CERUS CORP
Form 10-K
March 12, 2013
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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, 2012

OR

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

Commission file number 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2550 Stanwell Dr.	
Concord, California	**94520**
(Address of principal executive offices)	**(Zip Code)**

(925) 288-6000

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act:

Preferred Share Purchase Rights

(Title of Class)

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

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 x

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 x 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 x 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 x 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 x

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 $135.4 million. (1)

As of March 1, 2013, there were 60,103,000 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 2013 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, 2012, are incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of $3.32 per share on June 29, 2012. Excludes 14.0 million shares of the registrant s common stock held by executive officers, directors and affiliates at June 29, 2012.

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. The forward-looking statements are contained principally in Item 1, Business, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations and in Item 1A, Risk Factors. These statements 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 pre-clinical 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 pre-clinical 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 limited operating history and 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.

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We have worldwide rights for our INTERCEPT Blood System for three blood components: platelets, plasma and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received CE marks and are being marketed and sold in a number of countries around the world including those in Europe, The Commonwealth of Independent States, or CIS, 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 plan to perform *in vitro* studies and clinical trials. Subject to the availability of adequate funding from partners and/or capital markets, we intend to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. We are currently conducting a Phase II recovery and lifespan study and plan to complete that trial and certain other prerequisites before proposing a Phase III clinical trial protocol for the red blood cell system in support of 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.

The United States Food and Drug Administration, or FDA, accepted our proposed modular Premarket Approval Application, or PMA, shell for review of our plasma system. We will proceed with a modular PMA approach, in which we will submit sections, or modules, of the PMA at different times and the compilation of these sections or modules will become a complete PMA. We believe that the modular approach increases the likelihood that we will be able to resolve any deficiencies identified by FDA earlier in the review process. Based on our recent discussions with the FDA, we believe that our existing clinical data is sufficient for the clinical requirements of the PMA submission process for the plasma system. In February 2013, we also reached agreement with the FDA regarding our platelet system. The FDA indicated that our existing clinical trial and European haemovigilance data will be sufficient to submit a proposal for a modular PMA submission for the platelet system without the need to complete additional Phase III clinical trials at this time. The submission of the PMA modules for our plasma system, and potentially for our platelet system, will result in increased research and development expenses in future periods. Should the FDA require us to complete any additional clinical trials, our ability to conduct and complete any additional clinical trials 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 initiate any additional trials.

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 inactivates a broad array of pathogens and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective or is not currently 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.

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Products, Product Candidates and Development Activities

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

Product or Product Under Development	Product or Development Status
INTERCEPT Blood System Platelets	Commercialized in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world
	United States: Phase III clinical trial completed; seeking FDA concurrence on modular PMA submission proposal
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
	United States: Phase III clinical trials completed; FDA accepted proposed modular PMA shell; submission of PMA modules in process
INTERCEPT Blood System Red Blood Cells	Phase I clinical trial completed in 2010; preparing for initiation of Phase III clinical trials to support CE Mark approval in Europe
	United States: Phase II recovery and lifespan study in process and *in vitro* 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. In addition to regulatory approvals, some potential customers, may desire to conduct their own clinical studies before adopting the platelet system. For example, we have received indication that the German Red Cross plans to conduct their own clinical trials 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 in 2005. In February 2013, we reached agreement with the FDA that our clinical trial and European haemovigilance data will be sufficient to submit a proposal for a modular PMA submission without the need to complete additional Phase III clinical trials at this time. However, FDA has indicated that we will need to commit to post-marketing studies. 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.

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, and the Middle East. 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

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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. In addition to regulatory approvals, some potential customers may desire to conduct their own clinical studies before adopting the plasma system.

We have 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 received agreement by the FDA for our proposed modular PMA submission process for the plasma system. We are currently in the process of submitting the required modules necessary for PMA approval and expect the entire process will take in excess of one year. Although we have completed Phase III clinical trials in various patient populations, the FDA may require supportive supplemental data collected in commercial use in Europe, or they 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.

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 obtain CE mark approval, we have 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. If the clinical trial applications are approved, we expect to enroll and conduct these Phase III clinical trials in Europe using INTERCEPT-treated red blood cells. We plan on completing a further process validation study in Europe prior to commencement of such trials.

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 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 have been no adverse events 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 plan to conduct the planned acute and chronic anemia Phase III clinical trials in Europe using the modified process, if our clinical trial applications are approved by European regulators.

In the United States, the FDA has required us to complete at least an additional Phase II recovery and lifespan study, that 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.*

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Information regarding our revenues for the years ended December 31, 2012, 2011 and 2010 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 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, 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.

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.

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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. We also agreed to pay Baxter royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system, 3% of product sales for the plasma system, 5% of product sales for the red blood cell system, and 6.5% on sales of UVA illuminators. In March 2007, Baxter sold its transfusion therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to Fenwal, Inc., or Fenwal, which in turn, has been recently acquired by Fresenius Kabi AG, or Fresenius. 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.

BioOne

In August 2010, we completed an acquisition of certain assets of 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 that we and Fresenius had 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 six months from the close of the acquisition date on February 25, 2011.

Investment in Aduro BioTech

In November 2007, we spun-off our former immunotherapy business to Anza Therapeutics, Inc., or Anza Therapeutics. In exchange for our contribution of tangible and intangible assets to Anza Therapeutics, we received preferred stock representing an equity interest of approximately 20% of Anza Therapeutics preferred equity. We were informed in February 2009 that Anza Therapeutics had ceased operations.

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, 2012, 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.

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William Greenman, our President and Chief Executive Officer, is on the Board of Directors of Aduro. Mr. Greenman does not represent Cerus on Aduro s Board of Directors.

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 contract manufacturers for the production of 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.

In December 2008, we amended our manufacturing and supply agreement with Fresenius. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase, finished disposable kits for the platelet and plasma systems for both clinical and commercial use. The agreement permits us to purchase platelet and plasma kits from third-party manufacturers provided that we meet certain annual minimum purchase obligations to Fresenius. We are responsible for developing and delivering to Fresenius our proprietary inactivation compounds and adsorption media for incorporation into the final system configuration. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2013, and is automatically renewed for one year terms, 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 do not currently have alternate manufacturers validated for the manufacture of compound adsorption devices and may need to either identify and validate alternate suppliers for the manufacture of compound adsorption devices or agree with Porex on either a new or amended supply agreement. 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 2013, and will automatically renew each year, unless terminated by either party upon providing at least two year prior written notice. We do not currently have plans to terminate our agreement with Purolite and understand that Purolite currently plans to continue operating under the agreement.

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 extends through September 2013 and is automatically renewable for one year terms, subject to termination by either party upon twelve months prior written notice. We do not currently have plans to terminate our agreement with Nova upon the initial expiration and understand that Nova currently plans to continue operating under the agreement beyond September 2013.

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. In the past, we have incurred these maintenance fees. The term of the amended manufacturing and supply agreement with Ash Stevens extends through December 31, 2015 and will

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automatically renew thereafter for a period of two 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 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.

In France, broad product adoption is dependent on a central decision by the Etablissement Francais du Sang, or EFS, and then on a broad-based national supply contract being awarded. In 2011, we entered into a two-year contract with the EFS to supply platelet and plasma disposable kits. The contract contains two one-year renewal options and provides for minimum and maximum purchase commitments.

In England, decisions on product adoption are centralized in the National Blood Service. We understand that the National Blood Service has decided to implement bacterial detection testing for platelets before considering pathogen inactivation.

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 the 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. We rely on these distributors to obtain any necessary in-country regulatory approvals, 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. Areas where we have entered into geographically exclusive distribution agreements include certain countries in the CIS, southern Europe, the Middle East and Latin America. Our success in these regions is reliant on our distributor s ability to market and sell our products and to

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maintain and service customer accounts, including technical service. Our distribution agreements account for a significant amount of our revenues and as such, the loss of certain distributor relationships could harm our existing business and may impact our growth potential.

Competition

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 and MacoPharma International, 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. In addition to direct competition from other pathogen inactivation methods, we encounter indirect competition from other approaches to blood safety, including methods of testing blood products for bacterial and viral pathogens. Some of these indirect competitors have mature, well-established products and more resources than we have. 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 recently 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 TerumoBCTs platelet and plasma pathogen reduction product is currently being evaluated. 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.

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, ease of use, the scope and enforceability of patent or other proprietary rights, product value relative to perceived risk, product supply and marketing and sales capability. In addition, we believe the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval are also important competitive factors. We believe that the INTERCEPT Blood System will compete favorably with respect to these factors, although there can be no assurance that it will be able to do so. Our success will depend in part on our ability to convince prospective customers of the benefits

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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, 2012, we owned approximately 20 issued or allowed United States patents and approximately 75 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2013 and 2027. In addition, we have pending United States patent applications and have filed corresponding patent applications under the Patent Cooperation Treaty. We 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. 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

The platelet and plasma disposable kits have received regulatory approval for two-year shelf lives. Illuminators and replacement parts do not have regulated expiration dates. We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our consolidated balance sheet, may potentially take over one year to complete production before being utilized in finished disposable kits. We maintain an inventory balance 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 on our 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 which would consume cash faster than we have currently planned. Generally, we write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use to net realizable value in the period that it is first recognized, by using a number of factors, including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods.

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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-users comprise a significant amount of our existing sales. The loss of any one of these 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,		
	2012	2011	2010
Etablissement Francais du Sang	20%	24%	20%
Movaco, S.A.	19%	21%	19%
Delrus Inc.	12%	12%	16%
Service Francophone du Sang	*	*	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, 2012, 2011 and 2010, 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. We have incurred total research and development expenses of $7.6 million, $7.2 million and $5.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. 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, 2012, 2011 and 2010.

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. 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.

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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.

The FDA will require a PMA 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 blood safety products, we expect our PMA to 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 affect the approval of the products.

In order to support PMAs for the INTERCEPT Blood System for platelet and plasma, we have conducted various types of studies, including toxicology studies to evaluate product safety, laboratory and animal studies to evaluate product effectiveness and human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components. We have received authorization from the FDA regarding the outline, order and submission timing for our modular plasma PMA. For our platelet and red blood cell systems, the content, order and submission timing of the modules must still be approved by the FDA. A modular PMA application cannot be approved until all modules have been submitted to, reviewed by and accepted by the FDA.

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. In February 2013, we reached agreement with the FDA that our clinical trial and European haemovigilance data will be sufficient to submit a proposal for modular PMA submission without the need to complete additional Phase III clinical trials at this time. However, FDA has indicated that we will need to commit to post-marketing studies. 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 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 received agreement by the FDA for the proposed modular PMA submission process for the plasma system. Under the modular PMA process, sections, or modules, of the PMA are submitted at different times and the compilation of these sections or modules become a complete PMA. We are currently in the process of submitting the required modules necessary for PMA approval and expect the entire

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process will take in excess of one year. Although we have completed Phase III clinical trials in various patient populations, the FDA may require supportive supplemental data collected in commercial use in Europe, or they 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.

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 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.

In addition to regulating our blood safety products, CBER also regulates the blood collection centers and the blood products that they prepare using the INTERCEPT Blood System. If our products were to be approved by the FDA, US-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.

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 the system. 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 the system 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 recent 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, recently

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passed 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, 2012, we had 85 employees, 25 of whom were engaged in research and development and 60 in selling, general and administrative activities. Of the 60 employees engaged in selling, general, and administrative activities, 29 were employed by our European subsidiary, Cerus Europe B.V. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

Available Information

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

Financial Information

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

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

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this report. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business. Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations.

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

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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 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. 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.

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.

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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 availab