

CERUS CORP  
Form 10-K  
March 07, 2014  
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, 2013

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 \$257.3 million. (1)

As of February 26, 2014, there were 72,149,000 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 2014 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, 2013, are incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of \$4.42 per share on June 28, 2013. Excludes 11.5 million shares of the registrant's common stock held by executive officers, directors and affiliates at June 28, 2013.

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

|   | <b>Page</b> |
|---|-------------|
| <b><u>PART I</u></b>  |             |
| Item 1. <u>Business</u>   | 1           |
| Item 1A. <u>Risk Factors</u>  | 15          |
| Item 1B. <u>Unresolved Staff Comments</u>   | 35          |
| Item 2. <u>Properties</u>   | 35          |
| Item 3. <u>Legal Proceedings</u>  | 35          |
| Item 4. <u>Mine Safety Disclosures</u>  | 35          |
| <b><u>PART II</u></b>   |             |
| Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 36          |
| Item 6. <u>Selected Financial Data</u>  | 38          |
| Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | 39          |
| Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 57          |
| Item 8. <u>Financial Statements and Supplementary Data</u>  | 58          |
| Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 58          |
| Item 9A. <u>Controls and Procedures</u>   | 58          |
| Item 9B. <u>Other Information</u>   | 59          |
| <b><u>PART III</u></b>  |             |
| Item 10. <u>Directors, Executive Officers and Corporate Governance</u>  | 60          |
| Item 11. <u>Executive Compensation</u>  | 60          |
| Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>              | 60          |
| Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>                                   | 60          |
| Item 14. <u>Principal Accountant Fees and Services</u>  | 60          |
| <b><u>PART IV</u></b>   |             |
| Item 15. <u>Exhibits and Financial Statement Schedules</u>  | 61          |
| <b><u>SIGNATURES</u></b>  | 107         |

**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 involve known and unknown risks, uncertainties and other factors which 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. Examples of forward-looking statements include, but are not limited to, statements about our estimates regarding the sufficiency of our cash resources, our ability to commercialize and achieve market acceptance of the INTERCEPT Blood System, the anticipated progress of our research, development and clinical programs, our ability to manage cost increases associated with preclinical and clinical development for the INTERCEPT Blood System, our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System, the ability of our products to inactivate pathogens that may emerge in the future, and our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others. In some cases, you can identify forward-looking statements by terms such as anticipate, will, believe, estimate, expect, plan, 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 these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including our need for additional financing, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products, market acceptance of our products, reimbursement, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fresenius and third parties to manufacture certain components of the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete certain of our product components' commercial design, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, legal proceedings, and other factors discussed below and under the caption Risk Factors, in Item 1A of this Annual Report on Form 10-K and in our other documents filed with the Securities and Exchange Commission. We discuss many of these risks in this Annual Report on Form 10-K in greater detail in the section entitled 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 and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.*

**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 inactivate blood-borne pathogens in donated blood components intended for transfusion.

---

## **Table of Contents**

We have worldwide rights for our INTERCEPT Blood System for three blood components: plasma, platelets, and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals outside of the United States, including Class III CE marks, and are being marketed and sold in a number of countries around the world, including those in Europe, The Commonwealth of Independent States, or CIS, and the Middle East. We sell both the platelet and plasma systems using our direct sales force and through distributors.

We are developing the INTERCEPT Blood System for red blood cells, or red blood cell system, and are currently performing *in vitro* and license-enabling clinical trials for CE mark approval. Subject to the availability of adequate funding from partners and/or the capital markets, we intend to complete development activities for the red blood cell system necessary for potential CE mark approval. We are currently conducting a Phase II recovery and lifespan study and plan to complete that study and certain other prerequisites before proposing a Phase III clinical trial protocol for the red blood cell system in support of a potential regulatory approval in the United States. These development activities will result in increased research and development expenses in future periods, and our ability to conduct and complete any future clinical trials of the red blood cell system to support approval in the United States is subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources. In any event, we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system.

In 2012, the United States Food and Drug Administration, or FDA, accepted our proposed modular Premarket Approval Application, or PMA, shell for our plasma system. In November 2013, we submitted the fourth and final module under the PMA for plasma and have subsequently been informed that the FDA has confirmed the completeness of the filing and considers the application filed. The filed PMA for the plasma system is now in the 180 day substantive review period. During this review period we will need to satisfactorily respond to any minor or major deficiency letter we may receive before the FDA can complete their review of the PMA.

In February 2013, we reached agreement with the FDA regarding our proposed modular PMA shell for the platelet system. We have submitted two of the three modules agreed upon as part of the PMA shell and expect to submit the third and final module in the second quarter of 2014, pending our ability to successfully respond to the FDA's questions on the first two submitted modules and completing an *in vitro* study currently in process that will be submitted as part of the third and final module. The ongoing regulatory efforts for both the platelet and plasma system PMAs, as well as our development activities for the red blood cell system, will result in increased research and development expenses in future periods. Our ability to conduct and complete additional clinical trials required by the FDA to support approval in the United States, including any post-marketing studies, is subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources before we initiate any such trials or studies.

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

**Table of Contents**

and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective, available or is not performed. We believe that the INTERCEPT Blood System also has the potential to inactivate most new pathogens before they are identified and before tests are developed and adopted commercially to detect their presence in donated blood.

***Products, Product Candidates and Development Activities***

We have worldwide commercial rights for all INTERCEPT Blood System products. The following table identifies our products, product candidates and product development activities and their current status:

| <b>Product or Product Candidate Under Development</b> | <b>Product or Development Status</b>   |
|---|--|
| INTERCEPT Blood System Platelets                      | Commercialized in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world<br><br>United States: Phase III clinical trial completed; submission of PMA modules in process                    |
| INTERCEPT Blood System Plasma                         | Commercialized in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world<br><br>United States: Phase III clinical trials completed; PMA filed; FDA substantive review of filing in process |
| INTERCEPT Blood System Red Blood Cells                | Phase I clinical trial completed in 2010; Phase III trials for acute anemia and, separately, chronic anemia ongoing in Europe<br><br>United States: Phase II recovery and lifespan study in process and <i>in vitro</i> studies planned                |

***INTERCEPT Blood System for Platelets***

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

We completed a Phase III clinical trial of the platelet system in the United States in March 2001 and a supplemental analysis of data from this trial was completed in 2005. In 2013, we reached agreement with the FDA that our existing clinical trial and European haemovigilance data was sufficient to submit a modular PMA submission without the need to complete additional Phase III clinical trials. The platelet PMA shell we and the FDA agreed upon contains three modules:

Module 1: Preclinical, platelet function, pathogen inactivation data

Module 2: Clinical

Module 3: Quality systems, active compound, manufacturing, labeling, stability, post-marketing plan, integrated safety and efficacy, design verification and validation

The first two modules have been submitted to the FDA and, pending our ability to satisfactorily respond to FDA questions on the first two modules and complete an *in vitro* study currently in process that will be submitted



## **Table of Contents**

as part of the third and final module, we anticipate submitting the third and final module in the second quarter of 2014. Although FDA previously indicated that no prospective Phase III clinical trials were required, the FDA may require us to complete additional Phase III clinical trials before approval would be granted. If additional Phase III clinical trials are required for approval, we will likely only initiate such trials if adequate funding can be secured. In addition, the FDA will likely require a post-marketing clinical study, which can involve significant expense and will require us to secure adequate funding to complete.

### *INTERCEPT Blood System for Plasma*

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

We completed Phase III clinical trials of the plasma system in the United States, reports for which were filed with the FDA during 2005. We have completed the submission of our modular PMA for the plasma system and have been informed that the FDA considers the application filed. The filed plasma system PMA consisted of four modules:

Module 1: Preclinical, toxicology, pathogen inactivation data

Module 2: Clinical

Module 3: Quality systems, active compound, manufacturing

Module 4: Integrated safety and efficacy, labeling, design verification and validation, stability, and post marketing plan

Although we have completed Phase III clinical trials in various patient populations and have submitted supplemental data collected in commercial use in Europe, the FDA may require us to complete additional Phase III clinical trials before approval would be granted. We do not yet know if the FDA will require any additional clinical trials. If additional clinical trials are required for approval, we will likely only initiate such trials if adequate funding can be secured. In addition, the FDA will likely require a post-marketing clinical study, which can involve significant expense and will require us to secure adequate funding to complete.

### *INTERCEPT Blood System for Red Blood Cells*

The red blood cell system is designed to inactivate blood-borne pathogens in red blood cells donated for transfusion. We completed a series of *in vitro* and *in vivo* tests with the red blood cell system, including successfully completing recovery and survival studies measuring red cell recovery twenty-four hours after transfusion. In order to seek CE mark approval, we submitted clinical trial applications to European regulators for two proposed Phase III clinical trials, one for acute anemia patients and the other for chronic anemia patients. These Phase III clinical trials in Europe using INTERCEPT-treated red blood cells are currently ongoing.

Previously, we terminated Phase III clinical trials for acute and chronic anemia for 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



---

## **Table of Contents**

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 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 both acute anemia and, separately, chronic anemia. We are currently enrolling and conducting the acute anemia study in Germany and the chronic anemia study in Italy.

In the United States, the FDA has required us to complete at least one additional Phase II recovery and lifespan study, which we are currently conducting, and will likely require at least one additional Phase III clinical trial before we would be able to potentially obtain approval for INTERCEPT-treated red blood cells in the United States. We must successfully complete the additional recovery and lifespan study along with certain *in vitro* studies before the FDA will consider a Phase III clinical trial protocol submission from us. Even if we are able to reach agreement with the FDA on a protocol for a Phase III clinical trial evaluating the red blood cell system, we would only initiate such a trial if adequate funding can be secured.

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

Information regarding our revenues for the years ended December 31, 2013, 2012 and 2011 can be found in Item 7 *Management's Discussion and Analysis of Financial Condition and Results of Operations*, and Item 15(a) *Exhibits and Financial Statement Schedules Financial Statements* of this Annual Report on Form 10-K.

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

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

The disposable kits are then placed in an illumination device, or illuminator, where the mixture is exposed to ultra-violet A, or UVA, light. If pathogens such as viruses, bacteria or parasites 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

## **Table of Contents**

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 is rapidly excreted by humans.

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

Like the platelet and plasma systems, the red blood cell system is designed to act by using a small molecule additive compound to form bonds with nucleic acid in pathogens that may be present in donated red blood cell collections. The red blood cell system is designed to preserve the therapeutic qualities of the red blood cells, which, like platelets and plasma, do not rely on nucleic acid for their cellular function. The red blood cell system uses another of our proprietary compounds, S-303. Unlike the platelet and plasma systems, the chemical bonds from S-303 are not triggered by UVA light, but instead, by the pH level of the red blood cell components. After mixture with the red blood cell components in plastic disposable kits and resulting nucleic-acid bonding, S-303 is designed to rapidly break down into a form that is no longer chemically reactive with nucleic acid. As with the platelet and plasma systems, a high level of inactivation in a broad range of pathogens has been previously demonstrated with the red blood cell system in the clinical setting. We plan on conducting additional pathogen-inactivation studies of the red blood cell system, broadening our understanding of the pathogens the system is able to inactivate.

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

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

## **Collaborations**

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

We collaborated with Baxter International, Inc., or Baxter, on the development and commercialization of the INTERCEPT Blood System commencing in 1993. We obtained exclusive worldwide commercialization rights to the red blood cell system from Baxter in February 2005. In February 2006, we entered into a restructuring of our agreements with Baxter pursuant to which we obtained exclusive worldwide commercialization rights to the platelet and plasma systems, excluding certain Asian countries where the commercialization rights had been licensed to BioOne Corporation, or BioOne. As the successor-in-interest to Baxter, these agreements provide that we pay Fresenius Kabi AG, or Fresenius, royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. In March 2007, Baxter sold its transfusion therapies business, the unit of Baxter performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to Fenwal, Inc., or Fenwal, which in turn, was acquired by Fresenius in 2012. Fresenius has assumed Fenwal's rights and obligations under our agreements. In this report, references to Fresenius include references to its predecessors-in-interest, Fenwal and Baxter.

---

## **Table of Contents**

### *Investment in Aduro BioTech*

In November 2007, we spun-off our former immunotherapy business to Anza Therapeutics, Inc., or Anza Therapeutics. In August 2009, we entered into a three-way license agreement with Anza Therapeutics and Aduro BioTech, or Aduro, and separate agreements with each of Anza Therapeutics and Aduro, which we refer to collectively as the Assignment Agreements. In November 2009, Anza Therapeutics transferred all of its intellectual property to Aduro pursuant to the terms of the Assignment Agreements. In exchange for agreeing to the transfer and relinquishing our shares in Anza Therapeutics and releasing any claims against Anza Therapeutics, we received \$0.8 million in cash, preferred stock representing 10% of Aduro's capital, and a 1% royalty fee on any future sales resulting from the transferred technology. To date we have not received any royalty payments from Aduro pursuant to this agreement. As of December 31, 2013, our ownership in Aduro was less than 3% on a fully diluted basis. Since receiving preferred stock in Aduro, we have carried our investment in Aduro at zero on our consolidated balance sheet.

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

### **Manufacturing and Supply**

We have used, and intend to continue to use, third parties to manufacture and supply the devices, disposable kits and inactivation compounds that make up the INTERCEPT Blood System for use in clinical trials and for commercialization. We rely solely on Fresenius for the manufacture of INTERCEPT Blood System disposable kits and on other contract manufacturers for the production of our inactivation compounds, compound adsorption components of the disposable kits and UVA illuminators used in the INTERCEPT Blood System. We currently do not have alternate manufacturers for the components in our products beyond those that we currently rely on, but are currently in the process of identifying potential alternate manufactures.

In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufactures. The amended terms also provide for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. In addition, the amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. We do not currently have plans to terminate our agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement.

Components of compound adsorption devices used in platelet and plasma disposable kits are manufactured by Porex Corporation, or Porex. In November 2012, we amended our agreement for the manufacture of such components with Porex, effective as of January 1, 2013. Under the amended agreement, we are obligated to meet certain annual purchase order requirements. The term of the amended supply agreement with Porex extends through December 31, 2014. We have entered into a development agreement with another manufacturer for the development of compound adsorption devices that would be equivalent to those manufactured by Porex. Although we are actively seeking to develop alternative manufacturers and components, commercially viable alternatives are likely at least a year away. In addition, we will need to reach agreement with Porex on either a new or an amended supply agreement.

## **Table of Contents**

We also have contracts with suppliers of raw materials used to make the compound adsorption devices, which includes such companies as Brotech Corporation d/b/a Purolite Company, or Purolite. We entered into the supplier agreement with Purolite in 2007, which extends through December 2014. We and Purolite are currently seeking to amend the terms of that agreement for the production of raw materials, which would extend the term beyond December 2014.

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 the NOVA agreement currently extends through September 2014 and is automatically renewed for successive one year terms in the event neither party delivers twelve months prior written notice. We do not currently have plans to terminate our agreement with Nova and understand that Nova currently plans to continue operating under the agreement beyond September 2014.

In September 2011, we amended our manufacturing and supply agreement with Ash Stevens, Inc., or Ash Stevens, for the synthesis of amotosalen, the inactivation compound used in our platelet and plasma systems. Under this amended agreement, we are not subject to minimum annual purchase requirements. However, if specified quantities of amotosalen are not purchased in any year, we are required to pay a maintenance fee of up to \$50,000 for such year. We have incurred these maintenance fees in the past. The term of the amended manufacturing and supply agreement with Ash Stevens extends through December 31, 2015 and will automatically renew thereafter for a period of two additional years, unless terminated by either party upon providing at least one year prior written notice, in our case, or at least two years prior written notice, in the case of Ash Stevens.

We and our contract manufacturers, including Fresenius and NOVA, purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound adsorption devices and UVA illuminators from a limited number of suppliers. Some of our suppliers require minimum annual purchase amounts. While we believe that there are alternative sources of supply for such materials, parts and devices, we have not validated or qualified any alternate manufacturers. As such, establishing additional or replacement suppliers for any of the raw materials, parts and devices, if required, will likely not be accomplished quickly and could involve significant additional costs and potential regulatory reviews.

## **Marketing, Sales and Distribution**

The market for the INTERCEPT Blood System is dominated by a relatively small number of blood collection organizations. Many of these organizations are national blood transfusion services or Red Cross organizations who collect, store and distribute virtually all of their respective nations' blood and blood component supplies. The largest European markets for our products are in Germany, France, and England.

In Germany, decisions on product adoption are made on a regional or blood center-by-blood center basis. While obtaining CE marks allow us to sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute or PEI, a German governmental regulatory body overseeing the marketing authorization of certain medical products, before being allowed to sell platelet and plasma components treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, several blood centers in Germany have received such requisite approvals and authorizations for the platelet system and/or the plasma system. Given the competitive nature of the German blood banking market, pricing for blood components is relatively low compared to other markets. This dynamic, in turn, requires us to focus our marketing efforts on the potential economic and logistical benefits of using INTERCEPT compared to conventional blood components as well as the potential safety benefits of INTERCEPT-treated blood components.

In France, broad product adoption is dependent on a central decision by the Établissement Français du Sang, or EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France, and then on a broad-based national supply contract being awarded. In 2011, we entered into a two-year

---

**Table of Contents**

contract with the EFS to supply platelet and plasma disposable kits, which was extended until November 2014, at which time the EFS will have a one-year renewal option. We understand that the EFS may be considering taking action to further protect platelet components from bacterial contamination.

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

Our ability to successfully commercialize our products will depend in part on the availability of adequate reimbursement for product costs and related treatment of blood components from governmental authorities and private health care insurers (including health maintenance organizations), which are increasingly attempting to contain health care costs by limiting both the extent of coverage and the reimbursement rate for new tests and treatments.

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 also have a small scientific affairs group in the United States and the Netherlands that supports our commercialization efforts.

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our products directly. In certain of these jurisdictions, we rely on these distributors to obtain any necessary in-country regulatory approvals, in addition to marketing and selling the INTERCEPT Blood System, providing customer and technical product support, maintaining inventories, and adhering to our quality system in all material respects, among other activities. Areas where we have entered into geographically exclusive distribution agreements include certain countries in the CIS, southern Europe, the Middle East, the People's Republic of China and Latin America. Our success in these regions is dependent on our distributor's ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements account for a significant amount of our revenues. As such, declining performance or the outright termination or loss of certain distributor relationships could harm our existing business, may impact our growth potential, and could result in higher operating costs for us. For example, due to declining performance by certain of our distributors during 2013, we experienced weaker than expected growth for the year. As our distributors play a critical role in our commercialization efforts, we evaluate their performance on an ongoing basis. Over the course of 2013, we implemented several changes designed to improve market penetration in our distributor territories, including additional sales, technical and marketing support, as well as supplementary training to improve the effectiveness of distributor field personnel. More recently, we began transitioning certain territories to new distribution partners who we feel are capable of improved performance relative to their predecessors. For 2014, we will continue our focus on optimizing INTERCEPT penetration in key distributor territories, including potentially transitioning some of these territories to a Cerus direct sales effort, which we believe will provide us with better visibility into and control of sales execution. Discussions regarding changes to certain of these distributor territories are currently in progress and we believe these transitions will largely take place in the near term. Although we do not anticipate any disruption to end user customers as a result of these changes, we do expect that these changes may temporarily impact the volume of INTERCEPT disposable kit sales as distribution partners sell through their disposable kit inventory, as well as require additional resources within the impacted territories. In addition, it may take longer for us to be paid with some companies or customers taking longer to pay invoices than the payment terms we have been experiencing to date. However, we believe that these strategic actions will allow us to maintain and potentially improve pricing and therefore, margins, creating a potentially healthier business and improved operating contribution from these territories.

---

## 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, other products which are sold to blood centers and more resources than we have. In addition, competitors may choose to seek a lower class of approval than our products, which may be easier and less costly for them to maintain and may be perceived as sufficient by the marketplace. We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen inactivation methods that are either on the market or in development. The INTERCEPT Blood System is designed for use in blood centers, which allows for integration with current blood collection, processing and storage procedures. Certain competing products currently on the market, such as solvent detergent-treated plasma, use centralized processing that takes blood products away from the blood center in order to be treated at a central facility before being shipped back out to the blood centers or hospitals for ultimate transfusion.

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

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

In the United States, should our plasma product be approved for use, we would face competition from Octapharma AG, who 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, including bacterial and viral pathogens. Should our platelet product be approved for use in the United States, we would face competition from a number of diagnostic and testing companies currently approved for the detection of pathogens including bacterial and viral pathogens and may face competition from other technologies if approved.

In Japan, we understand that TerumoBCT's platelet and plasma pathogen reduction product is currently being evaluated by the Japan 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 TerumoBCT's product be approved for use and commercialized in Japan, we would likely directly compete with them and we believe we would likely require us either to establish operations in Japan or partner with a local Japanese company. We believe that the primary competitive factors in the market for pathogen inactivation of blood products include the breadth and effectiveness of pathogen inactivation processes, the amount of demonstrated reduction in transfusion related adverse events subsequent to adopting pathogen inactivation 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 inactivation 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

---

## **Table of Contents**

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

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

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2013, we owned approximately 15 issued or allowed United States patents and approximately 121 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2014 and 2027. In addition, we have pending United States patent applications and have filed corresponding patent applications under the Patent Cooperation Treaty. We also have a license from Fresenius to United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2015 and 2024. Due to the complexity of our products, we believe it is the protection afforded to our products by the portfolio of intellectual property rights that best protect our proprietary system rather than any one particular patent or trade secret. Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

### **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 inactivation system to treat blood products for transfusion. Since our customers' needs are not based on seasonal trends, seasonality does not have a material effect on our business although purchasing patterns and inventory levels can fluctuate.

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

Our platelet and plasma disposable kits have received regulatory approval for two-year shelf lives. Illuminators and replacement parts do not have regulated expiration dates, although certain components are no longer routinely manufactured. We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our consolidated balance sheet, may potentially take over one year to complete production before being utilized in finished disposable kits. Beginning in 2014, under our amended agreement with Fresenius, we will sell certain levels of work-in-process to Fresenius, somewhat mitigating the impact on our consolidated balance sheet. We maintain inventory based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory would be consumed for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for our production cycle for inventory to exceed twelve months. Instead, we use our best judgment to factor in lead times for the production of our finished units to meet our current demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. Inventory is recorded at the lower of cost, determined on a first in, first out basis, or market value. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. We rely on our direct sales team and distributors to provide accurate forecasts of sales in their territory. If our forecasts or those of our distributors are inaccurate, we could face backlog situations or conversely, may produce and carry an abundance of inventory that would consume cash faster than we have

**Table of Contents**

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, |      |      |
|--------------------------------|-------------------------|------|------|
|                                | 2013                    | 2012 | 2011 |
| Movaco, S.A.                   | 18%                     | 19%  | 21%  |
| Etablissement Francais du Sang | 17%                     | 20%  | 24%  |
| Delrus Inc.                    | *                       | 12%  | 12%  |

\* 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, 2013, 2012 and 2011, as well as information regarding our net revenues by geographical location and location of our long-lived assets, see Note 18 in the Notes to Consolidated Financial Statements under Item 15 (a) *Exhibits and Financial Statement Schedules Financial Statements* of this Annual Report on Form 10-K.

**Research and Development Expenses**

A significant portion of our operating expenses is related to research and development and we intend to maintain a strong commitment to our research and development efforts. We have incurred total research and development expenses of \$15.2 million, \$7.6 million and \$7.2 million for the years ended December 31, 2013, 2012 and 2011, respectively. As we look ahead, we anticipate that the regulatory submission processes for the plasma and platelet systems in the United States and elsewhere, will require increased investment in research and development activities, as will our ongoing clinical and development work for our red blood cell system. See Note 2 in the Notes to Consolidated Financial Statements under Item 15(a) *Exhibits and Financial Statement Schedules Financial Statements* of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for the years ended December 31, 2013, 2012 and 2011.

**Government Regulation**

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

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



---

## **Table of Contents**

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. We will need separately approved PMAs for each of the INTERCEPT systems for platelets, plasma and red blood cells because the FDA considers the INTERCEPT Blood System a biological medical device. The FDA Center for Biologics Evaluation and Research, or CBER, is principally responsible for regulating the INTERCEPT Blood System. However, before the FDA determines whether to approve our products, we expect each of our PMAs will be reviewed by the Blood Products Advisory Committee, or BPAC, an advisory committee convened by and reporting to the FDA. Should the FDA ask questions to BPAC, we expect BPAC will answer those questions and make recommendations to the FDA. If BPAC were to answer FDA questions recommending against approval of one or more of our products, the FDA would have to take into consideration the points of concern raised by BPAC, which could adversely affect the approval of the products.

The FDA inspects the facilities at which products are manufactured and will not permit clinical studies with a product or approve a product unless compliance with current Good Manufacturing Practice, or cGMP, or Quality System Regulation requirements is satisfactory. The facilities of the principal third-party suppliers that manufacture our products are not currently FDA-qualified for the manufacture of our products but will be subject to possible audit by the FDA in connection with the review of our PMA submissions. We can make no assurances regarding the outcome of these audits and if deficiencies are found in the course of the audit by the FDA, approval of our PMA could be adversely affected.

In addition to regulating our blood safety products, CBER also regulates the blood collection centers and would regulate any blood products that they prepare using the INTERCEPT Blood System. If our products were to be approved by the FDA, U.S.-based blood centers will be required to obtain site-specific licenses prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System. Any delay in obtaining these licenses would adversely impact our ability to sell products in the United States.

---

## **Table of Contents**

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 inactivating 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 INTERCEPT Blood System for red blood cells preclinical and clinical studies 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 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.*

### **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 healthcare reform 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 if we were to gain FDA approval to begin selling our products in the United States. Should we receive FDA approval to begin selling our products in the United States, current legislation surrounding health care reform may impose a 2.3% excise tax on the sale of our products, regardless of our profitability. This excise tax could reduce any potential operating profits or require us to pass on the cost to our customers.

### **Employees**

As of December 31, 2013, we had 115 employees, 40 of whom were engaged in research and development and 75 in selling, general and administrative activities. Of the 75 employees engaged in selling, general, and administrative activities, 36 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.

---

**Table of Contents****Financial Information**

Our financial information including our consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of stockholders' equity, consolidated statements of cash flows, and the related footnotes thereto, can be found under *Item 15 Exhibits and Financial Statement Schedules* in Part IV of this Annual Report on Form 10-K.

**Item 1A. Risk Factors**

*Our business faces significant risks. If any of the events or circumstances described in the following risk factors 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.*

***The INTERCEPT Blood System may not achieve broad market adoption.***

In order to increase market adoption of the INTERCEPT Blood System, we must address issues and concerns from broad constituencies involved in the healthcare system, from blood centers to patients, transfusing physicians, key opinion leaders, hospitals, private and public sector payors, regulatory bodies and public health authorities. We may be unable to demonstrate to these constituencies that the INTERCEPT Blood System is safe, effective and economical or that the benefits of using the INTERCEPT Blood System products justify their cost and outweigh their risks.

The use of the platelet system results in some processing loss of platelets. If the loss of platelets leads to increased costs for our customers, our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, prospective customers may not adopt our platelet system. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called *corrected count increment*) and may be more effective than transfusion of INTERCEPT-treated platelets. Although certain studies demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, customers may choose not to adopt our platelet system due to considerations relating to corrected count increment or efficacy.

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

We 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

## Table of Contents

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 differs 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 inactivation of pathogens, improper processing or user error, or if testing of INTERCEPT-treated blood samples fails to reliably confirm pathogen inactivation, whether or not directly attributable to the INTERCEPT Blood System, customers may refrain from purchasing the products. In addition, there is a risk that further studies we or others may conduct will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease use of our products. In certain markets, potential customers may require us to develop, sell, and support a data management application for their operations before they would consider adopting INTERCEPT. Such development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Failure to do so may limit market adoption.

Market adoption of our products is affected by blood center budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, or other third parties. In many cases, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, their 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 pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets to afford to purchase our products. Budgetary concerns may be further exacerbated by the economic austerity programs implemented in European countries, which may limit the adoption of new technologies, including our products. Furthermore, it is difficult to predict the reimbursement status of newly approved, novel medical device products.

For countries that do not recognize the CE Mark as being adequate for commercializing the INTERCEPT Blood System in those countries, product adoption may be negatively affected because we do not have FDA approval for any of our products. Even within countries that do recognize the CE Mark, the lack of widespread product adoption in key European countries has and may in the future be adversely affecting market adoption of the INTERCEPT Blood System.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even if our products receive regulatory approval and reimbursement is available, failure to effectively market, promote, distribute, price or sell our products to any of these large customers could significantly delay or even diminish potential product revenue in those geographies. The market for pathogen inactivation systems in the United States is highly concentrated and dominated by a small number of blood collection organizations. 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 PEI. Product specifications that receive marketing authorization from the PEI may differ from market requirements. Some potential customers may await further safety information or additional studies before choosing whether to adopt our products, and may conduct and complete their own clinical trials before adopting our products. 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. Decisions on product adoption in England are centralized with

## **Table of Contents**

the National Blood Service and we understand that the National Blood Service has implemented bacterial detection testing for platelets without first considering pathogen inactivation. The Japanese Red Cross controls a significant majority of blood transfusions in Japan 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 inactivation of blood over a number of years and has yet to make a formal determination to adopt any pathogen inactivation 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.

### ***We expect to continue to generate losses.***

We may never achieve a profitable level of operations. Our research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems are not approved in the United States or in many other countries around the world. The red blood cell system is in the clinical development stage and may never emerge from the clinical development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which may reduce or altogether eliminate our gross profit on sales. At our present and expected near-term sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer 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. We expect to incur additional research and development costs associated with our pursuit of the PMA application submission processes for our platelet and plasma systems, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, and with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, which costs could be substantial and could extend the period during which we expect to operate at a loss.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Health care reform in the United States has also placed downward pressure on the pricing of medical products and has introduced new taxation on medical devices that could further impact our profit margins if we were to gain FDA approval to begin selling our products in the United States. Should we receive FDA approval to begin selling our products in the United States, legislation surrounding health care reform may impose a 2.3% excise tax on the sale of our products, regardless of our profitability. This excise tax could reduce any potential operating profits or require us to pass on the costs to our customers.

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

Sales of our products are dependent on purchasing decisions and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economies and credit and financial markets, including the sovereign debt crisis in certain countries in Europe and disruptions due to political instability or otherwise, these organizations may defer purchases, may be unable to satisfy their reimbursement obligations, or may delay payment for the INTERCEPT Blood System. In addition, there are concerns for the overall stability and suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European Union, or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect our reported projected product revenue.

## **Table of Contents**

*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;

pre-market clearance or approval;

sales and distribution;

use standards and documentation;

post-launch surveillance;

quality;

advertising and promotion; and

reimbursement.

Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes before the FDA and international regulatory authorities can 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 FDA and other 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. Even if we are successful in obtaining FDA approval for our products, the FDA may limit the usage of the INTERCEPT Blood System to certain collection platforms or storage solutions or could restrict the claims that we are able to make for our products. For

instance, in Europe, we are able to claim that using the INTERCEPT Blood System can replace bacterial detection, CMV testing and gamma irradiation, which are all common practices with the preparation of conventional blood components. We cannot be certain that the FDA would allow such claims initially or ever, which may result in limited market adoption in the United States and elsewhere.

*Clinical and Preclinical*

Clinical trials are particularly expensive and have a high risk of failure. Any of our product candidates may fail in the testing phase 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

## **Table of Contents**

ongoing European Phase III trials for the red blood cell system. Significant delays in clinical testing could 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 to complete the clinical trials. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

We have conducted many toxicology studies to demonstrate the safety of the platelet and plasma systems, and we have conducted and plan to conduct toxicology studies for the red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay 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. We believe the FDA and other regulatory authorities are likely to weigh the potential risks of using our pathogen inactivation products against the incremental benefits, which may be difficult or impossible to quantify.

If our product candidates receive approval for commercial sale in the United States, the FDA may require a post-marketing clinical study, which can involve significant expense and will require us to secure adequate funding to complete. For example, although the FDA has indicated that no prospective Phase III clinical trials were required at this time in order to submit our proposal for a modular PMA submission for the platelet and plasma systems, the FDA has already indicated that we will likely need to commit to post-marketing studies. Other regulatory authorities outside of the United States may also require such post-marketing studies. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

Outside the United States, regulations vary by country, including the requirements for regulatory and marketing approvals or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore and elsewhere, may require, among other requirements, that our products be widely adopted commercially in Europe or approved by the FDA before they are considered for approval or may delay approval decisions until our products are more widely adopted commercially and approved by the FDA.



---

## **Table of Contents**

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, and 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 in each country before making available blood products processed with our pathogen inactivation systems to hospitals and transfusing physicians. Our customers may lack the resources or capability to obtain such regulatory approvals. 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 provide 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.

### *Platelet System*

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 may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals.

In the U.S., we will be required to successfully complete the submission to the FDA of all three modules of the PMA, including resolving any outstanding review letters received from the FDA, before the platelet system would be considered for approval. Once the PMA is considered filed, the FDA will commence its substantive review of the PMA, including potential inspection and audits of clinical sites and manufacturing facilities. In addition, after the PMA is considered filed, the substantive review is initially scheduled to last 180 days, although this 180-day time period can be reset if major deficiencies are identified and ultimately remediated or if we voluntarily submit a major amendment to the PMA during this period. We will not receive an approval decision from the FDA until the substantive review is complete and we cannot predict the timing or outcome of the decision. Any responses, correspondence, rejections or approvals that we may receive in connection with the plasma PMA process would not be indicative or dispositive of the status of the approval process for the platelet PMA.

We completed a Phase III clinical trial of the platelet system in the United States in March 2001 and a supplemental analysis of data from this trial in 2005. We submitted this information along with several other modules of our PMA, to the FDA. Although FDA has indicated that no prospective Phase III clinical trials are required at this time, the FDA may require us to complete additional Phase III clinical trials before approval would be granted. If additional Phase III clinical trials are required for approval, we will likely only initiate such trials if adequate funding can be secured. We have limited experience with the modular PMA process and may encounter unanticipated difficulties complying with the prescribed submission timing or other modular PMA requirements. Such difficulties could affect our ability to complete the PMA submission process successfully or in the anticipated timeframes that we expect. Should significant questions arise during the submission process or if we are required to conduct additional clinical trials to support our PMA submission, approval may take a significant period of time to obtain, if ever.

### *Plasma System*

In 2006, we obtained a CE mark approval (extended in 2011) from European Union regulators for our plasma system and final French approval of INTERCEPT-treated plasma in May 2007. SwissMedic approved INTERCEPT-treated plasma in September 2010. In February 2011, the first approval for use of INTERCEPT-treated plasma was obtained from the Paul Ehrlich Institute by a blood center in 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.

---

## **Table of Contents**

We have filed our agreed upon PMA for the plasma system with the FDA. The FDA is now reviewing the submission and may audit us, clinical sites or manufacturing facilities that produce our product. We may receive deficiency notices from the FDA at any time during the substantive review of the PMA and our ability to answer and remediate such deficiencies, should they arise, will be required before the FDA would consider approving our plasma product. Should we have difficulties answering or remediating any deficiency letters or if we are required to conduct additional clinical trials to support our planned PMA submission, approval may take a significant period of time to obtain, if ever.

Although we have completed Phase III clinical trials in various patient populations and have submitted supplemental data collected in commercial use in Europe, the FDA may require us to complete additional Phase III clinical trials, before approval would be granted. The FDA may also limit the particular indications or uses for our plasma system if they believe that our clinical data is insufficient for broader usage or if the collection and storage methods supporting our clinical data are considered to be incompatible with broad usage. Should the FDA require us to complete any additional clinical trials, our willingness and ability to conduct and complete any additional clinical trials of the plasma system to support approval in the United States would be subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources before we would initiate any such trials.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect the FDA to seek the advice of the BPAC. Even if BPAC were to recommend approval of one or more of our products, the FDA is not required to adopt BPAC's recommendation. If BPAC were to answer FDA questions recommending against approval of one or more of our products, the FDA would have to take into consideration the points of concern raised by BPAC which could affect the approval of the products.

### *Red Blood Cell System*

Our red blood cell system is currently in development and has not been commercialized anywhere in the world. Significant clinical, 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. We have not been successful in developing any product candidates that have received FDA approval in the past. Clinical testing and development of the red blood cell system will take many years to complete and failure can occur any time during the clinical trial process. Any failure or delay in completing clinical trials for the red blood cell system would prevent or delay its commercialization, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Many of the factors described above that can contribute to the failure or delay of a clinical trial could impact the trials we conduct for our red blood cell system. Even if we are successful in earlier clinical trials, the results of those early trials may not be predictive of results obtained in later and larger clinical trials of the red blood cell system. In those cases, the FDA or foreign regulatory agencies may require we engage in additional clinical trials or conduct further studies or analysis which may be costly and time-consuming. In some instances, we are relying on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials for the red blood cell system. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. Additionally, if we, our contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in those trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving the red blood cell system for commercialization. We cannot assure you that, upon inspection, the FDA or foreign 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.

---

**Table of Contents**

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

The FDA has required that we successfully complete an additional Phase II recovery and survival study, which we are currently conducting, prior to reaching agreement on any Phase III clinical trial protocol which we would likely need to successfully conduct and complete before the FDA would consider our red blood cell product for approval. 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. 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. 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 are currently enrolling patients in two European Phase III clinical trials of our red blood cell system: one for acute anemia patients and separately, one for chronic anemia patients. Such studies, including the studies required by the FDA prior to its review of any proposed U.S. Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a number of years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe if the results are positive, a successful outcome in the Phase III chronic anemia clinical trial would also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells. 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. We will also 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 or the United States. Many of these activities will require capital beyond that which we currently have, and we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our research and development expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we continue to experience delays in testing, conducting trials or approvals, our product development costs will increase. Even if we were to successfully complete and receive approval for our red blood cell system, potential customers may object to working with a potent chemical, like S-303, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system.

---

**Table of Contents**

***We have limited experience operating a global commercial organization. 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. We will need to maintain and continue to increase our competence in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems not only for these existing markets, but also if and as we expand into the Latin and South American and Asian markets. Many of these competencies require compliance with European Union, South American, Asian and local standards and practices, with which we have limited experience.

Should we be successful in commercializing our products in geographies beyond the current markets in which we sell our products, we may need to add resources and develop competencies to ensure compliance with local regulatory, legal and tax requirements. 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.

***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 countries where we have limited abilities to commercialize our products directly. We rely on these distributors to obtain any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may impact our financial results. 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, we experienced weaker than expected growth due to declining performance by certain of our distributors. We recently announced that we have and are planning to continue to pursue certain strategic changes to our distribution territories. In 2013, we began transitioning certain territories

---

**Table of Contents**

to new distribution partners who we felt were capable of improved performance relative to their predecessors. Because these are new distribution partners who have limited experience marketing and selling our products, we cannot be certain that these new distribution partners will perform better than their predecessors. For 2014, we are evaluating additional ways to optimize INTERCEPT penetration in key distributor territories, including potentially transitioning some of these territories to a Cerus direct sales model, which we believe will provide us with better visibility into and control of sales execution. However, implementing these changes to our distributor territories may temporarily impact the volume of INTERCEPT disposable kit sales as distribution partners sell through their disposable kit inventory, as well as require additional resources within the impacted territories. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. The loss of these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us which may be difficult to do in a timely manner, or at all. We expect that our product revenues will be adversely impacted with the loss or transition of one or more of these distributors. If we chose to terminate our distributor agreements, we would either need to reach agreement with, qualify, train and supply a replacement distributor or supply and service end-user customer accounts in those territories ourselves. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us, there can be no assurance that this will happen in a timely manner or at all. Doing so may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. Further, if we were to service end-user accounts directly ourselves rather than through distributors, we will likely incur additional expense and our working capital may be damaged. 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.

***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. Certain of our suppliers that we rely on for the manufacture of the platelet, plasma and red blood cell systems and components thereof, have not been FDA-approved for the manufacture of our products. In order to be used in clinical studies or sold in the United States, our products would be required to be manufactured in FDA-approved facilities. FDA approval for the manufacture of INTERCEPT, whether in facilities owned by Fresenius or by other parties, may be costly and time-consuming. Before our 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.

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

---

**Table of Contents**

manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business.

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

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

Our supply agreement with Porex was amended in November 2012 and now expires on December 31, 2014. Porex is our sole supplier for such 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. Our supply agreement with Purolite extends through December 2014, and automatically renews each year for additional one year terms absent written notice of non-renewal delivered at least two (2) years in advance of any term expiration. Purolite may terminate the supply agreement provided that Purolite notifies us in writing at least two years in advance. We are currently in discussions with Purolite to amend our agreement. Our agreement with NOVA, which manufactures our illuminators, extends through September 2014 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, causing at least temporary interruptions in supply. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. Although we are actively evaluating alternate suppliers for certain of our products and components, we do not have qualified suppliers beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. Identification and qualification of alternate suppliers will be time consuming and costly. If we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources and may cause our supply chain to be less efficient.

Currently NOVA is manufacturing illuminators to meet customer demand and maintain our own inventory levels. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. Certain of our components are in limited supply and are used as spare parts for the maintenance of illuminators

---

**Table of Contents**

used by our customers. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. Due to the obsolescence of certain parts, we will likely need to redesign the illuminators used in the platelet and plasma systems. Such redesign may be expensive and could lead to regulatory delays in obtaining approvals to market the redesigned device.

In the event that alternate manufacturers are identified and qualified, we will need to transfer know-how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers; however, certain of our supplier's materials, manufacturing processes and methods are proprietary to them, which will impair our ability to establish alternate sources of supply, even if we are required to do so as a condition of regulatory approval. We may be unable to establish alternate sources of supply to Fresenius, NOVA, or other suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. Fresenius is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms favorable to those that we currently have with our manufacturers. Should we enter into agreements with any manufacturer with less favorable terms, 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.

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, manufacturing overhead variances or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or may not accurately forecast demand ourselves for the INTERCEPT Blood System. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. We have entered into certain public tenders, some which call for us

---

## **Table of Contents**

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. 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, which would require that we destroy or consume the outdated inventory in product demonstration activities. Product expiration 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.

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.

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

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the United States and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe, and the pooled random donor method, which is used in the United States. Our platelet system is designed to work with platelets collected and stored in storage solutions, called Intersol and SSP+, and for platelets suspended in 100% plasma. 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. Should Fresenius or MacoPharma fail to obtain or maintain regulatory approval for Intersol or SSP+, respectively, or if either should decide to cease distribution of their respective additive solutions to customers and



---

**Table of Contents**

prospective customers, our ability to sell the INTERCEPT Blood System may be impaired. In addition, we may be required to produce and demonstrate additional acceptable data for usage of the INTERCEPT Blood System with various combinations of collection platforms and storage solutions before we could receive regulatory approval from the FDA and elsewhere.

In order to address the entire market in the United States, Japan, and potentially elsewhere, we would need to develop and test additional configurations of the platelet system. For example, in the United States, we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. In order to gain regulatory approvals for a pathogen inactivation system compatible with random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. 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. These development activities would 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.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System for platelets compatible with their platforms and may have competing pathogen inactivation technologies. In addition, regulatory agencies such as the FDA may limit usage of the INTERCEPT Blood System to certain collection platforms, platelet additive solutions and plasma. Attaining compatibility or receiving regulatory approval with collection platforms manufactured by others in combination with additive solutions or 100% plasma may require additional clinical testing, adaptations to either the INTERCEPT Blood System or to the collection platforms, which may be difficult to engineer, expensive to implement and test, require additional clinical trials, cause delays in regulatory approval and/or be commercially unattractive to pursue. These development activities may increase our costs significantly and may not be successful. Market acceptance of the INTERCEPT Blood System may be delayed until the system receives regulatory approval for use on such other equipment, if required.

***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 manufacture the red blood cell system.***

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

The design and engineering effort required to complete the final commercial version of our red blood cell system will likely be substantial and time-consuming. As with any complex development effort, we expect to encounter design, engineering and manufacturing issues. Such issues have previously arisen, sometimes unexpectedly, and solutions to these issues have not always been readily forthcoming. 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.

---

## **Table of Contents**

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.

*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 inactivation 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 inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in platelets and plasma.

These alternative strategies may be more effective in inactivating certain types of pathogens from blood products, including certain non-lipid-enveloped viruses, such as hepatitis A virus, 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 or more cost effective 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 inactivation systems or services to treat fresh frozen plasma. TerumoBCT, a subsidiary of Terumo Corporation, has developed a pathogen inactivation system for blood products and has been issued CE marks for a pathogen reduction system for both platelets and plasma. We understand that TerumoBCT is also developing a pathogen inactivation system for whole blood. TerumoBCT's product candidate, if successful, may offer competitive advantages over our INTERCEPT Blood System. Terumo Corporation is a large Japanese-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo's resources and their pre-existing relationships with regulators and customers. Should TerumoBCT's product be approved for use and commercialized in Japan, we would likely directly compete with them 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 will likely be commercialized ahead of our own plasma product candidate. Should Octapharma enter into exclusive agreements with key customers, our plasma product candidate, should it receive approval in the United States, may encounter market resistance and have a more limited market into which we can sell.

## **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 inactivation and non-pathogen inactivation 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 rigorous 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 inactivation to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease.

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**

*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, costs associated with the modular PMA submission process for both the platelet and plasma systems, 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 two ongoing European Phase III clinical trials for the red blood cell system, 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, 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 subject to access to public and private equity and debt capital markets, as well as to collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that cash received from product sales, our available cash balances and access to debt will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect, which could adversely affect the 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 outside of our credit agreement with Comerica Bank, as described below, on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

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

Historically, we have received significant awards in funding under cooperative agreements with the DoD for the INTERCEPT Blood System. By March 31, 2012, we had exhausted the remaining availability under the August 2011 DoD grant. Access to federal grants and cooperative agreements is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding and we do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

---

**Table of Contents**

***We have issued debt containing certain covenants that we may be unable to comply with. Our operations may not provide sufficient cash to meet the repayment obligations of our debt.***

We currently maintain a credit agreement with Comerica Bank that provides a formula based revolving line of credit of up to \$7.0 million. The credit agreement is secured by all our current and future assets, except for intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V. The credit agreement requires that we comply with certain customary and routine covenants, including the requirement to maintain a minimum cash balance of \$2.5 million and achieve minimum revenue levels, which are measured monthly based on a six-month trailing basis and must be at least 75% of the pre-established future projected revenues for the trailing six-month period. If we are unable to comply with the covenants in the credit agreement, the lender may call the outstanding advances, which would require us to repay the advances sooner than we have anticipated. Our current credit agreement expires in June 2014. If we are unable to extend or amend the agreement, we will be required to pay-down the outstanding balance at that time.

***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.

***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.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be

---

**Table of Contents**

limited. Our prior and potential future equity offerings and other changes in our stock ownership, some of which are outside of our control could in the future result in an ownership change. If a limitation were to apply, utilization of a portion of our domestic net operating loss 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, a United States patent issued to a third-party 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, if and when those products are sold in the United States. As a result, in order to commercialize our platelet or plasma systems in the United States, we may be required to 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 2014 and 2027. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates from 2015 to 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products.

Our patents do not cover all of the countries in which we are selling, and planning to sell, our products. We will not be able to prevent potential competitors from using our technology in countries where we do not have patent coverage.

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.

---

## **Table of Contents**

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees, consultants and contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know-how and inventions.

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

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

Product sales of the INTERCEPT blood system are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of other income, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. In addition, in a period where the U.S. dollar is strengthening/weakening as compared to Euros, our revenues and expenses denominated in Euros are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility.

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

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

*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

**Table of Contents**

associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent stockholders. Our board of directors has also adopted a stockholder rights plan, or poison pill, which would significantly dilute the ownership of a hostile acquirer. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine. In addition, our executive employment agreements, change of control severance benefit plan and equity incentive plans and agreements thereunder provide for certain severance benefits in connection with a change of control of us, including single-trigger equity vesting acceleration benefits with respect to outstanding stock options and single-trigger vesting acceleration benefits with respect to outstanding restricted stock unit awards, which could increase the costs to a third party acquiror and/or deter such third party from acquiring us.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate headquarters, which include our principal executive offices, are 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, 2013.

| Location                    | Square  |                           | Primary Functions                                       |
|-----------------------------|---------|---------------------------|---|
|                             | Footage | Lease Expiration Date     |   |
| Concord, CA, United States  | 36,029  | November 2019             | Administrative, and research                            |
| Concord, CA, United States  | 21,440  | August 2015               | Sales, administrative, marketing, and technical support |
| Amersfoort, The Netherlands | 7,300   | January 2018 <sup>1</sup> | Sales and administrative                                |

(1) The lease may be terminated no earlier than January 2016.

**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, 2013:</b> |             |            |
| First Quarter                        | \$ 4.55     | \$ 2.90    |
| Second Quarter                       | \$ 5.58     | \$ 4.16    |
| Third Quarter                        | \$ 6.77     | \$ 4.34    |
| Fourth Quarter                       | \$ 7.13     | \$ 5.61    |
| <b>Year Ended December 31, 2012:</b> |             |            |
| First Quarter                        | \$ 4.53     | \$ 2.62    |
| Second Quarter                       | \$ 4.13     | \$ 3.00    |
| Third Quarter                        | \$ 3.78     | \$ 3.00    |
| Fourth Quarter                       | \$ 3.52     | \$ 2.68    |

On February 26, 2014, the last reported sale price of our common stock on the Nasdaq Global Market was \$6.58 per share. On February 26, 2014, we had approximately 157 holders of record of common stock. We have not declared or paid dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. Additionally, any cash dividends declared or paid would require prior written consent under the terms of the loan and security agreement entered on September 30, 2011, as amended on December 13, 2011, and June 30, 2012, with Comerica Bank, or collectively, the Amended Credit Agreement.

**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, 2008 and tracked the performance through December 31, 2013 for (i) our common stock, (ii) the NASDAQ Biotechnology Stocks Index, (iii) the Amex Biotech Index, and (iv) the NASDAQ Stock Market (United States) Index. Our stock price performance shown in the graph below is based upon historical data and is not indicative of future stock price performance.

**Comparison of 5-year Cumulative Total Return on Investment**

|                      | 2008      | 2009      | December 31, |           | 2012      | 2013      |
|----------------------|-----------|-----------|--------------|-----------|-----------|-----------|
|                      |           |           | 2010         | 2011      |           |           |
| Cerus Corporation    | \$ 100.00 | \$ 284.29 | \$ 351.43    | \$ 400.00 | \$ 451.43 | \$ 921.43 |
| NASDAQ Biotech Index | 100.00    | 115.63    | 132.98       | 148.69    | 196.12    | 324.80    |
| AMEX Biotech Index   | 100.00    | 145.58    | 200.51       | 168.65    | 239.05    | 360.10    |
| NASDAQ               | 100.00    | 143.89    | 168.22       | 165.19    | 191.47    | 264.84    |

- (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, 2013, 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, |           |           |                   |                   |
|--|-------------------------|-----------|-----------|-------------------|-------------------|
|  | 2013                    | 2012      | 2011      | 2010 <sup>1</sup> | 2009 <sup>2</sup> |
| <b>Consolidated Statements of Operations Data:</b>                                     |                         |           |           |                   |                   |
| Product related:   |                         |           |           |                   |                   |
| Product revenue  | \$ 39,657               | \$ 36,695 | \$ 30,602 | \$ 21,677         | \$ 16,751         |
| Cost of product revenue  | 22,602                  | 20,616    | 18,535    | 12,046            | 1,231             |
| Gross profit on product revenue  | 17,055                  | 16,079    | 12,067    | 9,631             | 15,520            |
| Government grants and cooperative agreements revenue                                   | 0                       | 91        | 2,442     | 1,432             | 1,231             |
| Loss from operations   | (28,299)                | (17,300)  | (15,924)  | (15,958)          | (23,833)          |
| Net loss   | (43,337)                | (15,917)  | (16,982)  | (16,911)          | (24,135)          |
| Net loss per common share:   |                         |           |           |                   |                   |
| Basic  | \$ (0.64)               | \$ (0.29) | \$ (0.35) | \$ (0.42)         | \$ (0.69)         |
| Diluted  | \$ (0.64)               | \$ (0.33) | \$ (0.35) | \$ (0.42)         | \$ (0.69)         |
| Weighted average common shares outstanding used for calculating loss per common share: |                         |           |           |                   |                   |
| Basic  | 67,569                  | 54,515    | 48,050    | 40,300            | 34,750            |
| Diluted  | 67,569                  | 55,061    | 48,050    | 40,300            | 34,750            |

| (in thousands)                                    | December 31, |           |           |           |           |
|---|--------------|-----------|-----------|-----------|-----------|
|   | 2013         | 2012      | 2011      | 2010      | 2009      |
| <b>Consolidated Balance Sheets Data:</b>          |              |           |           |           |           |
| Cash, cash equivalents and short-term investments | \$ 57,676    | \$ 26,696 | \$ 25,784 | \$ 30,009 | \$ 19,931 |
| Working capital                                   | 38,730       | 18,383    | 18,625    | 22,052    | 19,446    |
| Total assets                                      | 83,381       | 48,919    | 45,367    | 48,167    | 34,491    |
| Long-term obligations                             | 1,162        | 4,199     | 5,940     | 4,732     | 130       |
| Total stockholders' equity                        | 42,795       | 19,107    | 18,313    | 23,732    | 21,448    |

- (1) The statements of operations data for the year ended December 31, 2010 included (i) acquisition related costs of \$0.5 million related to our acquisition of certain assets of BioOne in August 2010 and (ii) a gain of \$0.3 million associated with relinquishing our shares in BioOne as part of the consideration for the acquisition of BioOne.
- (2) The statements of operations data for the year ended December 31, 2009 included (i) an impairment charge of \$2.3 million related to our investment in BioOne, (ii) a gain of \$0.8 million associated with relinquishing our shares in Anza Therapeutics, (iii) a settlement gain of \$1.4 million associated with certain transition services provided by Baxter in 2006, and (iv) a charge of \$0.8 million related to an approved restructuring plan.

---

## **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, 2013. Operating results for the year ended December 31, 2013 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 and, from 2001 until late 2007, immunotherapies for cancer and infectious disease. The INTERCEPT Blood System is designed for three blood components. The INTERCEPT Blood System for platelets, or platelet system, and our INTERCEPT Blood System for plasma, or plasma system, have received CE marks and are being marketed and sold in a number of countries around the world including those in Europe, The Commonwealth of Independent States, or CIS, and the Middle East.

In 2012, the United States Food and Drug Administration, or FDA, accepted our proposed modular Premarket Approval Application, or PMA, shell for our plasma system. In November 2013, we submitted the fourth and final module under the PMA for plasma and have subsequently been informed that the FDA has confirmed the completeness of the filing and considers the application filed. The filed PMA for the plasma system is now in the 180 day substantive review period. During this review period, we will need to satisfactorily respond to any minor or major deficiency letter we may receive before the FDA can complete their review of the PMA.

In February 2013, we reached agreement with the FDA regarding our proposed modular PMA shell for the platelet system. We have submitted two of the three modules agreed upon as part of the PMA shell and expect to submit the third and final module in the second quarter of 2014, pending our ability to successfully respond to questions posed by the FDA on the first two submitted modules and completing an *in vitro* study currently in process that will be submitted as part of the third and final module. The ongoing regulatory efforts for both the platelet and plasma system PMAs, as well as our development activities for the red blood cell system, will result in increased research and development expenses in future periods. Our ability to conduct and complete additional clinical trials required by the FDA to support approval in the United States is subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources before we initiate any such trials or studies.

We are developing the INTERCEPT Blood System for red blood cells, or red blood cell system, and are currently performing *in vitro* and license-enabling clinical trials for CE mark approval. Subject to the availability of adequate funding from partners and/or the capital markets, we intend to complete development activities for the red blood cell system necessary for potential CE mark approval. We are currently conducting a Phase II recovery and lifespan study and plan to complete that study and certain other prerequisites before proposing a Phase III clinical trial protocol for the red blood cell system in support of a potential regulatory approval in the United States. These development activities will result in increased research and development expenses in future periods, and our ability to conduct and complete any clinical trials of the red blood cell system to support approval in the United States and Europe is subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources. In any event, we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with the modular PMA submission process for both the platelet and plasma systems, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma

---

**Table of Contents**

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 two ongoing European Phase III clinical trials for the red blood cell system, 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, 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 subject to access to public and private equity and debt capital markets, as well as to collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that cash received from product sales, our available cash balances and access to debt will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect.

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

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

We recognize product revenues from the sale of our platelet and plasma systems in a number of countries around the world including those in Europe, the CIS and the Middle East. Although our revenues have grown over time and increased during the year ended December 31, 2013 as compared to December 31, 2012, if we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, we will have difficulties achieving profitability. In order to commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our product candidates, which, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

In addition to the product revenues from sales of our platelet and plasma systems, we have recognized revenue from government grants and cooperative agreements. Historically, we have received significant awards in funding under cooperative agreements with the United States Department of Defense, or DoD, for the INTERCEPT Blood System. Any such funding is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. In August 2011, we were awarded a \$2.1 million grant from the DoD to support the development of our red blood

---

**Table of Contents**

cell system. We have recognized revenue associated with this award as qualified costs were incurred for reimbursement over the performance period of one year from the date of issuance. We have exhausted the remaining availability under the grant and recognized \$0 and \$0.1 million during the years ended December 31, 2013 and 2012, respectively. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding and we do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

**Collaborations***Aduro BioTech*

In 2007, we spun-off our immunotherapy business, and in 2009, we entered into agreements to out-license certain immunotherapy technologies to Aduro BioTech, or Aduro. In connection with those agreements, we received preferred shares of Aduro. Pursuant to these license agreements, we are eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. To date we have not received any royalty payments from Aduro pursuant to this agreement. As of December 31, 2013, our ownership in Aduro was less than 3% on a fully diluted basis. Since receiving preferred stock in Aduro, we have carried our investment in Aduro at zero on our consolidated balance sheet.

*Fresenius Kabi*

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

We also paid Fresenius certain costs associated with the amended manufacturing and supply agreement we executed with Fresenius in December 2008, the Original Supply Agreement, for the manufacture of INTERCEPT finished disposable kits for our platelet and plasma systems through December 31, 2013. Under the Original Supply Agreement, we paid Fresenius a set price per disposable kit, which was established annually, plus a fixed surcharge per disposable kit. In addition, volume driven manufacturing overhead was paid or refunded if actual manufacturing volumes were higher or lower than the annually estimated production volumes. We were also obligated under the Original Supply Agreement to supply certain disposable kit components to Fresenius, at no cost, for the manufacture of our kits. This required us to enter into manufacturing and supply arrangements with certain other manufacturers for those components, some of which contain minimum purchase commitments.

In November 2013, we amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014, the 2013 Amendment. Under the 2013 Amendment, Fresenius is obligated to sell, and we are obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provides for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. In addition, the 2013 Amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and adsorption media from us at fixed prices. The term of the 2013 Amendment extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written

**Table of Contents**

notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. We do not currently have plans to terminate our agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement.

During the year ended December 31, 2012, we provided for and settled claims for warranty obligations of \$0.9 million related to replacement costs for certain of our products that we identified were defective or had the potential of being defective. In connection with the warranty claims incurred by us and remediation of those claims during the year ended December 31, 2012, we filed a warranty claim against Fresenius, which they accepted. As a result, we recorded a current asset of \$1.8 million on our consolidated balance sheets as of December 31, 2012 representing the full amount of the warranty claim against Fresenius. We also wrote-down the value of certain unsalable inventory of \$1.7 million related to these products as an offsetting warranty claim against Fresenius. As of December 31, 2013 the Company no longer has a warranty claim against Fresenius.

In August 2010, we completed an acquisition of certain assets of BioOne Corporation, or BioOne, including the commercialization rights that both Fresenius and we granted to BioOne for both the platelet and plasma systems. Concurrent with the acquisition, Fresenius and we terminated the commercialization rights we and Fresenius granted to BioOne. As a consequence of the termination, and pursuant to a pre-existing agreement with Fresenius, our commercialization rights to the platelet and plasma systems under our 2005 and 2006 agreements with Fresenius became worldwide. As consideration for the acquired BioOne assets, we relinquished all shares we held in BioOne valued at approximately \$0.3 million and issued approximately 1.2 million shares of our common stock to BioOne valued at approximately \$3.4 million, of which approximately 1.0 million shares were issued at the close of the acquisition on August 24, 2010 and the remaining 0.2 million shares were issued on February 25, 2011. Accordingly, at the acquisition date, we recorded the fair value of the assets acquired, consisting of commercialization rights in Asia of \$2.0 million and illuminators of \$0.4 million, with the excess of the purchase price over the fair value of the asset acquired recorded as goodwill of \$1.3 million. The recognition of goodwill was attributable to the buyer-specific value derived by us as a result of acquiring the commercialization rights in certain Asian countries in order to complete the global commercialization rights for our platelet and plasma systems.

**Equity and Debt Agreements***MLV and Cantor*

We entered into an At-The-Market Issuance Sales Agreement in June 2011, as amended in January 2012 and August 2012, or collectively the MLV Agreement, with MLV & Co. LLC, formerly McNicoll, Lewis & Vlak LLC, or MLV, that provides for the issuance and sale of shares of our common stock over the term of the MLV Agreement having an aggregate offering price of up to \$20.0 million from time to time through MLV as our sales agent. We also entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement, or the Cantor Agreement, in August 2012, with Cantor Fitzgerald & Co., or Cantor, that provides for the issuance and sale of shares of our common stock over the term of the Cantor Agreement having an aggregate offering price of up to \$30.0 million through Cantor as our sales agent. During the year ended December 31, 2011, approximately 3.5 million shares of our common stock were sold under the MLV Agreement for aggregate net proceeds of \$9.7 million. During the year ended December 31, 2012, we sold an aggregate of approximately 4.5 million additional shares of our common stock under the MLV Agreement and the Cantor Agreement for aggregate net proceeds of \$13.8 million. During the year ended December 31, 2013, we sold an aggregate of approximately 5.4 million shares of our common stock under the Cantor Agreement for aggregate net proceeds of \$23.5 million. At December 31, 2013, we had less than \$0.1 million and approximately \$1.5 million of common stock available to be sold under the MLV Agreement and Cantor Agreement, respectively.

*Debt Agreements*

We entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, or collectively, the Amended Credit Agreement, with Comerica Bank, or

---

**Table of Contents**

Comerica. The Amended Credit Agreement provides for an aggregate borrowing of up to \$12.0 million, comprised of a growth capital loan of up to \$5.0 million, or Growth Capital Loan, and a formula based revolving line of credit of up to \$7.0 million. 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 Amended Credit Agreement. We are required to maintain compliance with certain customary and routine financial covenants, including maintaining a minimum cash balance of \$2.5 million with Comerica and achieving certain minimum revenue levels. On September 30, 2011, we borrowed \$5.0 million under the Growth Capital Loan, substantially all of which was used to repay our prior debt with Oxford Finance Corporation, or Oxford, with the remainder used for general corporate purposes. In addition, we have drawn against our revolving line of credit and had an outstanding balance of \$3.4 million at December 31, 2013. In April 2013, we repaid in full the Growth Capital Loan balance and all accrued interest, as well as a scheduled final payment, in an aggregate amount of \$4.2 million. We have no further obligations, nor are there any further funds available under the Growth Capital Loan.

**Critical Accounting Policies and Management Estimates**

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventory valuation, certain accrued liabilities, valuation and impairment of purchased intangibles and goodwill, valuation of warrants, valuation of stock options under share-based payments, valuation allowance of our deferred tax assets and uncertain income tax positions. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

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

**Revenue** Revenue is recognized when (i) persuasive evidence of an agreement exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is reasonably assured.

Revenue related to product sales is generally recognized when we fulfill our obligations for each element of an agreement. For all sales of our INTERCEPT Blood System products, we use a binding purchase order and signed sales contract as evidence of a written agreement. We sell INTERCEPT Blood System for platelets and plasma directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. 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 our 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 based on the best estimated selling price. We have determined that vendor specific objective evidence is not discernible due to variability in our pricing across the regions into which we sell our products. Since our products are novel and unique and are not sold by others, third-party evidence of selling price is unavailable. Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs* and value-added-taxes, or VAT, that we invoice to our customers and remit to governments, are recorded on a net basis, which excludes such VAT from product revenue.



---

**Table of Contents**

Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects are incurred. We receive certain United States government grants and contracts that support research in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants.

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

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

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

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

Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. Generally, we write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of product revenue on our consolidated statements of operations. We also wrote-down the value of certain unsalable inventory related to the products covered under the warranty claims against Fresenius.

---

**Table of Contents**

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

**Goodwill and intangible assets** In August 2010, we acquired certain assets from BioOne. We accounted for the acquisition as a business combination in accordance with ASC Topic 805, *Business Combinations*. In connection with the acquisition, we used significant judgment, including, but not limited to, judgments as to cash flows, discount rates, and economic lives, in identifying the assets acquired and in determining the fair values to record the purchased assets on our consolidated balance sheet. 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. Effective January 1, 2012, 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 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, 2013, we performed our annual review of goodwill as described above and determined that goodwill was not impaired during the year ended December 31, 2013. We will continue to monitor events and changes in circumstances that could indicate carrying amounts of our intangible assets may not be recoverable. When such events or changes in circumstances occur, we assess recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, we then measure the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets. No events or changes in circumstances arose during the year ended December 31, 2013, 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. We classified the warrants as a liability on our consolidated balance sheets as the warrants contain certain material terms which require us (or our successor)

**Table of Contents**

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

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

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

Warrants to purchase approximately 0.2 million and 5,000 shares of common stock were exercised during the years ended December 31, 2013 and 2012, respectively, resulting in aggregate net proceeds of approximately \$0.6 million and \$ 16,000, respectively. At December 31, 2013 approximately 5.9 million warrants remain outstanding.

**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 the provisions, 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. We recognize stock-based compensation expense for the fair value of the vested portion of the non-employee awards in our consolidated statements of operations.

**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.

**Table of Contents**

We recognize accrued interest and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our consolidated statements of operations, nor have we accrued for or made payments for interest and penalties. We continue to carry a full valuation allowance on all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed. Our tax years 1998 through 2013 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

**Results of Operations****Years Ended December 31, 2013, 2012 and 2011****Revenue**

| (in thousands, except percentages)                   | Year Ended December 31, |           |           | % Change     |              |
|--|-------------------------|-----------|-----------|--------------|--------------|
|  | 2013                    | 2012      | 2011      | 2013 to 2012 | 2012 to 2011 |
| Product revenue                                      | \$ 39,657               | \$ 36,695 | \$ 30,602 | 8%           | 20%          |
| Government grants and cooperative agreements revenue | 0                       | 91        | 2,442     | (100)%       | (96)%        |
| Gross profit on product revenue                      | \$ 39,657               | \$ 36,786 | \$ 33,044 | 8%           | 11%          |

Product revenue increased by \$3.0 million during the year ended December 31, 2013 compared to the year ended December 31, 2012, primarily as a result of higher unit sales volume of our disposable kits, notably our plasma system kits. The increase in sales of plasma disposable kits was due in part to first time purchases of plasma kits by certain existing platelet kit customers in 2013. Also contributing to the year-over-year increase in product revenue was higher unit sales volume for our illuminator devices driven by the continued increase in our overall customer base.

Product revenue increased by \$6.1 million during the year ended December 31, 2012 compared to the year ended December 31, 2011 primarily as a result of higher sales volume of our disposable platelet and plasma system kits sold to new customers. These sales were predominately generated by our distributors penetrating markets in Europe, the CIS, and the Middle East not previously utilizing the INTERCEPT Blood System. In addition, the increase in volume sales in 2012 as compared to 2011 is attributable to 2012 reflecting a full year of sales for existing customers who adopted throughout 2011. This increase was partially offset by a decline in the sales volume of our illuminators in 2012.

We anticipate product revenue for both our platelet and plasma systems will continue to increase over the long-term in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway. Currently, a fairly concentrated number of distributors make up a significant portion of our product revenue. In 2013, we experienced weaker than expected growth due to declining performance by certain of our distributors. We recently announced that we have and are planning to continue to pursue certain strategic changes to our distribution territories. In 2013, we began transitioning certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors. Because these are new distribution partners who have limited experience marketing and selling our products, we cannot be certain that these new distribution partners will perform better than their predecessors. For 2014, we are evaluating additional ways to optimize INTERCEPT penetration in key distributor territories, including potentially transitioning some of these territories to a Cerus direct sales model, which we believe will provide us with better visibility into and control of sales execution. However, implementing these changes to our distributor territories may temporarily impact the volume of INTERCEPT disposable kit sales as distribution partners sell through their disposable kit inventory, as well as require additional resources within the impacted territories. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular

**Table of Contents**

geography. The loss of these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us which may be difficult to do in a timely manner, or at all. We expect that our product revenues will be adversely impacted with the loss or transition of one or more of these distributors and will remain relatively flat to 2013 product revenue as we begin to transition to new distribution partners or begin selling direct in certain territories, with a disproportionate impact anticipated in the first half of 2014. However, we can provide no assurances that there will not be an adverse impact on future periods as well. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us or our designee, there can be no assurance that this will happen in a timely manner or at all. 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. The historical results may not be indicative of INTERCEPT Blood System revenue in the future.

Revenue from government grants and cooperative agreements decreased by \$0.09 million during the year ended December 31, 2013 compared to the year ended December 31, 2012. This decrease was attributable to the use of all of the remaining award balance available under our DoD grant during the year ended December 31, 2012.

Revenue from government grants and cooperative agreements decreased by \$2.4 million during the year ended December 31, 2012 compared to the year ended December 31, 2011. This decrease was attributable to the relatively low remaining award balance available under our DoD grant at the beginning of 2012, compared to the availability at the beginning of 2011, and the level of revenue generating activities under the award during the year ended December 31, 2012. We do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

**Cost of Product Revenue**

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

| (in thousands, except percentages) | Year Ended December 31, |           |           | % Change     |              |
|------------------------------------|-------------------------|-----------|-----------|--------------|--------------|
|                                    | 2013                    | 2012      | 2011      | 2013 to 2012 | 2012 to 2011 |
| Cost of product revenue            | \$ 22,602               | \$ 20,616 | \$ 18,535 | 10%          | 11%          |

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

Cost of product revenue increased by \$2.1 million during the year ended December 31, 2012 compared to the year ended December 31, 2011 primarily due to a higher volume of INTERCEPT disposable kits sold during 2012 compared to 2011. This was offset by lower per unit carrying costs in 2012 as compared to 2011 as a result of improved overhead absorption.

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

Our realized gross margins on product sales were 44% during the year ended December 31, 2012, up from 39% during the year ended December 31, 2011. The improvement in gross margins on product sales was due to lower per unit carrying costs in 2012 as compared to 2011 as a result of improved overhead absorption.

**Table of Contents**

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

We expect to maintain inventory at a level sufficient to meet forecasted demand for a relatively short time period and expect that inventory levels will remain flat as we transition certain of our distributor partnerships or begin selling direct in certain distributor territories. Our 2013 Amendment with Fresenius fixes pricing based on certain specified annual production levels. We expect the revised terms in the 2013 Amendment with Fresenius will provide for more stable and declining annual per unit cost of goods sold if we are able to increase the number of units that we procure from them and ultimately sell; however, actual manufacturing levels may differ from our assumptions and the time period during which we expect our inventory to remain flat may last longer than we currently expect.

**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. We do not maintain or evaluate our research and development expenses on a project-by-project basis. Our research and development expenses are allocated based on our assessment of the importance of a development project to our business, the probability of success and the amount of expense required to complete the project. We review all of our ongoing development projects on a regular basis and, as necessary, reallocate resources in a manner that we believe will best support the future growth of our business.

| (in thousands, except percentages) | Year Ended December 31, |          |          | % Change     |              |
|------------------------------------|-------------------------|----------|----------|--------------|--------------|
|                                    | 2013                    | 2012     | 2011     | 2013 to 2012 | 2012 to 2011 |
| Research and development           | \$ 15,187               | \$ 7,603 | \$ 7,178 | 100%         | 6%           |

Research and development expenses increased by \$7.6 million during the year ended December 31, 2013 compared to the year ended December 31, 2012 and increased by \$0.4 million during the year ended December 31, 2012 compared to the year ended December 31, 2011, primarily due to increased costs associated with clinical development of our red blood cell system and pursuing the modular PMA submission process with the FDA for the platelet and plasma systems. Of the total research and development expenses incurred, non-cash stock-based compensation represented \$0.5 million, \$0.6 million and \$0.5 million for the years ended December 31, 2013, 2012 and 2011, respectively.

We anticipate our research and development spending will continue to increase over the near term as we continue our two Phase III clinical trials for the red blood cell system in Europe and the Phase II recovery and lifespan study in the U.S. In addition, we have undertaken and plan to perform certain additional *in vitro* studies and clinical development in the United States, which would result in further increased research and development spending. Subject to our ability to fund further development, clinical and regulatory efforts, we may also perform additional research and development activities in order to pursue regulatory approval for our products in the United States, including additional research and development that may be required in connection with our modular PMA submissions to the FDA for our platelet and plasma systems, including potential post-marketing studies if requested by the FDA. In addition, we may choose to invest in ongoing research and development efforts for our existing INTERCEPT products, including a full or partial redesign of the INTERCEPT illuminator. Due to the inherent uncertainties and risks associated with developing biomedical products,

**Table of Contents**

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 Europe, the CIS and the Middle East, expenses for accounting, tax, and internal control, legal and facility and infrastructure related expenses, and insurance premiums.

| (in thousands, except percentages)  | Year Ended December 31, |           |           | % Change        |                 |
|-------------------------------------|-------------------------|-----------|-----------|-----------------|-----------------|
|                                     | 2013                    | 2012      | 2011      | 2013 to<br>2012 | 2012 to<br>2011 |
| Selling, general and administrative | \$ 29,965               | \$ 25,665 | \$ 23,053 | 17%             | 11%             |

Selling, general, and administrative expenses increased by \$4.3 million during the year ended December 31, 2013 compared to the year ended December 31, 2012 primarily due to increased spending in 2013 related to general corporate services, and the preparatory activities for a potential U.S. launch of our plasma and/or platelet systems. Selling, general, and administrative expenses increased by \$2.6 million during the year ended December 31, 2012 compared to the year ended December 31, 2011 primarily due to increased spending related to general corporate services, including legal fees, higher stock-based compensation charges, and to a lesser extent, higher workforce costs. Of the total selling, general, and administrative expenses incurred, non-cash stock-based compensation represented \$2.8 million, \$2.0 million and \$1.4 million for the years ended December 31, 2013, 2012 and 2011, respectively.

We anticipate our selling, general and administrative expenses will increase as we continue to on-board resources, develop marketing plans and prepare for a potential commercial launch of our plasma and platelet systems in the U.S. The anticipated increase in our selling, general, and administrative costs will not be fully realized unless we can successfully complete the PMA process and obtain approval for one or both of the plasma or platelet systems. In addition, we expect additional increases to our selling, general and administrative costs as a result of adding additional resources to assist with our commercialization efforts in those distributor territories that we determine to transition to a different distribution partner or to a direct sales model in connection with the strategic changes we are implementing in our distributor territories.

***Amortization of Intangible Assets***

Amortization of intangible assets relates to a license to commercialize the INTERCEPT Blood System in certain Asian countries in connection with our acquisition of certain assets from BioOne. The BioOne transaction was accounted for as a business combination under ASC Topic 805, *Business Combination*, which assigned a fair value of \$2.0 million to the intangible assets in August 2010. These intangible assets are being amortized over an estimated useful life of ten years and will be reviewed for impairment as facts and circumstances arise.

| (in thousands, except percentages) | Year Ended December 31, |        |        | % Change        |                 |
|------------------------------------|-------------------------|--------|--------|-----------------|-----------------|
|                                    | 2013                    | 2012   | 2011   | 2013 to<br>2012 | 2012 to<br>2011 |
| Amortization of intangible assets  | \$ 202                  | \$ 202 | \$ 202 | 0%              | 0%              |

Amortization of intangible assets remained flat during the year ended December 31, 2013, compared to both the years ended December 31, 2012 and 2011, as there were no changes to the composition of our intangible

**Table of Contents**

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, 2013, 2012 and 2011.

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

***Non-Operating Income (Expense), Net***

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

| (in thousands, except percentages)               | Year Ended December 31, |                 |                 | % Change        |              |
|--|-------------------------|-----------------|-----------------|-----------------|--------------|
|  | 2013                    | 2012            | 2011            | 2013 to 2012    | 2012 to 2011 |
| Revaluation of warrant liability                 | \$ (15,099)             | \$ 2,059        | \$ 486          | (833)%          | 324%         |
| Foreign exchange gain (loss)                     | 533                     | 86              | (529)           | 520%            | 116%         |
| Interest expense                                 | (520)                   | (551)           | (964)           | 6%              | 43%          |
| Other income, net                                | 266                     | 31              | 92              | 758%            | (66)%        |
| <b>Total non-operating (expense) income, net</b> | <b>\$ (14,820)</b>      | <b>\$ 1,625</b> | <b>\$ (915)</b> | <b>(1,012)%</b> | <b>278%</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. The fair value of these outstanding warrants, which uses the Black-Scholes model and/or binomial-lattice option-pricing model, is classified as a liability on the consolidated balance sheets and is adjusted at each subsequent reporting period, until such time the instruments are exercised or otherwise modified to remove the provisions which require this treatment. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders' equity and no further adjustment to the fair value would be made in subsequent periods. Further changes in stock price will result in similar adjustment as needed.

We recorded a non-cash loss from the revaluation of the warrant liability of \$15.1 million for the year ended December 31, 2013, compared to a non-cash gain of \$2.1 million for the year ended December 31, 2012, for a net change of \$17.2 million. This change is primarily due to the change in our underlying stock price as compared to the strike price of the warrants. The non-cash gain from the revaluation of the warrant liability increased by \$1.6 million during the year ended December 31, 2012 compared to the year ended December 31, 2011 primarily due to a decline in the estimated volatility, which was derived by the movement of our underlying stock price, an overall decrease in our common stock price and the reduced duration of the remaining warrant terms.

***Foreign exchange gain (loss)***

Foreign exchange improved by \$0.4 million during the year ended December 31, 2013 compared to year ended December 31, 2012, and improved by \$0.6 million during the year ended December 31, 2012 compared to the year ended December 31, 2011, which was primarily attributable to favorable foreign currency variations over that time period between the Euro and U.S. dollar, our functional currency.

***Interest expense***

Interest expense remained consistent for the year ended December 31, 2013 compared to the year ended December 31, 2012. In connection with the early repayment of our term loan with Comerica in April 2013 the



**Table of Contents**

remaining unaccrued balance of the loan's final payment fee and the unamortized discount were charged to interest expense. Interest expense decreased by \$0.4 million during the year ended December 31, 2012 compared to the year ended December 31, 2011, due to lower interest rates from borrowings on our current credit facility with Comerica compared to our prior credit facility with Oxford, offset by interest paid for draws against our revolving credit facility with Comerica during the year ended December 31, 2012.

*Other income, net*

Other income, net increased \$0.2 million for the year ended December 31, 2013 compared to the year ended December 31, 2012 primarily as a result of higher cash and investment balances during 2013. Other income, net was relatively consistent during the years ended December 31, 2012 and 2011.

**Provision for Income Taxes**

| (in thousands, except percentages) | Year Ended December 31, |        |        | % Change     |              |
|------------------------------------|-------------------------|--------|--------|--------------|--------------|
|                                    | 2013                    | 2012   | 2011   | 2013 to 2012 | 2012 to 2011 |
| Provision for income taxes         | \$ 218                  | \$ 242 | \$ 143 | (10)%        | 69%          |

Provision for income taxes for the years ended December 31, 2013, 2012 and 2011 primarily consists of foreign taxes as our wholly-owned subsidiary headquartered in Europe drives the commercialization efforts of the platelet and plasma systems in Europe, the CIS and the Middle East. We do not provide for United States income taxes on undistributed earnings of our foreign operations as we intend to permanently reinvest such earnings outside the United States. We also incurred income taxes associated with timing differences for acquired goodwill that is amortizable for tax purposes.

**Liquidity and Capital Resources**

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

At December 31, 2013, we had cash and cash equivalents of \$29.5 million. Our cash equivalents primarily consist of money market instruments, which are classified for accounting purposes as available-for-sale. Excess cash is typically invested in highly liquid instruments with high-quality credit rated corporate and government agency fixed-income securities in accordance with our investment policy.

*Operating Activities*

Net cash used in operating activities was \$26.8 million for the year ended December 31, 2013, compared to \$13.9 million during the year ended December 31, 2012. The increase in net cash used in operating activities was primarily related to additional operating expenditures in support of the business. Also impacting this increase in net cash used in operating activities were changes in working capital with a net increase in the combined total for our accounts payable and accrued liabilities as a result of the timing of payments, and an increase in accounts receivable during the year ended December 31, 2013, relative to the corresponding period in 2012 due to a heavy concentration of sales transactions in the final weeks of the year ended December 31, 2013 as well as a higher rate of inventory build during the year ended December 31, 2013 compared to the corresponding period in 2012.

Net cash used in operating activities was \$13.9 million for the year ended December 31, 2012, compared to \$15.6 million during the year ended December 31, 2011. The decrease in net cash used in operating activities was primarily related to 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

---

**Table of Contents**

ended December 31, 2012, relative to the corresponding period in 2011 due to increased efforts in cash collections. This was offset by a higher rate of inventory build during the year ended December 31, 2012 compared to the corresponding period in 2011. This increased inventory build in 2012 was a result in the increase in revenue growth for 2012 over 2011. In addition, at December 31, 2012, we recorded a current asset representing the accepted warranty claim we filed against Fresenius relating to product warranty claims incurred and remediated by us, which all occurred during the year ended December 31, 2012.

*Investing Activities*

Net cash used in investing activities was \$29.1 million for the year ended December 31, 2013, compared to \$0.2 million provided by investing activities during the year ended December 31, 2012. The change was primarily the result of our decision to invest proceeds from a public offering of our common stock completed in March 2013 into short-term available-for-sale corporate debt securities and United States government agency securities.

Net cash provided by investing activities was \$0.2 million for the year ended December 31, 2012, compared to \$0.6 million during the year ended December 31, 2011. The decrease in investing activities was primarily due to the reinvestment of the proceeds received from the maturities of our then-existing investments into money market funds with original maturities of less than 90 days.

*Financing Activities*

Net cash provided by financing activities was \$58.6 million during the year ended December 31, 2013, compared to \$14.9 million during the year ended December 31, 2012. The increase in financing activities was primarily due to proceeds received from our underwritten common stock offering which generated \$38.0 million (net of \$1.8 million in underwriter's discounts and \$0.5 in offering costs) and an additional \$23.5 million received from sales of our common stock offerings pursuant to the Cantor Agreement, offset slightly by repayment of debt principal.

Net cash provided by financing activities was \$14.9 million during the year ended December 31, 2012, compared to \$11.6 million during the year ended December 31, 2011. The increase in financing activities was primarily due to higher cash proceeds received from sales of our common stock offerings pursuant to the Cantor Agreement and the MLV Agreement. We also received the benefit of making nine months of interest-only payments on our growth capital facility with Comerica during the year ended December 31, 2012, compared to payments of both principal and interest on our prior debt during the corresponding period in 2011.

*Working Capital*

Working capital increased to \$38.7 million at December 31, 2013, from \$18.4 million at December 31, 2012, primarily due to proceeds from our underwritten common stock offering as well as sales of our common stock pursuant to the Cantor Agreement, offset by cash used in operations. This was partially offset by increases in our warrant liability.

Working capital decreased to \$18.4 million at December 31, 2012, from \$18.6 million at December 31, 2011, primarily due to a net increase in the combined total for our accounts payable and accrued liabilities due to our vendors, and increases on the current portion of our debt as our obligation to pay principal payments occurred in October 2012, and decreases in accounts receivable due to our increased efforts to collect cash from our customers. This was partially offset by increases in inventory levels in order to be able to fulfill anticipated future customer demand for our products coupled with the management of our supply chain, decreases in our warrant liability and increases in other current asset primarily related to an accepted warranty claim we filed against Fresenius relating to product warranty claims incurred and remediated by us.

---

## **Table of Contents**

### *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, costs associated with the modular PMA submission process for both the platelet and plasma 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 two ongoing European Phase III clinical trials for the red blood cell system 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, 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 subject to access to public and private equity and debt capital markets, as well as to collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that cash received from product sales, our available cash balances and access to debt will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth outside of our Amended Credit Agreement with Comerica Bank 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 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 general global economic uncertainty and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we will need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. We do not plan on conducting any additional clinical trials of the red blood cell, platelet or plasma systems in the United States unless and until we can obtain sufficient additional funding or, at such time our existing operations provide sufficient cash flow to conduct these trials.

### *Other Information*

Historically, we have received significant awards in funding under cooperative agreements with the DoD for the INTERCEPT Blood System. Any such funding is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. As of March 31, 2012, we had exhausted the remaining availability under the August 2011 DoD grant. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding and we do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

We entered into the MLV Agreement in June 2011, as amended in January 2012 and August 2012, which provides for the issuance and sale of shares of our common stock over the term of the MLV Agreement having

**Table of Contents**

an aggregate offering price of up to \$20.0 million from time to time through MLV as our sales agent. We also entered into the Cantor Agreement in August 2012 with Cantor that provides for the issuance and sale of shares of our common stock over the term of the Cantor Agreement having an aggregate offering price of up to \$30.0 million through Cantor as our sales agent. Future issuances and sales of shares of common stock by us under the MLV Agreement and Cantor Agreement, or the Sales Agreements, are subject to the continued effectiveness of our shelf registration statement referred to below. Sales of our common stock through MLV and Cantor will be made on the Nasdaq Global Market by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by us and MLV or Cantor, as applicable. Subject to the terms and conditions of the MLV Agreement and Cantor Agreement, MLV and Cantor will use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are not obligated to make any sales of common stock under the Sales Agreements.

The offering of common stock pursuant to each Sales Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the applicable Sales Agreement and (2) termination of that Sales Agreement. Each Sales Agreement may be terminated by MLV or Cantor, as applicable, or us at any time upon 10 days notice to the other party, or by MLV or Cantor, as applicable, at any time in certain circumstances, including our undergoing a material adverse change. We pay MLV an aggregate commission rate equal to 3% of the gross proceeds of the sales price per share of any common stock sold through MLV under the MLV Agreement, and we pay Cantor 2% of the gross proceeds of the sales price per share of any common stock sold through Cantor under the Cantor Agreement. During the year ended December 31, 2011, approximately 3.5 million shares of our common stock were sold under the MLV Agreement for aggregate net proceeds of \$9.7 million. During the year ended December 31, 2012, we sold an aggregate of approximately 4.5 million additional shares of our common stock under the MLV Agreement and the Cantor Agreement for aggregate net proceeds of \$13.8 million. During the year ended December 31, 2013 we sold an aggregate of approximately 5.4 million shares of our common stock under the Cantor Agreement for aggregate net proceeds of \$23.5 million. At December 31, 2013, we had less than \$0.1 million and approximately \$1.5 million of common stock available to be sold under the MLV Agreement and Cantor Agreement, respectively, subject to the continued effectiveness of our shelf registration statement referred to below.

In December 2011, we filed a shelf registration statement on Form S-3 to offer and sell up to \$150.0 million of common stock, preferred stock, warrants, and/or debt securities, less amounts sold under the Sales Agreement following the effectiveness of the shelf registration statement. The registration statement was declared effective in January 2012 and expires in January 2015.

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

We did not have any off-balance sheet arrangements as of December 31, 2013 or 2012.

*Contractual Commitments*

The following summarizes our contractual commitments at December 31, 2013:

| (in thousands)                       | Total            | Less than<br>1 year | 1 - 3<br>years  | 4 - 5<br>years | After 5<br>years |
|--------------------------------------|------------------|---------------------|-----------------|----------------|------------------|
| Minimum purchase requirements        | \$ 4,689         | \$ 3,380            | \$ 1,309        | \$ 0           | \$ 0             |
| Debt                                 | 3,457            | 3,457               | 0               | 0              | 0                |
| Operating leases                     | 1,919            | 1,147               | 695             | 77             | 0                |
| Other commitments                    | 1,143            | 415                 | 309             | 287            | 132              |
| <b>Total contractual obligations</b> | <b>\$ 11,208</b> | <b>\$ 8,399</b>     | <b>\$ 2,313</b> | <b>\$ 364</b>  | <b>\$ 132</b>    |

---

## **Table of Contents**

### *Minimum purchase requirements*

Our minimum purchase commitments include certain components of our INTERCEPT Blood System which we purchase from third party manufacturers and have historically supplied to Fresenius at no cost for use in manufacturing finished INTERCEPT disposable kits. Under the 2013 Amendment that we entered into with Fresenius, we also have certain minimum purchase commitments for the disposable kits that we purchase from Fresenius for our platelet and plasma systems.

### *Operating leases*

We generally lease our office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. Our lease payments have increased as we exercised a ten year extension option on December 10, 2009 to extend the term of our lease in Concord, California for our headquarters and exercised a five year extension option in January 2012, to extend the term of our lease in Amersfoort, The Netherlands for an additional five years following the original lease expiration of January 2013. However, we have the right to early terminate both our Concord lease and our Amersfoort lease, which may occur as early as January 2015 and February 2016, respectively. In June of 2013, we executed a new two year lease for additional space in Concord, California. The term of this new lease commenced on August 1, 2013 and continues for two years with four (4) two -year options for us to renew. Our facility leases qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on our consolidated balance sheets.

### *Other commitments*

Our other commitments primarily consist of obligations for landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space. We pay for the financed leasehold improvements as a component of rent and are required to reimburse our landlords over the remaining life of the respective leases. If we exercise our right to early terminate the lease in Concord, California for our headquarters, which may occur as early as January 2015, we would be required to pay for any remaining portion of the landlord financed leasehold improvements at such time. At December 31, 2013, we had an outstanding liability of \$0.7 million related to these leasehold improvements. Our agreements with Fresenius require us to pay royalties on sales of the INTERCEPT Blood System at rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Such royalties are calculated based on future product sales and are not provided for in the table above as they are dependent on events that have not yet occurred.

### *Debt*

The Amended Credit Agreement with Comerica Bank provides for an aggregate borrowing of up to \$12.0 million, comprised of a growth capital loan of \$5.0 million, or Growth Capital Loan, and a formula based revolving line of credit, or RLOC, of up to \$7.0 million. 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 Amended Credit Agreement.

Concurrent with the execution of the original loan and security agreement in September 2011, we borrowed \$5.0 million under the Growth Capital Loan, substantially all of which was used to repay our prior debt with Oxford, with the remainder used for general corporate purposes. The Growth Capital Loan, which was scheduled to mature on September 30, 2015, and bore a fixed interest rate of 6.37%, with interest only payments due for the first twelve months, followed by equal principal and interest payments for the remaining 36 months. In April 2013, the Company repaid in full the Growth Capital Loan balance and all accrued interest as well as a scheduled final payment fee of \$0.05 million, in an aggregate amount of \$4.2 million. The Company has no further obligations, nor are there any further funds available under the Growth Capital Loan.

## **Table of Contents**

In September 2011, we incurred a commitment fee of \$40,000 and loan fees of \$50,000, which were recorded as a discount to our Growth Capital Loan and were being amortized as a component of interest expense using the effective interest method over the term of the Growth Capital Loan (discount was based on an implied interest rate of 7.07%). The Company was also required to make a final payment fee of 1% of the amounts drawn under Growth Capital Loan due on its prepayment of the Growth Capital Loan. The final payment fee was accreted to interest expense using the effective interest method over the life of the Growth Capital Loan upon draw. The remaining unaccreted balance of the final payment fee and unamortized discount was taken as an interest charge in April 2013 in connection with the repayment of that loan.

The Amended Credit Agreement also provides for a RLOC of up to \$7.0 million, or the RLOC Loan Amount. The amount available under the RLOC is limited to the lesser of (i) 80% of eligible trade receivables or (ii) the RLOC Loan Amount. At December 31, 2013, and 2012, we had \$3.4 million and \$3.2 million, respectively, outstanding under the RLOC. We are required to repay the principal drawn from the RLOC at the end of the RLOC term on June 30, 2014, or earlier if a portion or all of the outstanding RLOC exceeds the amount available under the RLOC. The RLOC bears a floating rate based on the lender's prime rate plus 1.50%, with interest only payments due each month. At both December 31, 2013 and 2012, the floating rate of the RLOC was at 4.75%. In September 2011, we incurred a commitment fee of \$20,000. Upon amendment of the loan and security agreement in June 2012, we incurred another annual commitment fee of \$20,000 and received a credit for the unused portion of the initial fee. We will incur a \$20,000 commitment fee at each annual anniversary beginning June 30, 2013.

We are required to maintain compliance with certain customary and routine financial covenants under the Amended Credit Agreement, including maintaining a minimum cash balance of \$2.5 million at Comerica and achieving minimum revenue levels, which are measured monthly based on a six-month trailing basis and must be at least 75% of the pre-established future projected revenues for the trailing six-month period. Non-compliance with the covenants could result in the principal of the note becoming due and payable. As of December 31, 2013 and as of the date of this report, we were in compliance with the financial covenants as set forth in the Amended Credit Agreement.

## **Financial Instruments**

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our available-for-sale securities related to corporate debt and United States government agency securities and 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, 2013, and 2012. Adverse global economic conditions, including the sovereign debt crisis in Europe, have had, and may continue to have, a negative impact on the market values of potential investments.

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

At December 31, 2013, we held cash, cash equivalents and short-term investments of \$57.7 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 United States government agency securities with short-term maturities. The weighted average interest rates of our cash and cash equivalents at December 31, 2013 were 0.31%.

---

**Table of Contents**

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

**Foreign Currency Risk**

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

Product sales for our blood safety products are predominantly made in Europe and generally are invoiced to customers in Euros. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems. These inventory purchases and operating expenses are generally paid in Euros and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of non-operating income (expense), net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. An unfavorable 10% change in foreign currency exchange rates for our accounts receivable, accounts payable and accrued liabilities that are denominated in foreign currencies at December 31, 2013 would have negatively impacted our annual financial results by \$0.2 million. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

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

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

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

None.

**Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e), promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of December 31, 2013, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective.

*Changes in Internal Control over Financial Reporting.* During the last quarter of our fiscal year ended December 31, 2013, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

*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 the principal executive officer and principal financial officer have concluded that these controls and procedures are effective at the reasonable assurance level.

*Management's Report on Internal Control over Financial Reporting.* Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2013, is discussed in the Management's Report on Internal Control over Financial Reporting included on page 67.

*Attestation Report of Independent Registered Public Accounting Firm.* Ernst & Young LLP, independent registered public accounting firm, has issued an audit report on our internal control over financial reporting, which report is included on page 68.

**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 2014 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 entitled 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>Management's Report on Internal Control Over Financial Reporting</u>                            | 67          |
| <u>Reports of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</u>             | 68          |
| <u>Consolidated Balance Sheets as of December 31, 2013 and 2012</u>                                | 70          |
| <u>Consolidated Statements of Operations for the three years ended December 31, 2013</u>           | 71          |
| <u>Consolidated Statements of Comprehensive Loss for the three years ended December 31, 2013</u>   | 72          |
| <u>Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2013</u> | 73          |
| <u>Consolidated Statements of Cash Flows for the three years ended December 31, 2013</u>           | 74          |
| <u>Notes to Consolidated Financial Statements</u>  | 75          |

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>   |
|-----------------------|---|
| 2.1(21)               | Asset Purchase and Redemption Agreement by and between Cerus Corporation and BioOne Corporation, dated as of August 24, 2010.   |
| 3.1(32)               | Amended and Restated Certificate of Incorporation of Cerus Corporation.   |
| 3.2(32)               | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.   |
| 3.3(32)               | Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.   |
| 3.4(10)               | Amended and Restated Bylaws of Cerus Corporation.   |
| 4.1(1)                | Specimen Stock Certificate.   |
| 4.2(16)               | 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(18)               | Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto). |
| 4.4(17)               | Form of 2009 Warrant to Purchase Common Stock.  |
| 4.5(22)               | Form of 2010 Warrant to Purchase Common Stock.  |
|                       | <b><i>Supply and/or Manufacturing Agreements</i></b>  |
| 10.1(8)               | Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.   |
| 10.2(8)               | Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus Corporation and Porex Corporation.  |
| 10.3(34)              |   |

Edgar Filing: CERUS CORP - Form 10-K

First Amendment to Supply and Manufacturing Agreement, dated November 28, 2012, by and between Cerus Corporation and Porex Corporation.

**Table of Contents**

| <b>Exhibit<br/>Number</b> | <b>Description of Exhibit</b>  |
|---------------------------|--|
| 10.4#                     | Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Fenwal, Inc.).  |
| 10.5#                     | Amendment No. 1 to the Amended and Restated Manufacturing and Supply Agreement, dated November 22, 2013, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.   |
| 10.6(12)                  | Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.  |
| 10.7(26)                  | Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.   |
| 10.8(35)                  | 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>   |
| 10.9(26)                  | Loan and Security Agreement, dated as of September 30, 2011, by and between Cerus Corporation and Comerica Bank.   |
| 10.10(30)                 | First Amendment to Loan and Security Agreement, dated as of December 13, 2011, by and between Cerus Corporation and Comerica Bank.   |
| 10.11(30)                 | Second Amendment to Loan and Security Agreement, dated as of June 30, 2012, by and between Cerus Corporation and Comerica Bank.  |
|                           | <b><i>Real Estate Lease Agreements</i></b>   |
| 10.12(4)                  | Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.  |
| 10.13(11)                 | Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.  |
| 10.14(19)                 | 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. |
| 10.15                     | 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>   |
| 10.16(23)*                | Employment Letter, by and between Cerus corporation and William M. Greenman, dated May 12, 2011.   |
| 10.17(34)*                | Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.  |
| 10.18*                    | Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.  |
| 10.19(20)*                | Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.  |
| 10.20(33)*                | Amended and Restated Employment Agreement with Howard G. Ervin, dated January 15, 2013.  |
| 10.21(16)*                | Employment Letter for Kevin D. Green dated May 1, 2009.  |
| 10.22(27)*                | Employment Agreement for Caspar Hogeboom dated March 6, 2006.  |
| 10.23(27)*                | Promotion Letter for Caspar Hogeboom dated December 11, 2009 and executed on September 21, 2010.   |

**Table of Contents**

| <b>Exhibit<br/>Number</b> | <b>Description of Exhibit</b>   |
|---------------------------|---|
| 10.24(27)*                | Addendum to Employment Agreement for Caspar Hogeboom dated February 17, 2011.   |
| 10.25(27)*                | Healthcare Contribution Letter for Caspar Hogeboom dated December 18, 2007.   |
| 10.26(27)*                | Home Telephone and Internet Expenses Letter for Caspar Hogeboom dated January 11, 2012.   |
| 10.27(34)*                | Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.                                |
| 10.28*                    | Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.                                   |
|                           | <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(1)*                 | 1996 Employee Stock Purchase Plan.  |
| 10.33(30)*                | Employee Stock Purchase Plan, as amended, effective June 6, 2012.   |
| 10.34(2)*                 | 1998 Non-Officer Stock Option Plan.   |
| 10.35(3)*                 | 1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.                                      |
| 10.36(5)*                 | 1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.  |
| 10.37(9)*                 | 2008 Equity Incentive Plan, approved by stockholders June 2, 2008.  |
| 10.38(25)*                | 2008 Equity Incentive Plan, as amended, reapproved by stockholders June 1, 2011.  |
| 10.39(30)*                | 2008 Equity Incentive Plan, as amended, effective June 12, 2013.  |
| 10.40(29)*                | Form of Option Agreement for employees under the 2008 Equity Incentive Plan, as amended.  |
| 10.41(29)*                | Form of Option Agreement for non-employee directors under the 2008 Equity Incentive Plan, as amended.                           |
| 10.42(29)*                | Form of Restricted Stock Unit Agreement under the 2008 Equity Incentive Plan, as amended.                                       |
|                           | <b><i>Other Compensatory Plans or Agreements</i></b>  |
| 10.43(34)*                | Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.   |
| 10.44(13)*                | Cerus Corporation Change of Control Severance Benefit Plan, as amended.   |
| 10.45(15)*                | Form of Severance Benefits Agreement.   |
| 10.46(27)*                | Non-Employee Director Compensation Policy.  |
| 10.47(29)*                | International Bonus Plan for 2012.  |
| 10.48*                    | International Bonus Plan for 2013.  |
|                           | <b><i>Other Material Agreements</i></b>   |
| 10.49(24)                 | At-The-Market-Issuance Sales Agreement, dated June 3, 2011, by and between Cerus Corporation and MLV & Co. LLC.                 |
| 10.50(28)                 | Amendment to At-The-Market-Issuance Sales Agreement, dated January 4, 2012, by and between Cerus Corporation and MLV & Co. LLC. |

**Table of Contents**

| <b>Exhibit Number</b> | <b>Description of Exhibit</b>  |
|-----------------------|--|
| 10.51(31)             | Amendment No. 2 to At-The-Market-Issuance Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and MLV & Co. LLC.  |
| 10.52(1)              | Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.   |
| 10.53(14)             | Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.  |
| 10.54(17)             | Form of Subscription Agreement.  |
| 10.55(31)             | Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.  |
| 10.56(19)             | 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).                      |
| 10.57(19)             | 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).                       |
| 10.58(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(36)              | 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.

**Table of Contents**

- (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 Annual Report on Form 10-K, for the year ended December 31, 2007.
- (8) 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.
- (9) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on June 6, 2008.
- (10) 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.
- (11) 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.
- (12) 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.
- (13) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
- (14) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on April 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 June 1, 2009.
- (16) 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.
- (17) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on August 20, 2009.
- (18) 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.
- (19) Incorporated by reference to the like-described exhibit to the Registrant s Annual Report on Form 10-K, for the year ended December 31, 2009.
- (20) 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.
- (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 30, 2010.
- (22) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on November 12, 2010.
- (23) 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.
- (24) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on June 6, 2011.
- (25) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant s Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2011.
- (26) 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.
- (27) Incorporated by reference to the like-described exhibit to the Registrant s Annual Report on Form 10-K, for the year ended December 31, 2011.
- (28) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant s Registration Statement on Form S-3/A, filed with the SEC on January 6, 2012.

**Table of Contents**

- (29) 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.
- (30) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2013.
- (31) 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.
- (32) 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.
- (33) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on January 17, 2013.
- (34) 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.
- (35) 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.
- (36) 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**

**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Management is responsible for establishing and maintaining effective internal control over the Company's financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) ( COSO ) in *Internal Control - Integrated Framework*. Based on this assessment, management has concluded that, as of December 31, 2013, the Company's internal control over financial reporting is effective.

The Company's independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2013. Ernst and Young LLP's attestation report on internal control over financial reporting is included herein.

The Company's internal control system is designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Accordingly, our internal control systems are designed to provide reasonable, not absolute, assurance that the objectives of our internal control systems are met and, as set forth above, 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 our internal control over financial reporting was effective. To provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles, we continue to implement, improve and refine our disclosure controls and procedures and 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, 2013, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 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, 2013, 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 of December 31, 2013, and 2012, 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, 2013, and our report dated March 7, 2014, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California

March 7, 2014

**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, 2013, and 2012, 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, 2013. 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, 2013, and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 7, 2014 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California

March 7, 2014

**Table of Contents****CERUS CORPORATION****CONSOLIDATED BALANCE SHEETS****(in thousands, except per share amounts)**

|  | December 31,     |                  |
|--|------------------|------------------|
|  | 2013             | 2012             |
| <b>ASSETS</b>  |                  |                  |
| Current assets:  |                  |                  |
| Cash and cash equivalents  | \$ 29,485        | \$ 26,696        |
| Short-term investments   | 28,191           |                  |
| Accounts receivable, net of allowance of \$0 at December 31, 2013 and 2012   | 6,125            | 4,444            |
| Inventories  | 13,063           | 10,180           |
| Prepaid expenses   | 848              | 638              |
| Other current assets   | 442              | 2,038            |
| <b>Total current assets</b>  | <b>78,154</b>    | <b>43,996</b>    |
| Non-current assets:  |                  |                  |
| Property and equipment, net  | 2,189            | 1,698            |
| Goodwill   | 1,316            | 1,316            |
| Intangible assets, net   | 1,344            | 1,546            |
| Restricted cash  | 308              | 304              |
| Other assets   | 70               | 59               |
| <b>Total assets</b>  | <b>\$ 83,381</b> | <b>\$ 48,919</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                  |                  |
| Current liabilities:   |                  |                  |
| Accounts payable   | \$ 5,674         | \$ 7,186         |
| Accrued liabilities  | 9,813            | 7,619            |
| Deferred revenue   | 181              | 77               |
| Debt current   | 3,366            | 4,828            |
| Warrant liability  | 20,390           | 5,903            |
| <b>Total current liabilities</b>   | <b>39,424</b>    | <b>25,613</b>    |
| Non-current liabilities:   |                  |                  |
| Debt non-current   |                  | 2,896            |
| Deferred income taxes  | 89               | 62               |
| Other non-current liabilities  | 1,073            | 1,241            |
| <b>Total liabilities</b>   | <b>40,586</b>    | <b>29,812</b>    |
| Commitments and contingencies  |                  |                  |
| Stockholders' equity:  |                  |                  |
| Preferred stock, \$0.001 par value 5,000 shares authorized, issuable in series; 0 shares issued and outstanding at December 31, 2013 and 2012          |                  |                  |
| Common stock, \$0.001 par value 112,500 shares authorized; 71,859 and 56,252 shares issued and outstanding at December 31, 2013 and 2012, respectively | 72               | 56               |
| Additional paid-in capital   | 545,905          | 478,903          |
| Accumulated other comprehensive income   | 7                |                  |
| Accumulated deficit  | (503,189)        | (459,852)        |
| <b>Total stockholders' equity</b>  | <b>42,795</b>    | <b>19,107</b>    |

Edgar Filing: CERUS CORP - Form 10-K

|  |           |           |
|--|-----------|-----------|
| Total liabilities and stockholders' equity | \$ 83,381 | \$ 48,919 |
|--|-----------|-----------|

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, |             |             |
|---|-------------------------|-------------|-------------|
|   | 2013                    | 2012        | 2011        |
| <b>Product related:</b>   |                         |             |             |
| Product revenue   | \$ 39,657               | \$ 36,695   | \$ 30,602   |
| Cost of product revenue   | 22,602                  | 20,616      | 18,535      |
| Gross profit on product revenue   | 17,055                  | 16,079      | 12,067      |
| Government grants and cooperative agreements revenue  |                         | 91          | 2,442       |
| <b>Operating expenses:</b>  |                         |             |             |
| Research and development  | 15,187                  | 7,603       | 7,178       |
| Selling, general and administrative   | 29,965                  | 25,665      | 23,053      |
| Amortization of intangible assets   | 202                     | 202         | 202         |
| Total operating expenses  | 45,354                  | 33,470      | 30,433      |
| Loss from operations  | (28,299)                | (17,300)    | (15,924)    |
| <b>Non-operating (expense) income, net:</b>   |                         |             |             |
| Revaluation of warrant liability  | (15,099)                | 2,059       | 486         |
| Foreign exchange gain (loss)  | 533                     | 86          | (529)       |
| Interest expense  | (520)                   | (551)       | (964)       |
| Other income, net   | 266                     | 31          | 92          |
| Total non-operating (expense) income, net   | (14,820)                | 1,625       | (915)       |
| Loss before income taxes  | (43,119)                | (15,675)    | (16,839)    |
| Provision for income taxes  | 218                     | 242         | 143         |
| Net loss  | \$ (43,337)             | \$ (15,917) | \$ (16,982) |
| <b>Net loss per common share:</b>   |                         |             |             |
| Basic   | \$ (0.64)               | \$ (0.29)   | \$ (0.35)   |
| Diluted   | \$ (0.64)               | \$ (0.33)   | \$ (0.35)   |
| <b>Weighted average common shares outstanding used for calculating net loss per common share:</b> |                         |             |             |
| Basic   | 67,569                  | 54,515      | 48,050      |
| Diluted   | 67,569                  | 55,061      | 48,050      |

See accompanying Notes to Consolidated Financial Statements.

**Table of Contents**

**CERUS CORPORATION**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(in thousands)

|  | Year Ended December 31, |             |             |
|--|-------------------------|-------------|-------------|
|  | 2013                    | 2012        | 2011        |
| Net loss   | \$ (43,337)             | \$ (15,917) | \$ (16,982) |
| Other comprehensive income (loss):   |                         |             |             |
| Net unrealized gains (losses) on available-for-sale securities, net of taxes | 7                       |             | (108)       |
| Comprehensive loss   | \$ (43,330)             | \$ (15,917) | \$ (17,090) |

See accompanying Notes to Consolidated Financial Statements.

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

(in thousands)

|  | Preferred Stock |         | Common Stock |        | Additional<br>Paid-in<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Income | Accumulated<br>Deficit | Total<br>Stockholders<br>Equity |
|--|-----------------|---------|--------------|--------|----------------------------------|---|------------------------|---------------------------------|
|  | Shares          | Amount  | Shares       | Amount |                                  |   |                        |                                 |
| Balance at December 31, 2010   | 3               | 9,496   | 47,329       | 47     | 441,034                          | 108   | (426,953)              | 23,732                          |
| Net loss   |                 |         |              |        |                                  |   | (16,982)               | (16,982)                        |
| Other comprehensive loss   |                 |         |              |        |                                  | (108)   |                        | (108)                           |
| Issuance of common stock from public offering, net of expenses of \$420                          |                 |         | 3,701        | 4      | 9,674                            |   |                        | 9,678                           |
| Issuance of common stock from exercise of stock options and/or warrants, and purchases from ESPP |                 |         | 181          |        | 143                              |   |                        | 143                             |
| Stock-based compensation   |                 |         |              |        | 1,850                            |   |                        | 1,850                           |
| Balance at December 31, 2011   | 3               | 9,496   | 51,211       | 51     | 452,701                          |   | (443,935)              | 18,313                          |
| Net loss   |                 |         |              |        |                                  |   | (15,917)               | (15,917)                        |
| Issuance of common stock from public offering, net of expenses of \$550                          |                 |         | 4,487        | 5      | 13,816                           |   |                        | 13,821                          |
| Issuance of common stock from exercise of stock options and/or warrants, and purchases from ESPP |                 |         | 221          |        | 349                              |   |                        | 349                             |
| Preferred stock conversion   | (3)             | (9,496) | 333          |        | 9,496                            |   |                        |                                 |
| Stock-based compensation   |                 |         |              |        | 2,541                            |   |                        | 2,541                           |
| 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 expenses of \$2,733                        |                 |         | 15,019       | 15     | 61,439                           |   |                        | 61,454                          |
| Issuance of common stock from exercise of stock options and/or 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                       |

See accompanying Notes to Consolidated Financial Statements.



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

(in thousands)

|   | Year Ended December 31, |                 |                 |
|---|-------------------------|-----------------|-----------------|
|   | 2013                    | 2012            | 2011            |
| <b>Operating activities</b>   |                         |                 |                 |
| Net loss  | \$ (43,337)             | \$ (15,917)     | \$ (16,982)     |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |                 |                 |
| Depreciation and amortization   | 557                     | 744             | 922             |
| Stock-based compensation  | 3,268                   | 2,541           | 1,850           |
| Changes in valuation of outstanding warrant liability                       | 15,099                  | (2,059)         | (486)           |
| (Interest expense paid) non-cash interest expense                           | (25)                    | 20              | 5               |
| Loss on disposal of equipment   | 56                      |                 |                 |
| Deferred income taxes   | 27                      | 62              |                 |
| Changes in operating assets and liabilities:                                |                         |                 |                 |
| Accounts receivable   | (1,681)                 | 1,652           | (1,304)         |
| Inventories   | (1,813)                 | (3,740)         | (601)           |
| Other assets  | 339                     | (1,663)         | (13)            |
| Accounts payable  | (1,512)                 | 2,506           | 1,450           |
| Accrued liabilities   | 2,121                   | 1,971           | (336)           |
| Deferred revenue  | 104                     | (34)            | (137)           |
| <b>Net cash used in operating activities</b>                                | <b>(26,797)</b>         | <b>(13,917)</b> | <b>(15,632)</b> |
| <b>Investing activities</b>   |                         |                 |                 |
| Purchases of furniture, equipment and leasehold improvements                | (663)                   | (81)            | (158)           |
| (Purchases) sales of certain other assets                                   | (15)                    | (1)             | 55              |
| Purchases of investments  | (30,010)                |                 |                 |
| Maturities of investments   | 1,631                   | 287             | 666             |
| <b>Net cash provided by (used in) investing activities</b>                  | <b>(29,057)</b>         | <b>205</b>      | <b>563</b>      |
| <b>Financing activities</b>   |                         |                 |                 |
| Net proceeds from equity incentives and the exercise of warrants            | 1,684                   | 332             | 143             |
| Net proceeds from public offering   | 61,425                  | 14,226          | 9,273           |
| Proceeds from revolving line of credit                                      | 3,102                   | 1,810           | 2,300           |
| Proceeds from debt, net of discount   |                         |                 | 4,910           |
| Payments on revolving line of credit  | (2,926)                 | (920)           |                 |
| Payments on debt and landlord provided leasehold incentives                 | (4,642)                 | (537)           | (5,008)         |
| <b>Net cash provided by financing activities</b>                            | <b>58,643</b>           | <b>14,911</b>   | <b>11,618</b>   |
| <b>Net increase (decrease) in cash and cash equivalents</b>                 | <b>2,789</b>            | <b>1,199</b>    | <b>(3,451)</b>  |
| Cash and cash equivalents, beginning of period                              | 26,696                  | 25,497          | 28,948          |
| Cash and cash equivalents, end of period                                    | \$ 29,485               | \$ 26,696       | \$ 25,497       |
| <b>Supplemental disclosures:</b>  |                         |                 |                 |
| Non-cash conversion of preferred stock to common stock                      | \$                      | \$ 9,496        | \$              |
| Cash paid for interest  | \$ 294                  | \$ 460          | \$ 1,024        |
| Cash paid for income taxes  | \$ 146                  | \$ 162          | \$ 125          |
| Non-cash settlement of warranty claim                                       | \$ 1,272                | \$              | \$              |

See accompanying Notes to Consolidated Financial Statements.



---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2013**

**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 inactivation. 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 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. (collectively 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 United States of America ( 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, the Company evaluates its 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 its deferred tax assets and uncertain income tax positions. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable under the circumstances, the results of which form its 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.

**Reclassifications**

In 2012, certain reclassifications have been made to prior period reported amounts to conform to the current period presentations. Previously the Company had presented its provision for income taxes as a component of other income (expense), net on the Consolidated Statements of Operations. The Company has reclassified the provision for income taxes to a separate line item in the Consolidated Statements of Operations, and as presented in Note 17. This reclassification had no impact on net loss, total assets or total stockholders' equity.

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

**Revenue**

Revenue is recognized when (i) persuasive evidence of an agreement exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is reasonably assured. The Company's main sources of revenues for the years ended December 31, 2013, 2012 and 2011 were product revenue from sales of the INTERCEPT Blood System for platelets and plasma ( platelet and plasma systems ) and United States government grants and awards.

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company's INTERCEPT Blood System products, the Company uses a binding purchase order and signed sales contract as evidence of a written agreement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract.

For revenue arrangements with multiple elements, the Company recognizes revenue in accordance with Financial Accounting Standards Board Accounting Standard Codification ( ASC ) Topic 605-25, *Revenue Recognition Arrangements with Multiple Deliverables*, as applicable. 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 based on its best estimate of selling price. The Company has determined that vendor specific objective evidence is not discernible due to the Company's variability in its pricing across the regions into which it sells its products. Since the Company's products are novel and unique and are not sold by others, third-party evidence of selling price is unavailable.

At both December 31, 2013 and 2012, the Company had \$0.2 million and \$0.1 million, respectively, of short-term deferred revenue on its consolidated balance sheets related to future performance obligations. Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs*. Value-added-taxes ( VAT ) that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such VAT from product revenue.

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

**Research and Development Expenses**

In accordance with ASC Topic 730, *Accounting for Research and Development Expenses*, research and development expenses are charged to expense when incurred, including cost incurred under each grant that has

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

been awarded to the Company by the United States government or development contracts. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

The Company's use of estimates in recording accrued liabilities for research and development activities (see "Use of Estimates" above) affects the amounts of research and development expenses recorded and revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

**Cash Equivalents**

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

**Short-Term Investments**

Investments with original maturities of greater than three months which included corporate debt and United States government agency securities, are designated as available-for-sale and classified as short-term investments. In accordance with ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities*, the Company classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. 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 gains (losses) on available-for-sale securities, net of taxes" on the Company's consolidated statements of comprehensive loss. Realized gains and 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 reviewed all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value.

**Restricted Cash**

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

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of investments and accounts receivable.

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

Pursuant to the Company's investment policy, substantially all of the Company's investments are maintained at a major financial institution in the United States of high credit standing, which at times, may exceed federally insured limits. The Company has not experienced any losses in its investments and believes it is not exposed to any significant risk.

Concentrations of credit risk with respect to trade receivables exist. However, in connection with the Company's revolving line of credit, as discussed in Note 11 in the Notes to Consolidated Financial Statements, the Company purchased a credit insurance policy that mitigates some of its credit risk, as the policy will pay either the Company or its lender on eligible claims filed on its outstanding receivables. On a regular basis, including at the time of sale, the Company performs credit evaluations of its customers. 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 two customers and three customers that accounted for more than 10% of the Company's outstanding trade receivables at December 31, 2013 and 2012, respectively. These customers cumulatively represented approximately 48% and 59% of the Company's outstanding trade receivables at December 31, 2013 and 2012, respectively. To date, the Company has not experienced collection difficulties from these customers.

**Inventories**

At December 31, 2013 and 2012, 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, which can exceed one year, before being incorporated and assembled by Fresenius Kabi AG ( Fresenius ) into the finished INTERCEPT disposable kits. Fresenius is the successor-in-interest to Fenwal, Inc., or Fenwal, and Baxter International, Inc., or Baxter, under certain agreements which arose from the sale of the transfusion therapies division of Baxter in 2007 to Fenwal. Fenwal was recently acquired by Fresenius, which assumed Fenwal's rights and obligations under these certain agreements, including the Company's manufacturing and supply agreement with Fenwal. In these footnotes references to Fresenius include references to its predecessors-in-interest. 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 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 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 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, 2013 and 2012, 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 consumed for production and subsequently sold within each respective subsequent twelve-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or market value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use to net

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

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 its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of product revenue on the Company's consolidated statements of operations. At December 31, 2013, and 2012, the Company had \$0.4 million and \$0.3 million, respectively, reserved for potential obsolete, expiring or unsalable product. At December 31, 2012, the Company also wrote-down the value of certain unsalable inventory of \$1.7 million for which the Company had an offsetting warranty claim against Fresenius. As of December 31, 2013 the Company no longer has a warranty claim against Fresenius and all unsalable inventory has been returned to Fresenius.

See below in Note 2 and Note 16 for further information regarding the Company's warranty claim against Fresenius.

**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.

**Goodwill and Intangible Assets, net**

Additions to goodwill and intangible assets, net are derived at the time of a business acquisition, in which the Company assigns the total consideration transferred to the acquired assets based on each asset's fair value and any residual amount becomes goodwill, an indefinite life intangible asset. Intangible assets, net, which include a license for the right to commercialize the INTERCEPT Blood System in Asia, are subject to ratable amortization over the estimated useful life of ten years. The amortization of the Company's intangible assets, net, is recorded in Amortization of intangible assets on the Company's consolidated statements of operations.

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

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

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 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 8 for further information regarding the Company's impairment analysis and the valuation of goodwill and intangible assets, net.

**Long-lived Assets**

The Company evaluates its long-lived assets for impairment by continually monitoring events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets. The Company did not recognize impairment charges related to its long-lived assets during the years ended December 31, 2013, 2012 and 2011.

**Foreign Currency Remeasurement**

The functional currency of the Company's foreign subsidiary is the United States dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in United States dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in United States dollars using historical exchange rates. Monetary revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company's consolidated statements of operations as a component of foreign exchange gain (loss). The Company recorded foreign currency gains of \$0.5 million and \$0.1 million and a loss of \$0.5 million during the years ended December 31, 2013, 2012 and 2011, respectively.

**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



---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

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

**Warrant Liability**

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

The fair value of these outstanding warrants is calculated using a combination of the Black-Scholes model and/or binomial-lattice option-pricing model and is adjusted accordingly at each reporting period. Option-pricing models require that the Company uses significant assumptions and judgment to determine appropriate inputs to the model. Some of the assumptions that the Company relies on include the volatility of the Company's stock over the life of the warrant, risk-free interest rate and the probability of a change of control occurring. The binomial-lattice option-pricing model also considers a certain number of share price movements and the probability of each outcome happening.

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

See Note 13 for further information regarding the Company's valuation of warrant liability.

**Income Taxes**

The Company accounts for income taxes using the asset and liability approach in accordance with ASC Topic 740 *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC Topic 740 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in ASC Topic 740 is not an appropriate substitute for the derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. The Company had no unrecognized tax benefits as of December 31, 2013 and 2012. The Company continues to carry a full

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

valuation allowance on all of its deferred tax assets. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's tax years 1998 through 2013 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

**Net Loss Per Common Share**

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common 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 common share also gives effect to potential adjustments to the numerator for changes 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 be dilutive.

Diluted net loss per common share used the same weighted average number of common shares outstanding for the years ended December 31, 2013 and 2011, as calculated for the basic net loss per common share as the inclusion of any potential dilutive securities would be anti-dilutive. In addition, certain potential dilutive securities were excluded from the dilution calculation for the years ended December 31, 2012, as their inclusion would have been anti-dilutive.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per common share for the years ended December 31, 2013, 2012 and 2011 (in thousands, except per share amounts):

|   | <b>Year Ended December 31,</b> |             |             |
|---|--------------------------------|-------------|-------------|
|   | <b>2013</b>                    | <b>2012</b> | <b>2011</b> |
| <b>Numerator:</b>   |                                |             |             |
| Net loss  | \$ (43,337)                    | \$ (15,917) | \$ (16,982) |
| Effect of revaluation of warrant liability  |                                | (2,059)     |             |
| Adjusted net loss used for dilution calculation   | \$ (43,337)                    | \$ (17,976) | \$ (16,982) |
| <b>Denominator:</b>   |                                |             |             |
| Basic weighted average number of common shares outstanding                                      | 67,569                         | 54,515      | 48,050      |
| Effect of dilutive potential common shares resulting from warrants accounted for as liabilities |                                | 546         |             |
| Diluted weighted average number of common shares outstanding                                    | 67,569                         | 55,061      | 48,050      |
| Basic   | \$ (0.64)                      | \$ (0.29)   | \$ (0.35)   |
| Diluted   | \$ (0.64)                      | \$ (0.33)   | \$ (0.35)   |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

The table below presents common 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 common shares outstanding used for the calculation of diluted net loss per common share. These were excluded from the calculation due to their anti-dilutive effect for the years ended December 31, 2013, 2012 and 2011 (shares in thousands):

|                             | <b>Year Ended December 31,</b> |             |             |
|-----------------------------|--------------------------------|-------------|-------------|
|                             | <b>2013</b>                    | <b>2012</b> | <b>2011</b> |
| Anti-dilutive common shares | 16,370                         | 8,716       | 13,595      |

**Guarantee and Indemnification Arrangements**

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company after December 31, 2002. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements that the Company is a party to contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company's technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company's products have caused personal injury or other damage or loss. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. During the year ended December 31, 2012, the Company provided for and settled the claims for warranty obligations of \$0.9 million related to replacement costs for certain of its products that the Company identified were defective or had the potential of being defective. Prior to this incident, there have been very few warranty costs incurred. As a result, the Company had not accrued for any potential future warranty costs at December 31, 2011. In addition, the Company believes that the defective products and those that had the potential of being defective identified during the year ended December 31, 2012 are isolated. Accordingly, the Company has not accrued for any other incremental potential future warranty costs for its products at December 31, 2013.

In connection with the warranty obligations provided for in relation to certain of its products during the year ended December 31, 2012, the Company filed a warranty claim against Fresenius, which Fresenius accepted. As a result, the Company recorded a current asset of \$1.8 million on its consolidated balance sheets as of December 31, 2012 representing the full amount of the warranty claim against Fresenius as Fresenius will supply the Company with replacement products or credit notes for those defective or potentially defective products. The Company also wrote-down the value of certain unsalable inventory of \$1.7 million related to these products as an offsetting warranty claim against Fresenius. As of December 31, 2013 the Company no longer has a warranty claim against Fresenius and all unsalable inventory has been returned to Fresenius.

**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

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

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

See Notes 4 and 13 for further information regarding the Company's valuation on financial instruments.

**New Accounting Pronouncements**

There have been no new accounting pronouncements issued during the year ended December 31, 2013, that are of significance, or potential significance, to the Company.

**Note 3. BioOne Acquisition**

On August 24, 2010, the Company acquired certain assets of BioOne, a privately held Japanese company established to develop technologies to improve the safety of blood products in Asia. The assets included the commercialization licenses that the Company had granted to BioOne for both the platelet and plasma systems, illuminators held as saleable inventory and demonstration illuminators. No liabilities were assumed.

The following table summarizes the fair value of assets acquired at the acquisition date (in thousands):

|                                 |                 |
|---------------------------------|-----------------|
| Commercialization rights - Asia | \$ 2,017        |
| Illuminators - inventory        | 270             |
| Demonstration illuminators      | 135             |
| Goodwill                        | 1,316           |
| <b>Total</b>                    | <b>\$ 3,738</b> |

The Company is amortizing the commercialization rights over a ten year period and annually evaluates the goodwill for impairment. See Note 8 for further information regarding the Company's impairment analysis and the valuation of goodwill and intangible assets, net.

Certain illuminators acquired in connection with this transaction which remain unsold are classified as consigned equipment or demonstration equipment and reflected in property and equipment, net. See Note 7 for further information regarding the Company's property and equipment, net.

**Note 4. Fair Value on Financial Instruments**

We determined the fair value of an asset or liability based on the assumptions that market participants would use in pricing the asset or liability in an orderly transaction between market participants at the measurement date.



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

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, 2013 our primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and United States government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

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

|   | Total     | Quoted<br>Prices in<br>Active<br>Markets for<br>Identical<br>Assets<br>(Level 1) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|---|-----------|--|---|--|
| Money market funds <sup>(1)</sup>                         | \$ 8,650  | \$ 8,650   | \$  | \$   |
| Corporate debt securities <sup>(2)</sup>                  | \$ 23,173 |  | \$ 23,173   |  |
| United States government agency securities <sup>(2)</sup> | \$ 5,018  |  | \$ 5,018  |  |
| Total financial assets                                    | \$ 36,841 | \$ 8,650   | \$ 28,191   | \$   |
| Warrant liability <sup>(3)</sup>                          | \$ 20,390 | \$   | \$  | \$ 20,390  |
| Total financial liabilities                               | \$ 20,390 | \$   | \$  | \$ 20,390  |

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

- (1) Included in cash and cash equivalents on the Company's consolidated balances sheets.
- (2) Included in short-term investments on the Company's consolidated balance sheets.
- (3) Included in current liabilities on the Company's consolidated balance sheets.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

The fair values of certain of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2012 (in thousands):

|                                   | <b>Total</b> | <b>Quoted<br/>Prices in<br/>Active<br/>Markets for<br/>Identical<br/>Assets<br/>(Level 1)</b> | <b>Significant<br/>Other<br/>Observable<br/>Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable<br/>Inputs<br/>(Level 3)</b> |
|-----------------------------------|--------------|---|--|--|
| Money market funds <sup>(1)</sup> | \$ 10,268    | \$ 10,268   | \$   | \$   |
| Total financial assets            | \$ 10,268    | \$ 10,268   | \$   | \$   |
| Warrant liability <sup>(2)</sup>  | \$ 5,903     | \$  | \$   | \$ 5,903   |
| Total financial liabilities       | \$ 5,903     | \$  | \$   | \$ 5,903   |

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

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

A reconciliation of the beginning and ending balances for warrant liability using significant unobservable inputs (Level 3) from December 31, 2011 to December 31, 2013 was as follows (in thousands):

|                                    |           |
|------------------------------------|-----------|
| Balance at December 31, 2011       | \$ 7,979  |
| Decrease in fair value of warrants | (2,059)   |
| Settlement of warrants exercised   | (17)      |
| Balance at December 31, 2012       | 5,903     |
| Increase in fair value of warrants | 15,099    |
| Settlement of warrants exercised   | (612)     |
| Balance at December 31, 2013       | \$ 20,390 |

See Notes 1 and 13 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, 2013 and 2012.



**Note 5. Available-for-sale Securities**

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

|  | Carrying Value | December 31, 2013<br>Gross<br>Unrealized Gain | Fair Value |
|--|----------------|---|------------|
| Money market funds                         | \$ 8,650       | \$  | \$ 8,650   |
| United States government agency securities | 5,019          | (1)   | 5,018      |
| Corporate debt securities                  | 23,165         | 8   | 23,173     |
| Total available-for-sale securities        | \$ 36,834      | \$ 7  | \$ 36,841  |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

The following is a summary of available-for-sale securities at December 31, 2012 (in thousands):

|                                     | Carrying Value | December 31, 2012        |            |
|-------------------------------------|----------------|--------------------------|------------|
|                                     |                | Gross<br>Unrealized Gain | Fair Value |
| Money market funds                  | \$ 10,268      | \$                       | \$ 10,268  |
| Total available-for-sale securities | \$ 10,268      | \$                       | \$ 10,268  |

Available-for-sale securities at December 31, 2013 and 2012 consisted of the following by original contractual maturity (in thousands):

|  | December 31, 2013 |            | December 31, 2012 |            |
|--|-------------------|------------|-------------------|------------|
|  | Carrying<br>Value | Fair Value | Carrying<br>Value | Fair Value |
| Due in one year or less                            | \$ 30,700         | \$ 30,701  | \$ 10,268         | \$ 10,268  |
| Due greater than one year and less than five years | 6,134             | 6,140      |                   |            |
| Total available-for-sale securities                | \$ 36,834         | \$ 36,841  | \$ 10,268         | \$ 10,268  |

The Company recorded minimal gross realized gains from the sale or maturity of available-for-sale investments during the year ended December 31, 2011 and did not record any gross realized gains from the sale or maturity of available-for-sale investments during the years ended December 31, 2013 and 2012. The Company recorded minimal 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, 2012 and 2011. The Company did not record losses on investments experiencing an other-than-temporary decline in fair value during the years ended December 31, 2013, 2012 and 2011.

**Note 6. Inventories**

Inventories at December 31, 2013 and 2012 consisted of the following (in thousands):

|                   | December 31, |           |
|-------------------|--------------|-----------|
|                   | 2013         | 2012      |
| Work-in-process   | \$ 4,863     | \$ 3,551  |
| Finished goods    | 8,200        | 6,629     |
| Total inventories | \$ 13,063    | \$ 10,180 |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013****Note 7. Property and Equipment, net**

Property and equipment, net at December 31, 2013 and 2012 consisted of the following (in thousands):

|  | December 31,    |                 |
|--|-----------------|-----------------|
|  | 2013            | 2012            |
| Leasehold improvements                     | \$ 5,628        | \$ 5,598        |
| Machinery and equipment                    | 1,751           | 1,594           |
| Demonstration equipment                    | 100             | 24              |
| Office furniture                           | 763             | 644             |
| Computer equipment                         | 651             | 550             |
| Computer software                          | 1,083           | 1,062           |
| Consigned demonstration equipment          | 642             | 493             |
| Construction-in-progress                   | 155             | 55              |
| <b>Total property and equipment, gross</b> | <b>10,773</b>   | <b>10,020</b>   |
| Accumulated depreciation and amortization  | (8,584)         | (8,322)         |
| <b>Total property and equipment, net</b>   | <b>\$ 2,189</b> | <b>\$ 1,698</b> |

Depreciation and amortization expense related to property and equipment, net was \$0.4 million, \$0.4 million and \$0.6 million for the years ended December 31, 2013, 2012 and 2011, respectively.

**Note 8. Goodwill and Intangible Assets, net***Goodwill*

During the year ended December 31, 2013, the Company did not dispose of or recognize additional goodwill. On August 31, 2013, the Company performed its annual review 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. Accordingly, at both December 31, 2013 and 2012, the carrying amount of goodwill was \$1.3 million.

*Intangible Assets, net*

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

|  | Gross Carrying<br>Amount | December 31, 2013<br>Accumulated<br>Amortization | Net Carrying<br>Amount |
|--|--------------------------|--|------------------------|
| Acquisition-related intangible assets: |                          |  |                        |

Edgar Filing: CERUS CORP - Form 10-K

|                                   |          |          |          |
|-----------------------------------|----------|----------|----------|
| Reacquired license INTERCEPT Asia | \$ 2,017 | \$ (673) | \$ 1,344 |
| Total intangible assets           | \$ 2,017 | \$ (673) | \$ 1,344 |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

The following is a summary of intangible assets, net at December 31, 2012 (in thousands):

|   | Gross Carrying<br>Amount | December 31, 2012<br>Accumulated<br>Amortization | Net Carrying<br>Amount |
|---|--------------------------|--|------------------------|
| <b>Acquisition-related intangible assets:</b> |                          |  |                        |
| Reacquired license INTERCEPT Asia             | \$ 2,017                 | \$ (471)   | \$ 1,546               |
| <b>Total intangible assets</b>                | <b>\$ 2,017</b>          | <b>\$ (471)</b>                                  | <b>\$ 1,546</b>        |

The Company recognized \$0.2 million in amortization expense related to intangible assets for each of the years ended December 31, 2013 and 2012. During the years ended December 31, 2013 and 2012, there were no impairment charges recognized related to the Company's intangible assets.

At December 31, 2013, the expected annual amortization expense of the intangible assets, net is \$0.2 million beginning with the year ending December 31, 2014 and each subsequent year thereafter through the year ending December 31, 2019, and \$0.1 million for the year ending December 31, 2020.

**Note 9. Long-Term Investments**

In connection with the agreements to license the immunotherapy technologies to Aduro BioTech (Aduro) in 2009, the Company received preferred shares of Aduro, a privately held company. Pursuant to these license agreements, the Company is eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. For the years ended December 31, 2013, 2012 and 2011, the Company has not received any royalty payments from Aduro pursuant to this agreement. As of December 31, 2013, the Company's ownership in Aduro was less than 3% on a fully diluted basis. Since receiving preferred stock in Aduro, the Company has carried its investment in Aduro at zero in its consolidated balance sheet.

**Note 10. Accrued Liabilities**

Accrued liabilities at December 31, 2013 and 2012 consisted of the following (in thousands):

|   | December 31,    |                 |
|---|-----------------|-----------------|
|   | 2013            | 2012            |
| Accrued compensation and related costs      | \$ 2,527        | \$ 2,692        |
| Accrued inventory costs                     | 3,553           | 2,352           |
| Accrued contract and other accrued expenses | 3,733           | 2,575           |
| <b>Total accrued liabilities</b>            | <b>\$ 9,813</b> | <b>\$ 7,619</b> |

Table of Contents

## CERUS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2013

**Note 11. Debt**

Debt at December 31, 2013 consisted of the following (in thousands):

|   | Principal | December 31, 2013<br>Unamortized<br>Discount | Total    |
|---|-----------|--|----------|
| Comerica Revolving Line of Credit, due 2014 | \$ 3,366  | \$   | \$ 3,366 |
| Total debt                                  | 3,366     |  | 3,366    |
| Less: debt current                          | (3,366)   |  | (3,366)  |
| Debt non-current                            | \$        | \$   | \$       |

Debt at December 31, 2012 consisted of the following (in thousands):

|   | Principal | December 31, 2012<br>Unamortized<br>Discount | Total    |
|---|-----------|--|----------|
| Comerica Growth Capital Loan A, due 2015    | \$ 4,583  | \$ (49)                                      | \$ 4,534 |
| Comerica Revolving Line of Credit, due 2014 | 3,190     |  | 3,190    |
| Total debt                                  | 7,773     | (49)   | 7,724    |
| Less: debt current                          | (4,857)   | 29   | (4,828)  |
| Debt non-current                            | \$ 2,916  | \$ (20)                                      | \$ 2,896 |

Principal and interest payments on debt at December 31, 2013 are expected to be \$3.5 million during 2014 after which the Revolving Line of Credit will have been retired.

*2011 Growth Capital Facility*

The Company entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, with Comerica Bank (Comerica) (collectively, the Amended Credit Agreement). The Amended Credit Agreement provides for an aggregate borrowing of up to \$12.0 million, comprised of a growth capital loan of \$5.0 million (Growth Capital Loan) and a formula based revolving line of credit (RLOC) of up to \$7.0 million. 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 Amended Credit Agreement.

Growth Capital Loan

Concurrent with the execution of the original loan and security agreement in September 2011, the Company borrowed \$5.0 million under the Growth Capital Loan, substantially all of which was used to repay the Company's prior debt with Oxford Finance Corporation (Oxford), with the

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

remainder used for general corporate purposes. The Growth Capital Loan, which was scheduled to mature on September 30, 2015, and bore a fixed interest rate of 6.37%, with interest only payments due for the first twelve months, followed by equal principal and interest payments for the remaining 36 months. In April 2013, the Company repaid in full the Growth Capital Loan balance and all accrued interest as well as a scheduled final payment fee of \$0.05 million, in an aggregate amount of \$4.2 million. The Company has no further obligations, nor are there any further funds available, under the Growth Capital Loan.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

In September 2011, the Company incurred a commitment fee of \$40,000 and loan fees of \$50,000, which were recorded as a discount to its Growth Capital Loan and were being amortized as a component of interest expense using the effective interest method over the term of the Growth Capital Loan (discount was based on an implied interest rate of 7.07%). The Company was also required to make a final payment fee of 1% of the amounts drawn under the Growth Capital Loan due on its prepayment of the Growth Capital Loan. The final payment fee was accreted to interest expense using the effective interest method over the life of the Growth Capital Loan upon draw. The remaining unaccreted balance of the final payment fee and unamortized discount was taken as an interest charge in April 2013 in connection with the repayment of that loan.

**Revolving Line of Credit**

The Amended Credit Agreement provides for a RLOC of up to \$7.0 million (the RLOC Loan Amount). The amount available under the RLOC is limited to the lesser of (i) 80% of eligible trade receivables or (ii) the RLOC Loan Amount. At December 31, 2013 and 2012, the Company had \$3.4 million and \$3.2 million, respectively, outstanding under the RLOC. The Company is required to repay the principal drawn from the RLOC at the end of the RLOC term on June 30, 2014, or earlier if a portion or all of the outstanding RLOC exceeds the amount available under the RLOC. The RLOC bears a floating rate based on the lender's prime rate plus 1.50%, with interest only payments due each month. At both December 31, 2013 and 2012, the floating rate of the RLOC was at 4.75%. In September 2011, the Company incurred a commitment fee of \$20,000. Upon amendment of the loan and security agreement in June 2012, the Company incurred another annual commitment fee of \$20,000 and received a credit for the unused portion of the initial fee. The Company incurs a \$20,000 commitment fee at each annual anniversary beginning June 30, 2013.

**Compliance with Covenants**

The Company is required to maintain compliance with certain customary and routine financial covenants under the Amended Credit Agreement, including maintaining a minimum cash balance of \$2.5 million at Comerica and achieving minimum revenue levels, which are measured monthly based on a six-month trailing basis and must be at least 75% of the pre-established future projected revenues for the trailing six-month period. Non-compliance with the covenants could result in the principal of the note becoming due and payable. As of December 31, 2013, the Company was in compliance with the financial covenants as set forth in the Amended Credit Agreement.

**Note 12. Commitments and Contingencies****Operating Leases**

The Company leases its office facilities, located in Concord, California and Amersfoort, The Netherlands, and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2019, with certain of the leases providing for renewal options, provisions for adjusting future lease payments, which is based on the consumer price index and the right to terminate the lease early, which may occur as early as January 2015. In June 2013 the Company entered into a new lease for additional space in Concord. The lease has a two year initial term with four (4) two year options for the Company to renew. The lease commenced on August 1, 2013 and obligates the Company to make rent payments of \$154,368 and \$90,048 in 2014 and 2015, respectively. 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.



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

Future minimum non-cancelable lease payments under operating leases as of December 31, 2013 are as follows (in thousands):

| <b>Year ended December 31,</b>               |          |
|--|----------|
| 2014   | \$ 1,147 |
| 2015   | 553      |
| 2016   | 142      |
| 2017   | 68       |
| 2018 and thereafter                          | 9        |
| Total minimum non-cancellable lease payments | \$ 1,919 |

Rent expense for office facilities was \$0.7 million, \$0.6 million and \$0.7 million for the years ended December 31, 2013, 2012 and 2011, respectively.

*Financed Leasehold Improvements*

In December 2010, the Company financed \$1.1 million of leasehold improvements. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the respective leases. If the Company exercises its right to early terminate the original Concord California lease, which may occur as early as January 2015, the Company would be required to repay for any remaining portion of the landlord financed leasehold improvements at such time. At December 31, 2013, the Company had an outstanding liability of \$0.7 million related to these leasehold improvements, of which \$0.1 million was reflected in *Accrued liabilities* and \$0.6 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 and supplies to Fresenius at no cost for use in manufacturing finished INTERCEPT disposable kits. Certain of these agreements require minimum purchase commitments from the Company. The Company has paid \$6.5 million, \$7.2 million and \$3.6 million for goods under agreements which are subject to minimum purchase commitments during the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, the Company has future minimum purchase commitments under these agreements of \$3.4 million for the year ending December 31, 2014 and less than \$1.3 million for each subsequent year thereafter through December 31, 2016.

**Note 13. Stockholders' Equity***Series B Convertible Preferred Stock*

In March 1999, the Company issued 3,327 shares of the Company's Series B convertible preferred stock to Fresenius. The Series B convertible preferred stock had no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B convertible preferred stock as to voting, liquidation or conversion or with respect to the determination of fair value of non-publicly traded shares received by the holder of Series B convertible preferred stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder had the ability to convert each share of Series B convertible preferred



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

stock into 100 shares of the Company's common stock. The Company had the right to redeem the Series B convertible preferred stock prior to conversion for a payment of \$9.5 million. In June 2012, Fresenius exercised its right to convert all 3,327 shares of the Company's Series B convertible preferred stock. As a result, the Company issued 332,700 shares of its common stock to Fresenius and retired the outstanding Series B convertible preferred stock.

*Common Stock and Associated Warrant Liability*

In August 2009, the Company issued warrants to purchase 2.4 million shares of common stock, exercisable at an exercise price of \$2.90 per share (2009 Warrants). The 2009 Warrants are exercisable for a period of five years from the issue date. The fair value on the date of issuance of the 2009 Warrants was determined to be \$2.8 million using the Black-Scholes model and/or binomial-lattice option valuation model and applying the following assumptions: (i) a risk-free rate of 2.48%, (ii) an expected term of 5.0 years, (iii) no dividend yield and (iv) a volatility of 77%.

In November 2010, the Company received net proceeds of approximately \$19.7 million, after deducting underwriting discounts and commissions and stock issuance costs of approximately \$1.3 million, from an underwritten public offering of 7.4 million units. Each unit sold consisted of one share of common stock and a warrant to purchase 1/2 of a share of common stock. Each unit was sold for \$2.85, resulting in the issuance of 7.4 million shares of common stock and warrants to purchase 3.7 million shares of common stock, exercisable at an exercise price of \$3.20 per share (2010 Warrants). The warrants issued in November 2010 became exercisable on May 15, 2011 and are exercisable for a period of five years from the issue date. The fair value on the date of issuance of the 2010 Warrants was determined to be \$5.8 million using the Black-Scholes model and/or binomial-lattice option valuation model and applying the following assumptions: (i) a risk-free rate of 1.23%, (ii) an expected term of 5.0 years, (iii) no dividend yield and (iv) a volatility of 85%.

The fair value of the 2009 Warrants and 2010 Warrants was recorded on the consolidated balance sheets as a liability pursuant to *Accounting for Derivative Instruments and Hedging Activities* and *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* Topics of ASC and will be adjusted to fair value at each financial reporting date thereafter until the earlier of exercise or modification to remove the provisions which require the warrants to be treated as a liability, at which time, these warrants would be reclassified into stockholders' equity. The Company classified the 2009 Warrants and 2010 Warrants as a liability as these warrants contain certain provisions that, under certain circumstances, which may be out of the Company's control, could require the Company to pay cash to settle the exercise of the warrants or may require the Company to redeem the warrants.

The fair value of the warrants at December 31, 2013 and 2012 consisted of the following (in thousands):

|                                | <b>December 31,</b> |                 |
|--------------------------------|---------------------|-----------------|
|                                | <b>2013</b>         | <b>2012</b>     |
| 2009 Warrants                  | \$ 8,542            | \$ 2,009        |
| 2010 Warrants                  | 11,848              | 3,894           |
| <b>Total warrant liability</b> | <b>\$ 20,390</b>    | <b>\$ 5,903</b> |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

The fair value of the Company's warrants was based on using the Black-Scholes model and/or binomial-lattice option valuation model and using the following assumptions at December 31, 2013 and 2012:

|                          | <b>December 31,</b> |             |
|--------------------------|---------------------|-------------|
|                          | <b>2013</b>         | <b>2012</b> |
| <b>2009 Warrants:</b>    |                     |             |
| Expected term (in years) | 0.65                | 1.65        |
| Estimated volatility     | 45%                 | 45%         |
| Risk-free interest rate  | 0.10%               | 0.25%       |
| Expected dividend yield  | 0%                  | 0%          |
| <b>2010 Warrants:</b>    |                     |             |
| Expected term (in years) | 1.86                | 2.86        |
| Estimated volatility     | 41%                 | 51%         |
| Risk-free interest rate  | 0.38%               | 0.36%       |
| Expected dividend yield  | 0%                  | 0%          |

The Company recorded a non-cash loss of \$15.1 million and non-cash gains of \$2.1 million and \$0.5 million during the years ended December 31, 2013, 2012, and 2011, respectively, in Revaluation of warrant liability on the consolidated statements of operations due to the changes in fair value of the warrants. Significant changes to the Company's market price for its common stock will impact the implied and/or historical volatility used to fair value the warrants. As a result, any significant increases in the Company's stock price will likely create an increase to the fair value of the warrant liability. Similarly, any significant decreases in the Company's stock price will likely create a decrease to the fair value of the warrant liability. During the years ended December 31, 2013 and 2012, 2010 Warrants to purchase 0.2 million and 5,000 shares of common stock, respectively were exercised. At December 31, 2013 no 2009 Warrants have been exercised and an aggregate 5.9 million 2009 and 2010 Warrants remain outstanding.

*Sales Agreements*

The Company entered into an At-The-Market Issuance Sales Agreement in June 2011, as amended in January 2012 and August 2012 (collectively, the MLV Agreement), with MLV & Co. LLC, formerly McNicoll, Lewis & Vlak LLC (MLV) that provides for the issuance and sale of shares of the Company's common stock over the term of the MLV Agreement having an aggregate offering price of up to \$20.0 million through MLV. Under the MLV Agreement, MLV acts as the Company's sales agent and receives compensation based on an aggregate of 3% 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 MLV Agreement are deemed an at-the-market offering and are registered under the Securities Act. During the year ended December 31, 2012 and 2011, approximately 3.1 million and 3.5 million shares, respectively, of the Company's common stock were sold under the MLV Agreement for aggregate net proceeds of \$9.5 million and \$9.7 million, respectively. At December 31, 2013, the Company had less than \$0.1 million of common stock available to be sold under the MLV Agreement.

The Company also entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the Cantor Agreement) in August 2012, with Cantor Fitzgerald & Co. (Cantor) that provides for the issuance and sale of shares of its common stock over the term of the Cantor Agreement having an aggregate offering price of up to \$30.0 million through Cantor. Under the 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 Cantor Agreement are deemed an at-the-market offering and are registered under the Securities Act. During the years ended December 31, 2013 and

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

2012, approximately 5.4 million and 1.4 million shares, respectively, of the Company's common stock were sold under the Cantor Agreement for aggregate net proceeds of \$23.5 million and \$4.3 million, respectively. At December 31, 2013, the Company had approximately \$1.5 million of common stock available to be sold under the Cantor Agreement.

*Stockholder Rights Plan*

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

**Note 14. 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. Although the Purchase Plan provides for an offering period to be no more than 27 months, the Company currently allows eligible employees to purchase shares of the Company's common stock at the end of each six-month offering period 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 prior to 2012. Prior to June 6, 2012, the Purchase Plan, as amended by the Company's stockholders, had authorized and provided for issuance an aggregate of 820,500 shares of common stock. On June 6, 2012, the stockholders approved a further amendment to the Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance by 500,000 shares, such that the Purchase Plan has reserved for issuance an amount not to exceed 1,320,500 shares. At December 31, 2013, the Company had 514,820 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") which increased the aggregate number of shares of common stock authorized for issuance by 3,000,000 shares and 6,000,000 shares, respectively, such that the Amended 2008 Plan has reserved for issuance an amount not to exceed 19,540,940 shares. Awards under the 2008 Plan generally have a maximum term of 10 years from the date of the award. The 2008 Plan generally requires options to be granted at 100% of the fair market value of the

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

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, 2013, no performance-based stock options were outstanding.

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

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

At December 31, 2013, the Company had an aggregate of approximately 18.6 million shares of its common stock remaining available for future issuance under the Amended 2008 Plan, the Prior Plans and the 1996 Plan, of which approximately 10.5 million shares were subject to outstanding options and other stock-based awards, and approximately 8.1 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options.

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

|                               | <b>Number of<br/>Options<br/>Outstanding</b> | <b>Weighted Average<br/>Exercise Price<br/>per<br/>Share</b> |
|-------------------------------|--|--|
| Balances at December 31, 2010 | 7,007  | \$ 6.42  |
| Granted                       | 2,169  | 2.36   |
| Forfeited                     | (465)  | 2.45   |
| Expired                       | (1,237)                                      | 11.52  |
| Exercised                     | (112)  | 0.81   |
| Balances at December 31, 2011 | 7,362  | \$ 4.70  |
| Granted                       | 1,782  | 3.68   |
| Forfeited                     | (98)   | 2.78   |
| Expired                       | (386)  | 30.44  |
| Exercised                     | (156)  | 1.30   |
| Balances at December 31, 2012 | 8,504  | \$ 3.40  |
| Granted                       | 2,621  | 3.82   |
| Forfeited                     | (234)  | 3.13   |
| Expired                       | (189)  | 6.71   |
| Exercised                     | (297)  | 3.14   |
| Balances at December 31, 2013 | 10,405                                       | \$ 3.46  |



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2013 was as follows (in thousands except weighted average exercise price and contractual term):

|   | Number<br>of Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic<br>Value |
|---|---------------------|--|---|---------------------------------|
| <b>Balances at December 31, 2013</b>      |                     |  |   |                                 |
| Stock options outstanding                 | 10,405              | \$ 3.46                                  | 6.34  | \$ 32,724                       |
| Stock options vested and expected to vest | 10,028              | \$ 3.45                                  | 6.25  | \$ 31,730                       |
| Stock options exercisable                 | 6,589               | \$ 3.43                                  | 5.05  | \$ 21,555                       |

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, 2013, 2012 and 2011 was \$0.6 million, \$0.3 million and \$0.2 million, respectively.

*Restricted Stock Units*

The Company has previously granted restricted stock units primarily to its senior management in accordance with the Amended 2008 Plan. Subject to each grantee's continued employment, the restricted stock units generally vest in three annual installments from the date of grant and are generally issuable at the end of the three-year vesting term. The fair value of restricted stock units which vested during the years ended December 31, 2013, 2012 and 2011 was \$0.05 million, \$0.05 million and \$0.1 million, respectively.

Activity under the Company's equity incentive plans related to restricted stock units is set forth below:

|                                      | Number<br>of RSUs | Weighted Average<br>Grant-Date Fair<br>Value |
|--------------------------------------|-------------------|--|
| <b>Balances at December 31, 2010</b> |                   |  |
| Granted                              | 88,400            | \$ 2.54                                      |
| Forfeited                            | (17,727)          | 1.85   |
| Vested                               | (37,378)          | 3.48   |
| <b>Balances at December 31, 2011</b> |                   |  |
| Granted                              | 33,295            | \$ 1.85                                      |
| Forfeited                            | 2,000             | 3.03   |
| Vested                               | (18,650)          | 1.98   |
| <b>Balances at December 31, 2012</b> |                   |  |
| Granted                              | 16,645            | \$ 1.85                                      |
| Forfeited                            |                   | 0.00   |
|                                      |                   | 0.00   |



Edgar Filing: CERUS CORP - Form 10-K

|                               |          |      |
|-------------------------------|----------|------|
| Vested                        | (16,645) | 1.85 |
| Balances at December 31, 2013 |          | \$   |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013****Stock-based Compensation Expense**

Stock-based compensation expense recognized on the Company's consolidated statements of operations for the years ended December 31, 2013, 2012 and 2011, was as follows (in thousands):

|  | <b>Year Ended December 31,</b> |             |             |
|--|--------------------------------|-------------|-------------|
|  | <b>2013</b>                    | <b>2012</b> | <b>2011</b> |
| Stock-based compensation expense by caption: |                                |             |             |
| Research and development                     | \$ 482                         | \$ 554      | \$ 450      |
| Selling, general and administrative          | 2,786                          | 1,987       | 1,400       |
| Total stock-based compensation expense       | \$ 3,268                       | \$ 2,541    | \$ 1,850    |

Stock-based compensation expense in the above table does not reflect any income taxes as the Company has experienced a history of net losses since its inception and has a full valuation allowance on its deferred tax assets. In addition, there was neither income tax benefits realized related to stock-based compensation expense nor any stock-based compensation costs capitalized as part of an asset during the years ended December 31, 2013, 2012 and 2011. The Company has also not recorded any stock-based compensation associated with performance-based stock options during the years ended December 31, 2013, 2012 and 2011 as the performance criteria was not probable of being achieved.

As of December 31, 2013, the Company expects to recognize the remaining unamortized stock-based compensation expense of \$5.9 million related to non-vested stock options, net of estimated forfeitures, over an estimated remaining weighted average period of 2.56 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.

*Expected Term*

The Company estimates the expected term for stock options based on grouping the population of stock options into discreet, homogeneous groups and then analyzing employee exercise and post-vesting termination behavior. The Company may also average the vesting term and the contractual term of the stock options, as illustrated in SAB 107 and SAB 110, if the Company is unable to obtain sufficient information for a particular homogeneous group of stock options. The expected term for the shares issuable under the employee stock purchase plan is the term of each purchase period, which is six months.

*Estimated Forfeiture Rate*

The Company estimates the forfeiture rate of stock options at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. The Company estimates the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term.

*Estimated Volatility*

The Company estimates the volatility of its common stock by using historical volatility of its common stock. The Company has used significant judgment in making these estimates and will continue to monitor the availability of actively traded stock options on its common stock. The Company may also consider a combination of historical and implied volatility, or solely implied volatility, if the Company determines that sufficient actively traded stock options on its common stock exists.

*Risk-Free Interest Rate*

The Company uses the risk-free interest rate based on the yield derived from United States Treasury zero-coupon issues with remaining terms similar to the expected term on the stock options.

*Expected Dividend Yield*

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, 2013, 2012 and 2011, was as follows:

|   | Year Ended December 31, |       |       |
|---|-------------------------|-------|-------|
|   | 2013                    | 2012  | 2011  |
| <b>Stock Options:</b>                       |                         |       |       |
| Expected term (in years)                    | 5.59                    | 5.54  | 5.30  |
| Estimated volatility                        | 60%                     | 67%   | 68%   |
| Risk-free interest rate                     | 0.87%                   | 1.03% | 1.23% |
| Expected dividend yield                     | 0%                      | 0%    | 0%    |
| <b>Employee Stock Purchase Plan Rights:</b> |                         |       |       |
| Expected term (in years)                    | 0.50                    | 0.50  | 0.50  |
| Estimated volatility                        | 39%                     | 101%  | 48%   |
| Risk-free interest rate                     | 0.10%                   | 0.14% | 0.08% |
| Expected dividend yield                     | 0%                      | 0%    | 0%    |

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2013, 2012 and 2011, was \$2.03 per share, \$2.13 per share and \$1.37 per share, respectively. The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2012 was \$3.03 per share. The weighted average grant-date fair value of employee stock purchase rights during the years ended December 31, 2013, 2012 and 2011, was \$1.18 per share, \$1.43 per share and \$0.68 per share, respectively.

**Note 15. 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.



---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

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, 2013, 2012 and 2011.

**Note 16. Development and License Agreements**

**Agreements with Fresenius**

The Company has certain agreements with Fresenius which require the Company to pay royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. During the years ended December 31, 2013, 2012 and 2011, the Company made royalty payments to Fresenius of \$3.0 million, \$2.7 million and \$2.2 million, respectively. At December 31, 2013 and December 31, 2012, the Company owed Fresenius \$0.7 million and \$0.8 million, respectively, for royalties.

We also paid Fresenius certain costs associated with the amended manufacturing and supply agreement we executed with Fresenius in December 2008, the Original Supply Agreement, for the manufacture of INTERCEPT finished disposable kits for our platelet and plasma systems through December 31, 2013. Under the Original Supply Agreement, we paid Fresenius a set price per disposable kit, which was established annually, plus a fixed surcharge per disposable kit. In addition, volume driven manufacturing overhead was paid or refunded if actual manufacturing volumes were higher or lower than the annually estimated production volumes. The Company made payments to Fresenius of \$15.0 million, \$12.2 million and \$9.6 million relating to the manufacturing of the Company products during the years ended December 31, 2013, 2012 and 2011, respectively. At December 31, 2013, and December 31, 2012, the Company owed Fresenius \$4.3 million and \$6.2 million, respectively, for INTERCEPT disposable kits manufactured.

In November 2013, we amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014, the 2013 Amendment. Under the 2013 Amendment, Fresenius is obligated to sell, and we are obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provides for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. In addition, the 2013 Amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and adsorption media from us at fixed prices. The term of the 2013 Amendment extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach.

In connection with the warranty claims incurred by the Company and remediation of those claims during the year ended December 31, 2012 (see Note 2 in the Notes to Consolidated Financial Statements under Guarantee and Indemnification Arrangements for more detail), the Company filed a warranty claim against Fresenius. Fresenius accepted the warranty claim and supplied the Company with replacement product or credit notes. As a

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

result, the Company had recorded a current asset of \$1.8 million on its consolidated balance sheets as of December 31, 2012 representing the full amount of the warranty claim against Fresenius. As of December 31, 2013 the Company no longer has a warranty claim against Fresenius.

**Cooperative Agreements with the United States Armed Forces**

Since February 2001, the Company had received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received these awards in order to develop its pathogen inactivation technologies for the improved safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the terms of the cooperative agreements, the Company was conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that were of concern to the United States Armed Forces. This funding supported advanced development of the Company's red blood cell system. The Company recognized \$0 million, \$0.1 million and \$2.4 million of revenue under these agreements during the years ended December 31, 2013, 2012 and 2011, respectively. The Company has fully utilized the remaining availability under these existing agreements, accordingly the Company will not recognize any additional revenue associated with these agreements.

**Note 17. Income Taxes**

U.S and foreign components of consolidated loss before income taxes for the years ended December 2013, 2012 and 2011 was as follows (in thousands):

|                                    | Year Ended December 31, |             |             |
|------------------------------------|-------------------------|-------------|-------------|
|                                    | 2013                    | 2012        | 2011        |
| Income (loss) before income taxes: |                         |             |             |
| U.S.                               | \$ (44,035)             | \$ (16,360) | \$ (17,461) |
| Foreign                            | 916                     | 685         | 622         |
| Loss before income taxes           | \$ (43,119)             | \$ (15,675) | \$ (16,839) |

The provision for income taxes for the years ended December 2013, 2012 and 2011 was as follows (in thousands):

|                             | Year Ended December 31, |        |        |
|-----------------------------|-------------------------|--------|--------|
|                             | 2013                    | 2012   | 2011   |
| Provision for income taxes: |                         |        |        |
| Current:                    |                         |        |        |
| Foreign                     | \$ 191                  | \$ 180 | \$ 143 |
| Federal                     |                         |        |        |
| State                       |                         |        |        |
| Total Current               | 191                     | 180    | 143    |
| Deferred:                   |                         |        |        |
| Foreign                     |                         |        |        |
| Federal                     | 21                      | 48     |        |
| State                       | 6                       | 14     |        |

Edgar Filing: CERUS CORP - Form 10-K

|                            |        |        |        |
|----------------------------|--------|--------|--------|
| Total Deferred             | 27     | 62     |        |
| Provision for income taxes | \$ 218 | \$ 242 | \$ 143 |



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

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, 2013, 2012 and 2011 was as follows (in thousands):

|   | Year Ended December 31, |            |            |
|---|-------------------------|------------|------------|
|   | 2013                    | 2012       | 2011       |
| Federal statutory tax   | \$ (14,661)             | \$ (5,329) | \$ (5,725) |
| Stock-based compensation  | (10)                    | 99         | 83         |
| Lobbying expenses   | 107                     | 51         | 112        |
| Warrants  | 4,926                   | (706)      | (165)      |
| Foreign rate differential   | (121)                   | (53)       | (68)       |
| Expiration of federal net operating losses and credits tax effected |                         | 4,352      | 1,744      |
| Change in valuation allowance                                       | 9,934                   | 1,761      | 4,158      |
| Goodwill amortization   | 21                      | 48         |            |
| Other   | 22                      | 19         | 4          |
| Provision for income taxes  | \$ 218                  | \$ 242     | \$ 143     |

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. The significant components of the Company's deferred tax assets at December 31, 2013 and 2012 were as follows (in thousands):

|   | December 31, |            |
|---|--------------|------------|
|   | 2013         | 2012       |
| Deferred tax assets:                          |              |            |
| Net operating loss carryforwards              | \$ 142,500   | \$ 137,700 |
| Research and development credit carryforwards | 32,100       | 30,800     |
| Capitalized inventory costs                   | 800          | 900        |
| Inventory reserve                             | 100          | 700        |
| Capitalized research and development          | 12,300       | 9,100      |
| Capitalized trademark                         | 400          | 400        |
| Capitalized revenue sharing rights            | 100          | 300        |
| Asia license intangible                       | 100          | 100        |
| Deferred compensation                         | 4,900        | 4,800      |
| Accrued liabilities                           | 200          | 100        |
| Depreciation                                  | 1,300        | 1,300      |
| Acquisition costs                             | 200          | 200        |
| Deferred tenant allowance                     | 100          | 200        |
| Capital loss carryforwards                    | 3,900        | 3,900      |
| Total deferred tax assets                     | 199,000      | 190,500    |
| Valuation allowance                           | (199,000)    | (190,500)  |
| Net deferred tax assets                       | \$           | \$         |

Edgar Filing: CERUS CORP - Form 10-K

|                                |    |    |       |
|--------------------------------|----|----|-------|
| Deferred tax liabilities:      |    |    |       |
| Amortization of goodwill       | \$ | 89 | \$ 62 |
| Total deferred tax liabilities | \$ | 89 | \$ 62 |

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2013**

The valuation allowance increased by \$8.5 million for the year ended December 31, 2013, compared to a decrease of \$0.8 million and an increase of \$2.0 million for the years ended December 31, 2012 and 2011, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a full valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization, expected near-term future losses and the absence of taxable income in prior carryback years. The Company expects to maintain a full valuation allowance until circumstances change.

Undistributed earnings of the Company's foreign subsidiary, Cerus Europe B.V., amounted to approximately \$2.8 million at December 31, 2013. The earnings are considered to be permanently reinvested and accordingly, no deferred United States income taxes have been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to United States income taxes. At the Federal statutory income tax rate of 34%, this would result in taxes of approximately \$0.9 million. In the event all foreign undistributed earnings were remitted to the U.S., any incremental tax liability would be fully offset by the Company's domestic net operating loss.

For the year ended December 31, 2013, the Company reported net losses of \$43.3 million on its consolidated statement of operations and calculated taxable losses for both federal and state taxes. The difference between reported net loss and taxable loss are due to temporary differences between book accounting and the respective tax laws.

At December 31, 2013, the Company had federal and state net operating loss carryforwards of approximately \$381.7 million and \$218.1 million, respectively. The net operating loss carryforwards for federal and state expire at various dates beginning in 2018 and 2014, respectively, and ending in 2033.

At December 31, 2013, the Company had federal research and development credit carryforwards of approximately \$21.6 million that expire in various years between 2018 and 2033. The state research and development credits are approximately \$15.9 million as of December 31, 2013 have an indefinite carryforward 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 of Internal Revenue Code Section 382.

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, 2013 and 2012. The Company's tax years 1998 through 2013 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013****Note 18. 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 United States include a wholly-owned subsidiary headquartered in Europe. The Company's operations in the United States are responsible for the research and development and global commercialization of the INTERCEPT Blood System, while operations in Europe are responsible for the commercialization efforts of the platelet and plasma systems in Europe, The Commonwealth of Independent States and the Middle East. Product revenues are attributed to each region based on the location of the customer, and in the case of non-product revenues, on the location of the collaboration partner.

The Company had the following significant customers that accounted for more than 10% of the Company's total product revenue, all of which operate in a country outside of the United States, during the years ended December 31, 2013, 2012 and 2011 (in percentages):

|                                | Year Ended December 31, |      |      |
|--------------------------------|-------------------------|------|------|
|                                | 2013                    | 2012 | 2011 |
| Movaco, S.A.                   | 18%                     | 19%  | 21%  |
| Etablissement Francais du Sang | 17%                     | 20%  | 24%  |
| Delrus Inc.                    | *                       | 12%  | 12%  |

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

The Company also recognized government grants and cooperative agreements revenue which represented less than 1% of total revenue and 7% of total revenue, during the years ended December 31, 2012 and 2011, respectively. The Company recognized no revenue from governmental grants and cooperative agreements during the year ended December 31, 2013.

Net revenues by geographical location was based on the location of the customer, in the case of product revenues, and in the location of the collaboration partner, in the case of non-product revenues, during the years ended December 31, 2013, 2012 and 2011 and was as follows (in thousands):

|   | Year Ended December 31, |          |          |
|---|-------------------------|----------|----------|
|   | 2013                    | 2012     | 2011     |
| Product Revenue:                              |                         |          |          |
| France  | \$ 7,030                | \$ 7,321 | \$ 7,385 |
| Spain and Portugal                            | 7,033                   | 7,061    | 6,504    |
| CIS   | 8,220                   | 8,016    | 3,754    |
| Belgium                                       | 3,971                   | 4,016    | 3,703    |
| Switzerland                                   | 4,078                   | 3,866    | 3,315    |
| Other countries                               | 9,325                   | 6,415    | 5,941    |
| Total product revenue                         | 39,657                  | 36,695   | 30,602   |
| Government grants and cooperative agreements: |                         |          |          |

Edgar Filing: CERUS CORP - Form 10-K

|  |           |           |           |
|--|-----------|-----------|-----------|
| United States                                      |           | 91        | 2,442     |
| Total government grants and cooperative agreements |           | 91        | 2,442     |
| Total revenue                                      | \$ 39,657 | \$ 36,786 | \$ 33,044 |

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

Long-lived assets by geographical location, which consist of property and equipment, net, intangible assets, net, and certain other assets, at December 31, 2013 and 2012 were as follows (in thousands):

|                                | <b>December 31,</b> |                 |
|--------------------------------|---------------------|-----------------|
|                                | <b>2013</b>         | <b>2012</b>     |
| United States                  | \$ 3,088            | \$ 2,895        |
| Europe                         | 445                 | 349             |
| <b>Total long-lived assets</b> | <b>\$ 3,533</b>     | <b>\$ 3,244</b> |

**Note 19. Quarterly Financial Information (Unaudited)**

The following tables summarize the Company's quarterly financial information for the years ended December 31, 2013 and 2012 (in thousands except per share amounts):

|  | <b>March 31,</b> | <b>Three Months Ended</b> |                      | <b>December 31,</b> |
|--|------------------|---------------------------|----------------------|---------------------|
|  | <b>2013</b>      | <b>June 30,</b>           | <b>September 30,</b> | <b>2013</b>         |
|  |                  | <b>2013</b>               | <b>2013</b>          |                     |
| <b>Revenue:</b>                                      |                  |                           |                      |                     |
| Product revenue                                      | \$ 9,733         | \$ 10,150                 | \$ 10,542            | \$ 9,232            |
| Cost of product revenue                              | 5,090            | 5,747                     | 6,826                | 4,939               |
| Gross profit on product revenue                      | 4,643            | 4,403                     | 3,716                | 4,293               |
| Government grants and cooperative agreements revenue |                  |                           |                      |                     |
| <b>Operating expenses:</b>                           |                  |                           |                      |                     |
| Research and development                             | 2,700            | 3,506                     | 4,363                | 4,618               |
| Selling, general and administrative                  | 6,853            | 7,954                     | 7,728                | 7,430               |
| Amortization of intangible assets                    | 50               | 51                        | 50                   | 51                  |
| Total operating expenses                             | 9,603            | 11,511                    | 12,141               | 12,099              |
| Loss from operations                                 | (4,960)          | (7,108)                   | (8,425)              | (7,806)             |
| Total non-operating income (expense), net            | (5,241)          | 438                       | (12,016)             | 1,999               |
| Loss before income taxes                             | (10,201)         | (6,670)                   | (20,441)             | (5,807)             |
| Provision for income taxes                           | 51               | 54                        | 60                   | 53                  |
| Net loss   | \$ (10,252)      | \$ (6,724)                | \$ (20,501)          | \$ (5,860)          |
| <b>Net loss per common share:</b>                    |                  |                           |                      |                     |
| Basic  | \$ (0.17)        | \$ (0.10)                 | \$ (0.29)            | \$ (0.08)           |
| Diluted  | \$ (0.17)        | \$ (0.10)                 | \$ (0.29)            | \$ (0.10)           |



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2013**

|  | <b>March 31,<br/>2012</b> | <b>June 30,<br/>2012</b> | <b>Three Months Ended<br/>September 30,<br/>2012</b> | <b>December 31,<br/>2012</b> |
|--|---------------------------|--------------------------|--|------------------------------|
| <b>Revenue:</b>                                      |                           |                          |  |                              |
| Product revenue                                      | \$ 8,691                  | \$ 9,224                 | \$ 8,252   | \$ 10,528                    |
| Cost of product revenue                              | 5,514                     | 5,574                    | 4,411  | 5,117                        |
| Gross profit on product revenue                      | 3,177                     | 3,650                    | 3,841  | 5,411                        |
| Government grants and cooperative agreements revenue | 91                        |                          |  |                              |
| <b>Operating expenses:</b>                           |                           |                          |  |                              |
| Research and development                             | 1,824                     | 1,712                    | 1,903  | 2,164                        |
| Selling, general and administrative                  | 5,966                     | 6,686                    | 6,219  | 6,794                        |
| Amortization of intangible assets                    | 50                        | 51                       | 50   | 51                           |
| Total operating expenses                             | 7,840                     | 8,449                    | 8,172  | 9,009                        |
| Loss from operations                                 | (4,572)                   | (4,799)                  | (4,331)  | (3,598)                      |
| Total non-operating income (expense), net            | (4,227)                   | 2,933                    | 926  | 1,993                        |
| Loss before income taxes                             | (8,799)                   | (1,866)                  | (3,405)  | (1,605)                      |
| Provision for income taxes                           | 35                        | 41                       | 55   | 111                          |
| Net loss   | \$ (8,834)                | \$ (1,907)               | \$ (3,460)   | \$ (1,716)                   |
| <b>Net loss per common share:</b>                    |                           |                          |  |                              |
| Basic  | \$ (0.17)                 | \$ (0.04)                | \$ (0.06)  | \$ (0.03)                    |
| Diluted  | \$ (0.17)                 | \$ (0.10)                | \$ (0.08)  | \$ (0.07)                    |



**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 7th day of March, 2014.

**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 7, 2014 |
| <b>William M. Greenman</b>          | Officer and Director<br><i>(Principal Executive Officer)</i>    |               |
| <i>/s/</i> KEVIN D. GREEN           | Vice President, Finance and                                     | March 7, 2014 |
| <b>Kevin D. Green</b>               | Chief Financial Officer<br><i>(Principal Financial Officer)</i> |               |
| <i>/s/</i> DANIEL N. SWISHER, JR.   | Chairman of the Board of Directors                              | March 7, 2014 |
| <b>Daniel N. Swisher, Jr.</b>       |   |               |
| <i>/s/</i> TIMOTHY B. ANDERSON      | Director  | March 7, 2014 |
| <b>Timothy B. Anderson</b>          |   |               |
| <i>/s/</i> LAURENCE M. CORASH, M.D. | Director  | March 7, 2014 |
| <b>Laurence M. Corash, M.D.</b>     |   |               |
| <i>/s/</i> BRUCE C. COZADD          | Director  | March 7, 2014 |
| <b>Bruce C. Cozadd</b>              |   |               |

/s/ GAIL SCHULZE

Director

March 7, 2014

**Gail Schulze**

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

| <b>Exhibit<br/>Number</b> | <b>Description of Exhibit</b>   |
|---------------------------|---|
| 2.1(21)                   | Asset Purchase and Redemption Agreement by and between Cerus Corporation and BioOne Corporation, dated as of August 24, 2010.   |
| 3.1(32)                   | Amended and Restated Certificate of Incorporation of Cerus Corporation.   |
| 3.2(32)                   | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.   |
| 3.3(32)                   | Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.   |
| 3.4(10)                   | Amended and Restated Bylaws of Cerus Corporation.   |
| 4.1(1)                    | Specimen Stock Certificate.   |
| 4.2(16)                   | 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(18)                   | Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto). |
| 4.4(17)                   | Form of 2009 Warrant to Purchase Common Stock.  |
| 4.5(22)                   | Form of 2010 Warrant to Purchase Common Stock.  |
|                           | <i>Supply and/or Manufacturing Agreements</i>   |
| 10.1(8)                   | Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.   |
| 10.2(8)                   | Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus Corporation and Porex Corporation.  |
| 10.3(34)                  | First Amendment to Supply and Manufacturing Agreement, dated November 28, 2012, by and between Cerus Corporation and Porex Corporation.   |
| 10.4#                     | Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Fenwal, Inc.).       |
| 10.5#                     | Amendment No. 1 to the Amended and Restated Manufacturing and Supply Agreement, dated November 22, 2013, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.          |
| 10.6(12)                  | Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.   |
| 10.7(26)                  | Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash Stevens Inc.  |
| 10.8(35)                  | Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.   |
|                           | <i>Loan and Security Agreements</i>   |
| 10.9(26)                  | Loan and Security Agreement, dated as of September 30, 2011, by and between Cerus Corporation and Comerica Bank.  |

**Table of Contents**

| <b>Exhibit<br/>Number</b> | <b>Description of Exhibit</b>  |
|---------------------------|--|
| 10.10(30)                 | First Amendment to Loan and Security Agreement, dated as of December 13, 2011, by and between Cerus Corporation and Comerica Bank.   |
| 10.11(30)                 | Second Amendment to Loan and Security Agreement, dated as of June 30, 2012, by and between Cerus Corporation and Comerica Bank.  |
|                           | <b><i>Real Estate Lease Agreements</i></b>   |
| 10.12(4)                  | Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.  |
| 10.13(11)                 | Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.  |
| 10.14(19)                 | 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. |
| 10.15                     | 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>   |
| 10.16(23)*                | Employment Letter, by and between Cerus corporation and William M. Greenman, dated May 12, 2011.   |
| 10.17(34)*                | Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.  |
| 10.18*                    | Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.  |
| 10.19(20)*                | Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.  |
| 10.20(33)*                | Amended and Restated Employment Agreement with Howard G. Ervin, dated January 15, 2013.  |
| 10.21(16)*                | Employment Letter for Kevin D. Green dated May 1, 2009.  |
| 10.22(27)*                | Employment Agreement for Caspar Hogeboom dated March 6, 2006.  |
| 10.23(27)*                | Promotion Letter for Caspar Hogeboom dated December 11, 2009 and executed on September 21, 2010.   |
| 10.24(27)*                | Addendum to Employment Agreement for Caspar Hogeboom dated February 17, 2011.  |
| 10.25(27)*                | Healthcare Contribution Letter for Caspar Hogeboom dated December 18, 2007.  |
| 10.26(27)*                | Home Telephone and Internet Expenses Letter for Caspar Hogeboom dated January 11, 2012.  |
| 10.27(34)*                | Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.   |
| 10.28*                    | Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.  |

**Table of Contents**

| <b>Exhibit<br/>Number</b>                            | <b>Description of Exhibit</b>   |
|--|---|
| <i><b>Stock Plans and Related Forms</b></i>          |   |
| 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(1)*  | 1996 Employee Stock Purchase Plan.  |
| 10.33(30)*   | Employee Stock Purchase Plan, as amended, effective June 6, 2012.   |
| 10.34(2)*  | 1998 Non-Officer Stock Option Plan.   |
| 10.35(3)*  | 1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.  |
| 10.36(5)*  | 1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.  |
| 10.37(9)*  | 2008 Equity Incentive Plan, approved by stockholders June 2, 2008.  |
| 10.38(25)*   | 2008 Equity Incentive Plan, as amended, reapproved by stockholders June 1, 2011.  |
| 10.39(30)*   | 2008 Equity Incentive Plan, as amended, effective June 12, 2013.  |
| 10.40(29)*   | Form of Option Agreement for employees under the 2008 Equity Incentive Plan, as amended.  |
| 10.41(29)*   | Form of Option Agreement for non-employee directors under the 2008 Equity Incentive Plan, as amended.                                 |
| 10.42(29)*   | Form of Restricted Stock Unit Agreement under the 2008 Equity Incentive Plan, as amended.   |
| <i><b>Other Compensatory Plans or Agreements</b></i> |   |
| 10.43(34)*   | Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.   |
| 10.44(13)*   | Cerus Corporation Change of Control Severance Benefit Plan, as amended.   |
| 10.45(15)*   | Form of Severance Benefits Agreement.   |
| 10.46(27)*   | Non-Employee Director Compensation Policy.  |
| 10.47(29)*   | International Bonus Plan for 2012.  |
| 10.48*   | International Bonus Plan for 2013.  |
| <i><b>Other Material Agreements</b></i>              |   |
| 10.49(24)  | At-The-Market-Issuance Sales Agreement, dated June 3, 2011, by and between Cerus Corporation and MLV & Co. LLC.                       |
| 10.50(28)  | Amendment to At-The-Market-Issuance Sales Agreement, dated January 4, 2012, by and between Cerus Corporation and MLV & Co. LLC.       |
| 10.51(31)  | Amendment No. 2 to At-The-Market-Issuance Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and MLV & Co. LLC. |
| 10.52(1)   | Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.                  |
| 10.53(14)  | Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.   |
| 10.54(17)  | Form of Subscription Agreement.   |

**Table of Contents**

| <b>Exhibit<br/>Number</b> | <b>Description of Exhibit</b>  |
|---------------------------|--|
| 10.55(31)                 | Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.  |
| 10.56(19)                 | 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).                      |
| 10.57(19)                 | 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).                       |
| 10.58(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(36)                  | 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.

**Table of Contents**

- (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 Annual Report on Form 10-K, for the year ended December 31, 2007.
- (8) 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.
- (9) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on June 6, 2008.
- (10) 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.
- (11) 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.
- (12) 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.
- (13) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
- (14) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on April 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 June 1, 2009.
- (16) 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.
- (17) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on August 20, 2009.
- (18) 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.
- (19) Incorporated by reference to the like-described exhibit to the Registrant s Annual Report on Form 10-K, for the year ended December 31, 2009.
- (20) 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.
- (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 30, 2010.
- (22) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on November 12, 2010.
- (23) 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.
- (24) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K, filed with the SEC on June 6, 2011.
- (25) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant s Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2011.
- (26) 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.
- (27) Incorporated by reference to the like-described exhibit to the Registrant s Annual Report on Form 10-K, for the year ended December 31, 2011.
- (28) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant s Registration Statement on Form S-3/A, filed with the SEC on January 6, 2012.
- (29) 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.
- (30) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2013.
- (31) 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.

**Table of Contents**

- (32) 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.
- (33) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on January 17, 2013.
- (34) 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.
- (35) 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.
- (36) 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.