compensation Arrangements.
	<b><i>Other Material Agreements</i></b>
10.45(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.46(12)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.47(21)	Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.48(27)	Amendment No 1. to Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated March 21, 2014, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.49(16)	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).
10.50(16)	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).
10.51(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(34)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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 19, 2008.
- (9) 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.
- (10) 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.
- (11) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
- (12) 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.
- (13) 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.
- (14) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.
- (15) 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.
- (16) Incorporated by reference to the like-described exhibit to the Registrant s Annual Report on Form 10-K, for the year ended December 31, 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 March 8, 2010.
- (18) 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.
- (19) 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.

**Table of Contents**

- (20) 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.
- (21) 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.
- (22) 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.
- (23) 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.
- (24) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2013.
- (25) 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.
- (26) 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.
- (27) 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.
- (28) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2014.
- (29) 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.
- (30) Incorporated by reference to the like-described exhibit to Registrant's Annual Report on Form 10-K, for the year ended December 31, 2014.
- (31) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2015.
- (32) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2015.
- (33) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2015.
- (34) 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.