CERUS CORP
Form 10-K
March 11, 2010
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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, 2009

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 0-21937

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.)
2411 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 $.001 per share	NASDAQ Global Market

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

Title of each class	Name of each exchange on which registered
Preferred Share Purchase Rights	None

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 ¨ 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 accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting Company)	Smaller reporting company x

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 $28.3 million.(1)

As of February 19, 2010, there were 38.8 million 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 2010 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, 2009, are incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of $1.03 per share on June 30, 2009. Excludes 5.1 million shares of the registrant s common stock held by executive officers, directors and affiliates at June 30, 2009.

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PART I

This report contains forward-looking statements that involve risks and uncertainties. When used herein, the words anticipate, believe, estimate, expect, plan and similar expressions are intended to identify such forward-looking statements. 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, a transition away from a reliance on Baxter International, Inc. and Fenwal, Inc. for sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fenwal and third parties to manufacture certain components of the INTERCEPT Blood System, our successful completion of our product components commercial design, our reliance on our relationship with BioOne Corporation for commercialization of the INTERCEPT Blood System for platelets and plasma in Asian markets, 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, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002 and other factors discussed below and under the caption Risk Factors, in Item 1A of this Annual Report on Form 10-K and in our other documents filed with the Securities and Exchange Commission. We undertake no obligation to update any of the forward-looking statements contained herein to reflect any future events or developments.

Cerus, *INTERCEPT* and *INTERCEPT Blood System* are United States registered trademarks of Cerus Corporation.

Item 1. *Business*

Overview

We are a biomedical products company focused on commercializing the INTERCEPT Blood System to enhance blood safety. The INTERCEPT system is designed to inactivate blood-borne pathogens in donated blood components intended for transfusion. We currently market the INTERCEPT system for both platelets and plasma in Europe, Russia, the Middle East and selected countries in other regions around the world. We are also pursuing regulatory approval of the platelet and plasma systems in the United States and other countries. The INTERCEPT red blood cell system is currently in clinical development.

We have worldwide commercialization rights for the INTERCEPT Blood System for platelets, plasma and red blood cells, excluding certain countries in Asia. Commercialization rights to the platelet and plasma systems in Asia have been licensed to BioOne Corporation, or BioOne. The INTERCEPT platelet and plasma systems have both received CE mark approval and are being marketed for commercial sale directly or through distributors in a number of countries in Europe, Russia, the Middle East and selected countries in other regions around the world. We continue to prioritize commercialization of the INTERCEPT Blood System for platelets and plasma in these countries and regions. In addition, subject to the availability of adequate funding from partners, government grants and/or capital markets, we also plan to continue to pursue regulatory approval of the INTERCEPT platelet and plasma systems in the United States and the continued development of the INTERCEPT red blood cell system in pursuit of regulatory approvals worldwide.

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

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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, and 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. In addition, data from commercial use suggests that treating platelet components with the INTERCEPT platelet system substantially reduces the rate of transfusion-related adverse events as compared to the incidence of such events prior to adoption of the INTERCEPT platelet system. The INTERCEPT Blood System is based on our proprietary technology for controlling biological replication.

Products, Product Candidates and Development Activities

The following table identifies our products and product development programs and their current status:

Product or Product Under Development	Product or Development Status	Commercial Rights
INTERCEPT Blood System Platelets	Commercialized in Europe, Russia, the Middle East and other selected countries United States: Phase III clinical trial completed; Seeking FDA concurrence on additional Phase III protocol	Worldwide, other than rights granted to BioOne in certain Asian countries
INTERCEPT Blood System Plasma	Commercialized in Europe, Russia, the Middle East and other selected countries United States: Phase III clinical trials completed	Worldwide, other than rights granted to BioOne in certain Asian countries
INTERCEPT Blood System Red Blood Cells	Phase I clinical trial completed in first quarter of 2010; Seeking concurrence of regulatory pathway from regulators in Europe	Worldwide

INTERCEPT Blood System for Platelets

The INTERCEPT Blood System for platelets, or platelet system, is designed to inactivate blood-borne pathogens in donated platelets for transfusion. The platelet system has received CE mark approval in Europe and is being marketed and sold in several countries in Europe, Russia, the Middle East and selected countries in other regions around the world. France, Switzerland, Germany, and Austria require separate approvals for use of INTERCEPT-treated platelet products. Such approvals have been obtained in France and Switzerland. In Germany, where approvals are granted to individual blood centers, several centers have obtained such approvals. Many countries outside 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.

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In addition to regulatory approvals, some potential customers desire to conduct their own clinical studies before adopting the platelet system. The largest branch of the German Red Cross is conducting such a study. We also expect the Japanese Red Cross to require a clinical study before adoption of any pathogen inactivation system.

In the United States, we will not be able to market the platelet system until we have conducted an additional Phase III clinical trial. We are currently working with the United States Food and Drug Administration, or FDA, to establish a protocol for such a trial. However, we have no plans to initiate such a trial unless adequate funding from partners or government agencies is secured.

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

Information regarding our revenues from the platelet system for the years ended December 31, 2009, 2008 and 2007 can be found in Item 7 *Management s Discussion and Analysis of Financial Condition and Results of Operation* , and Item 15(a) *Consolidated Financial Statements and Supplementary Data* of this Annual Report on Form 10-K.

INTERCEPT Blood System for Plasma

The INTERCEPT Blood System for plasma, or plasma system, is designed to inactivate blood-borne pathogens in donated plasma for transfusion. The plasma system has received CE mark approval in Europe and is marketed and sold in several countries in Europe and in Russia. France, Switzerland, Germany, and Austria require separate approvals for use of INTERCEPT-treated plasma products. Such approvals have been obtained in France. In Germany and Austria, such approvals will need to be obtained before INTERCEPT plasma can be sold on a commercial basis. Many countries outside 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 desire to conduct their own clinical studies before adopting the plasma system.

In the United States, we will not be able to market the plasma system until we have submitted a product marketing applications based upon our completed Phase III clinical trials. We do not know if the FDA will require any additional studies. We do not plan to prioritize regulatory approval for the plasma system in the near term.

Information regarding our revenues from the plasma system for the years ended December 31, 2009, 2008, and 2007 can be found in Item 7 *Management s Discussion and Analysis of Financial Condition and Results of Operation*, and Item 15(a) *Consolidated Financial Statements and Supplementary Data of this Annual Report on Form 10-K.*

INTERCEPT Blood System for Red Blood Cells

The INTERCEPT Blood System for red blood cells, or red blood cell system, is designed to inactivate blood-borne pathogens in donated red blood cells for transfusion. In September 2003, we terminated the Phase III clinical trials of the red blood cell system due to the detection of antibody reactivity to INTERCEPT-treated red

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blood cells in one patient in the chronic arm of the trial. However, there were no adverse events associated with INTERCEPT-treated red blood cells evident in this trial. The antibody cleared and the patient had no adverse health consequences. After unblinding the data from the Phase III clinical trial, we found that we had met the primary end-point in the acute arm of the clinical trial. We evaluated the antibodies detected in the clinical trial and have developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process.

In 2008, we completed a series of *in vitro* and *in vivo* tests with further modifications to the red blood cell system. We completed a Phase I clinical trial of the modified process in the first quarter of 2010, meeting the trial s primary end point. Subject to the availability of adequate funding from partners, government grants, and/or capital markets, we expect that a minimum of one year is needed to develop and implement commercial product and system design changes to the original red blood cell system before we can enter Phase III clinical trials. We may be unable to continue commercial product and system design efforts and required Phase III clinical trials, unless we obtain third-party funding for such efforts.

INTERCEPT Blood System Technology

Each of the platelet system and plasma system employ the same technology. Platelet components or plasma components collected from blood donors are transferred into plastic INTERCEPT disposable kits in which they are mixed with a proprietary Cerus compound, amotosalen, 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 (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 of the pathogens. 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 Cerus 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.

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.

Following the inactivation process, any residual amotosalen and by-products are reduced by more than 99% through use of a compound adsorption device, which is part 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 system and plasma system, the red blood cell system acts by using a compound to form bonds with nucleic acid in pathogens that may be present in red blood cell components destined for transfusion. The red blood cell system is designed to preserve the therapeutic qualities of the red blood cells, which do not rely on nucleic acid for their cellular function. The red blood cell system uses a proprietary Cerus compound called S-303. Unlike the platelet and plasma systems, the chemical bonds from S-303 are not triggered by UVA

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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 demonstrated with the red blood cell system.

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 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 we have not yet been tested with our systems, including emerging and future threats to the blood supply. We do not claim, however, that our system will inactivate all pathogens, including prions; and our inactivation claims are limited to those contained in our product specifications.

Collaborations

Baxter

We collaborated with Baxter on the development and commercialization of the INTERCEPT Blood System commencing in 1993. We obtained worldwide commercialization rights to the red blood cell system from Baxter in February 2005. Effective February 1, 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. We 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% for the plasma system, 5% 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 a new company, Fenwal, Inc., or Fenwal. Fenwal has assumed Baxter s rights and obligations under our agreements.

BioOne

In June 2004, we and Baxter entered into a definitive agreement with BioOne for commercialization of our platelet system in specified parts of Asia. Under the terms of the 2004 agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for and commercializing, the platelet system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore. Under that agreement, BioOne received exclusive marketing and distribution rights in each of those countries. We believe Baxter transferred its rights and obligations with regard to BioOne to Fenwal. We have received a total of $10.0 million in up-front payments under the terms of the 2004 agreement and will be eligible to receive contingent milestone payments and royalties on future product sales, which will be shared equally between Fenwal and us.

In June 2005, we and Baxter entered into a definitive agreement with BioOne for commercialization of our plasma system in specified parts of Asia. Under the terms of the 2005 agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for and commercializing the plasma system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore. BioOne received exclusive marketing and distribution rights in each of those countries. We received a total of $9.5 million in cash as well as equity securities in BioOne valued at $10.0 million at the time of issuance in connection with the 2005 agreement and will be eligible to receive (i) contingent milestone payments, payable to us solely; and (ii) royalties on future product sales, which will be shared by Fenwal and us. We understand that BioOne has reduced its operations considerably in order to conserve cash. At December 31, 2009, we evaluated the carrying value of our investment in BioOne using a

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variety of criteria. These criteria included, but were not limited to: third-party investor interest and participation in recent equity offerings at current pricing, business outlook of BioOne and available financial information. As a result of BioOne s position relative to these criteria at December 31, 2009, we have recorded an impairment of $2.3 million which brings the carrying value of our equity interest in BioOne to zero.

United States Armed Forces

In February 2001, we were awarded $2.6 million under a cooperative agreement with the Army Medical Research Acquisition Activity division of the Department of Defense, or DoD. Since then, we have been awarded an aggregate of $31.7 million under awards and cooperative agreements with the DoD, all of which was for the continued funding of projects to develop our pathogen inactivation technologies to improve the safety and availability of blood for medical transfusions. Under the terms of the cooperative agreements, we are conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites, which are of concern to the United States Armed Forces.

Settlement Agreement with Baxter

During the fourth quarter of 2009, we and Baxter resolved several outstanding issues and disputes resulting from the 2006 transition services agreement and manufacturing agreement. As an outcome of those negotiations, on December 30, 2009, we and Baxter entered into a Mutual Release and Settlement Agreement, or the MRSA. The MRSA called for the complete and permanent waiver and release of any and all claims we or Baxter had on any amounts generated under the transition services agreement. As a result of entering into the MRSA, we eliminated approximately $4.7 million in payment obligations to Baxter and $2.8 million in receivables due from Baxter which were generated under the 2006 agreements and recorded on our balance sheet. The MRSA required us to pay $0.5 million to Baxter for the settlement. As such, we recorded a $1.4 million gain during the year ended December 31, 2009, and a $0.5 million obligation on our December 31, 2009 balance sheet. We paid the $0.5 million payment in satisfaction of the MRSA on January 4, 2010.

Investment in Aduro BioTech

In November 2007, we announced that we had sold certain assets that made up our former immunotherapy business, including our Listeria and killed but metabolically active, or KBMA, platform technologies, to a newly-formed independent company, Anza Therapeutics, Inc., or Anza, financed by venture capital firms. In exchange for our contribution of tangible and intangible assets to Anza, we received preferred stock representing an equity interest of approximately 20% of Anza s preferred equity. However, due to the early clinical and pre-clinical stages of Anza s technology and relatively high risk of failure for such technologies, we determined that it would be unlikely that we would be able to derive any value from our equity interest in Anza and as such, we did not assign a value on our balance sheet to the equity interest we held in Anza. We were informed in February 2009 that Anza had ceased operations.

In July 2009, we entered into a three-way license agreement with Anza and Aduro BioTech, or Aduro, and separate agreements with each of Anza and Aduro (collectively, the Assignment Agreements). In November 2009, Anza transferred all of its intellectual property to Aduro pursuant to the terms of the Assignment Agreements. In addition, for agreeing to the transfer and surrendering our ownership in Anza, we received preferred stock representing a 10% equity interest in Aduro, a 1% royalty on all future product sales that Aduro may recognize in the future from the transferred technology, and $0.5 million in cash from Aduro. Furthermore, we received cash of approximately $0.3 million from Anza. As a result of entering into the Assignment Agreements, we no longer hold any equity in Anza. We believe that Aduro s technology platforms, which are largely based on Anza s in-process development programs, have a high risk of failure and we have no basis to believe that we will receive economic benefit from our equity ownership in Aduro. As such, we did not assign any value to our equity ownership in Aduro on our December 31, 2009 balance sheet.

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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 have no experience in manufacturing products for clinical or commercial purposes. We are dependent on Fenwal 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 illumination devices used in the INTERCEPT Blood System.

On December 12, 2008, we entered into an Amended and Restated Manufacturing and Supply Agreement with Fenwal. Under the amended agreement, Fenwal 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 Fenwal. We are responsible for developing and delivering to Fenwal our proprietary inactivation compounds and adsorption media for incorporation into the final system configuration. The term of the Fenwal agreement 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 Fenwal, or twenty-four months prior written notice, in our case. We and Fenwal each have normal and customary termination rights, including termination for material breach.

Following the December 2008 Fenwal agreement, we are responsible for the full management and control of the supply chain for the INTERCEPT illuminator devices and certain other components of the platelet and plasma kits. In anticipation of this obligation, we entered into a manufacturing and supply agreement with NOVA Biomedical Corporation, or NOVA, on September 24, 2008. Under the terms of the NOVA agreement, we have the ability to purchase illuminators directly from NOVA. NOVA has manufactured illuminators for Baxter and us in the past. In addition, we previously contracted with NOVA for the calibration and maintenance of the illuminators that we previously purchased from Baxter and Fenwal. NOVA has also previously supplied to us components of the INTERCEPT platelet and plasma systems to cover repair contingencies and for preventive maintenance. 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 have contracted with one manufacturing facility for the synthesis of amotosalen, the inactivation compound used in our platelet and plasma systems. Under this contract, 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 currently have a stock of the compound sufficient to support the anticipated commercial demand for the platelet and plasma systems.

We and our contract manufacturers, including Fenwal and NOVA, purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound absorption devices and UVA illumination devices from a limited number of suppliers, some of which may require minimum annual purchase amounts. While we believe that there are alternative sources of supply for such materials, parts and devices, establishing additional or replacement suppliers for any of the raw materials, parts and devices, if required, may not be accomplished quickly and could involve significant additional costs and potential regulatory reviews. Any failure to obtain from alternative suppliers of the materials used to manufacture our disposable kits, inactivation compounds or materials and parts used to manufacture our compound absorption devices and UVA illumination devices, if required, would limit our ability to supply these materials, parts or devices.

Marketing, Sales and Distribution

The market for the INTERCEPT Blood System is dominated by a small number of blood collection organizations in the United States, Western Europe, Russia, the Middle East, and Japan, where various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective

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nations blood and blood component supplies. The largest European markets for our products are in England, Germany and France. In England, decisions on product adoption are centralized in the National Blood Service. In Germany, decisions on product adoption are made on a regional or blood center-by-blood center basis. While obtaining CE marks allows 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 platelets 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. In France, broad product adoption is dependent on a central decision by the Etablissement Francais du Sang, or EFS, and then a national supply contract being negotiated.

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. National reimbursement rates for pathogen inactivated platelet and plasma have been agreed upon between the French Ministry of Health and the EFS; however, a budget for adopting pathogen inactivation technologies must be established before we would expect broad commercial adoption of the platelet and plasma systems in France.

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 Europe, Russia, the Middle East and selected countries in other regions around the world. We also have a small scientific affairs group in the Netherlands that supports the commercialization efforts.

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. One competitor has recently received a CE mark for a pathogen inactivation system for the treatment of platelets and plasma in blood centers. Other competitors are marketing pathogen inactivation products or systems for treating donated plasma in Europe. There are no known competitors in the clinical development stage for pathogen inactivation of red blood cells, though one competitor has initiated a study on pathogen inactivation of whole blood. 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. Further discussion of the major competitors to our blood product business can be found in the risk factor entitled *If our competitors develop and market products that are more effective than our products and product candidates, our commercial opportunity will be reduced or eliminated. If competitors encounter difficulties or failures in human clinical trials or in commercial settings, we may face additional clinical, regulatory, and commercial challenges.*

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, 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. The

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medical device and biopharmaceutical field is characterized by rapid and significant technological change. Accordingly, our success will depend in part on our ability to respond quickly to medical and technological changes through the development and introduction of new products. Product development involves a high degree of risk, and there can be no assurance that our product development efforts will result in any commercially successful products.

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, 2009, we owned approximately 25 issued or allowed United States patents and approximately 72 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2012 and 2026. 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 Fenwal to United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2010 to 2023. 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. There can be no assurance that any patents owned by or licensed to us will afford protection against competitors or that any pending patent applications now or hereafter filed by, or licensed to, us will result in patents being issued. In addition, 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 customer s needs are not based on seasonal trends, seasonality does not have a material effect on our business.

Inventory Requirements and Product Return Rights

Our platelet and plasma systems 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 balance sheet, can take over one year for production to be complete before being utilized in finished disposable kits. Inventory is recorded at the lower of cost or market value, determined on a first in, first out basis. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable. Our limited history selling the INTERCEPT Blood System limits the amount of historical data we have to perform such analysis. Generally, we write-down specifically identified obsolete, slow-moving, or known unsalable inventory using a number of factors, including product expiration dates, open and unfulfilled orders, and sales forecasts.

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 product.

Customers

At December 31, 2009, we had four customers that each accounted for more than 10% of our outstanding trade receivables and together accounted for approximately 73% of our outstanding trade receivables. The loss of

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any one of these customers would have an adverse impact on our business. To date, we have not experienced collection difficulties from these customers. See Item 15a Financial Statements of this Annual Report on Form 10-K for additional details about these customers.

Research and Development Expenses

A significant portion of our operating expenses is related to research and development and we intend to maintain our strong commitment to research and development. We have incurred total research and development expenses from continuing operations of $6.4 million, $10.2 million, and $15.0 million for the years ended December 31, 2009, 2008 and 2007, respectively. See Item 15a Financial Statements of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for fiscal years 2009, 2008, and 2007.

Government Regulation

We and our products are comprehensively regulated in the United States by the FDA and, in some instances, by state and local governments, 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. The INTERCEPT Blood System for platelets received the CE mark in October 2002. The INTERCEPT Blood System for plasma received the CE mark in November 2006. 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 have separate approval processes for use of the INTERCEPT-treated 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 pre-market approval application, or 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. BPAC will make a recommendation to the FDA for, or against, approval.

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In order to support our PMA for the INTERCEPT Blood System, 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. Since assuming responsibility for regulatory approval of the INTERCEPT Blood System in the United States under terms of our February 2005 and 2006 agreements with Baxter, we have used the same modular process for our PMA application that Baxter used for the platelet system in the United States. The content, order and submission timing of the modules must be approved by the FDA, and 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, and we submitted this information along with several other modules of our PMA, to the FDA. The FDA has indicated that the clinical trial data and supplemental analysis are not sufficient to support a PMA and we have had several interactions with the FDA subsequent to the clinical trial. In November 2009, we presented a plan for a proposed Phase III clinical trial for platelets to the BPAC. The outcome of that meeting was the support for the design and endpoints of a clinical trial for INTERCEPT-treated platelets, subject to changes regarding the sensitivity of the safety endpoint. We are currently in discussions with the FDA regarding further details of the proposed additional Phase III clinical trial.

The FDA also inspects the facilities at which the product is manufactured and will not approve the product unless compliance with current Good Manufacturing Practice or Quality System Regulation requirements is satisfactory.

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. As such, prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System, the FDA will require that our United States-based blood center customers obtain site-specific licenses. 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 are likely 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, and 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 from human clinical studies is required to demonstrate the safety of treated blood components and their therapeutic comparability to untreated blood components, but that only data 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.

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, and submitted this information along with several other modules of our pre-market approval application, to the United States Food and Drug Administration, or FDA. The FDA has indicated that the clinical trial data and supplemental analysis are not sufficient to support a pre-market approval application. We have had several interactions with the FDA subsequent to the clinical trial. In November 2009, we presented a plan for a proposed Phase III clinical trial for platelets to the FDA s Blood Products Advisory Committee, or BPAC. The outcome of that meeting was the support for the design and endpoints of a clinical trial for INTERCEPT-treated platelets, subject to changes regarding the sensitivity of the safety endpoint. We are currently in discussions with the FDA regarding further details of that proposed

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additional Phase III trial. However, we have no plans to initiate such a trial unless adequate funding from partners or government agencies is secured.

The INTERCEPT Blood System for red blood cells preclinical and clinical studies have been conducted using prototype system disposables and devices. We have or plan to perform laboratory studies to demonstrate equivalency between the prototype and the commercial configuration. We cannot be certain that these studies will be successful or the FDA or foreign regulatory bodies will not require additional studies, which could delay commercialization.

Health Care Reimbursement and Reform

The future revenue and profitability of biopharmaceutical and related companies as well as the availability of capital to such companies may be affected by the continuing efforts of the United States and foreign governments and third-party payors to contain or reduce costs of health care through various means. In the United States, given federal and state government initiatives directed at lowering the total cost of health care, it is likely that the United States Congress and state legislatures will continue to focus on health care reform and the cost of pharmaceuticals and on the reform of the Medicare and Medicaid systems.

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 from governmental authorities, private health insurers and other organizations, such as Health Maintenance Organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for pharmaceuticals, medical devices and services. The trend toward managed health care in the United States and other countries and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all affect the prices for our products and our profitability.

Employees

As of December 31, 2009, we had 73 employees, 25 of whom were engaged in research and development and 48 in selling, general, and administrative activities. Of the 48 employees engaged in selling, general, and administrative activities, 26 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 SEC.

Financial Information

Our financial information including our consolidated balance sheets, results of operations, statements of cash flows, statements of stockholder s equity and the related footnotes, can be found under Item 15 in Part IV of this Annual Report on Form 10-K. Our financial information includes references to geographic areas.

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

We may encounter governmental and transfusion medicine community resistance to commercial adoption for any or all of our products. In addition to blood banks, our direct customers, we must also address issues and concerns from broad constituencies involved in the healthcare system, from patients, to transfusing physicians, hospitals, private and public sector payors, regulatory bodies and public health authorities. Any one of these constituencies may be able to delay or block adoption of the INTERCEPT Blood System. We may be unable to adequately demonstrate to these constituencies that the INTERCEPT Blood System is safe, effective and economical. Some potential customers may await further safety information or additional studies before choosing whether to adopt our products. For instance, we have been informed by the largest group of blood centers in Germany that it will need to complete a clinical trial before purchasing our products on a routine basis. We can not predict the final trial design, number of transfusions, enrollment duration, estimated time it will take to complete such a trial, or trial outcome.

For logistical and financial reasons, the transfusion medicine industry has not always integrated new technologies into its processes, even those with the potential to improve the safety of the blood supply, such as the INTERCEPT Blood System. Our products may require significant changes to our potential customers blood component collection methods, space and staffing requirements and potential customers may not believe that the benefits of using the INTERCEPT Blood System justify their cost. There is some loss of platelets as a result of our pathogen inactivation process. If the loss of platelets leads to increased costs, or our process requires changes in blood center or clinical regimens, 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. While studies also 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.

Our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may limit their acceptance. For example, due to the biology of certain non-lipid enveloped viruses, including hepatitis A virus, our products have not been demonstrated to inactivate these viruses. In addition, for human parvovirus B-19, which is also a non-lipid-enveloped virus, our testing has not demonstrated a high level of inactivation. 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. In addition, since prions do not contain nucleic acid, our products do not inactivate prions. 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 acceptance of our products.

We have conducted pre-clinical and clinical studies of our products in both *in vivo* and *in vitro* 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

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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.

Furthermore, due to limitations of those 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 acceptance of our products.

Our products may not demonstrate economic value sufficient to offset their price, imposing a financial burden on the healthcare system that may limit market acceptance. We may need to develop new product configurations to address market needs, which may be technically challenging, expensive and negatively affect potential contribution from product sales. 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 a shortcoming of 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 acceptance of our products may also be 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 will 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, its hospital customers may not accept, or may not have the budget to purchase, INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for pathogens prior to transfusion, even after implementing our products some blood centers may not be able to afford to purchase our products. Furthermore, it is difficult to predict the reimbursement status of newly approved, novel medical device products. In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical products companies. There also have been proposals in the United States, at both the Federal and state government level, to implement similar controls. The widespread adoption of managed care in the United States has also placed downward pressure on the pricing of medical products. These pressures, as well as proposed health care reform measures in the United States, can be expected to continue and may limit the prices we can obtain for our products.

Product adoption in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products. In addition, failure to gain approval or achieve widespread product adoption in key European countries for reasons within and outside our control may limit adoption in other countries.

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 properly market, promote, distribute, price or sell our products to any of these large customers could significantly diminish potential product revenue in those geographies. The market for our pathogen inactivation systems in the United States is highly concentrated, 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 England, Germany and France. Decisions on product adoption in England are centralized with the National Blood Service. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a regional or even blood center-by-blood center basis, but depend on both local and centralized regulatory approval from the Paul Ehrlich Institute, or PEI. Product characteristics relating to platelet dose of INTERCEPT-treated platelets

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that have received marketing authorization from the PEI may be incompatible with market requirements. 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. 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 the INTERCEPT Blood System or any other competitive approach. If approvals are not obtained to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue will be significantly impaired.

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 regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue. Our 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.

Clinical trials in particular are 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 and conduct planned clinical trials on schedule, if at all. Significant delays in clinical testing could materially impact our clinical trials. We also do not know whether planned clinical trials will need to be revamped or will be completed on schedule, if at all. Criteria for regulatory approval in blood safety indications are evolving with competitive advances in the standard of care against which new product candidates are judged, as well as with 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. In addition to the reasons stated above, 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 approval to conduct a study at a prospective clinical site and delays in recruiting subjects to participate in a study. We do not know whether any clinical trials will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical and clinical trials and products emerging from any successful trial may not reach the market for several years.

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It may take us several years to complete our clinical testing, and failure can occur at any stage of testing. Enrollment criteria for certain of our clinical trials may be quite narrow. Consequently, we may be unable to recruit suitable patients into the trial on a timely basis, if at all. 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.

The FDA and other agencies in the United States and in foreign countries impose substantial requirements upon the manufacturing and marketing of products such as those we are developing. The process of obtaining FDA and other required regulatory approvals is long, expensive and uncertain, and typically takes a number of years, depending on the type, complexity and novelty of the product. In addition, we may be required to obtain approval from the Food and Drug Branch of the California State Department of Health for any product manufactured by us in California, including for clinical trial use. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

We have received CE mark approval for the INTERCEPT platelet and plasma systems, which, is sufficient to allow us to sell our platelet and plasma systems in the European Union and allows us to sell the INTERCEPT platelet and plasma systems under import licenses to many countries outside of the European Union. In Germany, France, Switzerland, and Austria, additional regulatory approval of the blood products treated by our products has been required before those blood products can be transfused into a human patient. INTERCEPT-treated blood products have received those additional regulatory approvals from the Paul Ehrlich Institute in Germany (as to the largest branch of the German Red Cross), the Agence Française de Sécurité Sanitaire Des Produits de Santé, or Afssaps, in France, and SwissMedic in Switzerland. We have also obtained in-country regulatory approvals for the sale of INTERCEPT platelet and plasma systems in Russia. We have not received regulatory approval for commercial sale of the INTERCEPT Blood System in the United States and many other countries around the world. Our products are in various stages of development and regulatory approval, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. 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. 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.

Distribution of our products in markets outside the United States also is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In some countries, we may be required to register as a medical device manufacturer, even though we outsource manufacturing to third parties. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation.

In May 2007, we obtained a CE mark extension in our name from European Union regulators for our platelet system, originally obtained by Baxter in 2002, and will need to obtain an extension every five years. In addition to European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries to market our products. 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.