

CERUS CORP  
Form 10-K  
March 11, 2010  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-K**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 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)

Edgar Filing: CERUS CORP - Form 10-K

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**2411 Stanwell Dr.**  
**Concord, California**  
(Address of principal executive offices)  
**(925) 288-6000**

**68-0262011**  
(I.R.S. Employer  
Identification No.)  
**94520**  
(Zip Code)

(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
<b>Preferred Share Purchase Rights</b>	<b>None</b>

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting Company)	Smaller reporting company <input checked="" type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The approximate aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock listed on the Nasdaq Global Market, was \$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.

Edgar Filing: CERUS CORP - 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.

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

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	13
Item 1B. <u>Unresolved Staff Comments</u>	30
Item 2. <u>Properties</u>	30
Item 3. <u>Legal Proceedings</u>	30
Item 4. <u>(Removed and Reserved)</u>	
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	31
Item 6. <u>Selected Financial Data</u>	33
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	34
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	46
Item 8. <u>Consolidated Financial Statements and Supplementary Data</u>	47
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	47
Item 9A. <u>Controls and Procedures</u>	48
Item 9B. <u>Other Information</u>	48
<b><u>PART III</u></b>	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	49
Item 11. <u>Executive Compensation</u>	49
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	49
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	49
Item 14. <u>Principal Accountant Fees and Services</u>	49
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	50
<b><u>SIGNATURES</u></b>	84

---

**Table of Contents**

**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.

**Table of Contents****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:

<b>Product or Product Under Development</b>	<b>Product or Development Status</b>	<b>Commercial Rights</b>
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.

## **Table of Contents**

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

---

## **Table of Contents**

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



## **Table of Contents**

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

---

## **Table of Contents**

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.

## **Table of Contents**

### **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 adsorption 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 adsorption 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

---

## **Table of Contents**

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

---

## **Table of Contents**

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

---

## **Table of Contents**

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.



## **Table of Contents**

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



## **Table of Contents**

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

---

## **Table of Contents**

### **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

---

**Table of Contents**

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

**Table of Contents**

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.

## **Table of Contents**

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.

---

## **Table of Contents**

We completed our Phase III clinical trial of the platelet system in the United States in March 2001 and submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we performed an additional blinded analysis of the clinical trial data, under the direction of an independent expert physician panel, to determine if apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to discrepancies in safety results. The reassessment of primary patient records by the expert physician panel showed no statistically significant differences between groups. This reassessment differed from the earlier analysis of adverse events that was based on clinical trial case report forms and had shown statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. We now understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the FDA's questions. In November 2009, we and the FDA presented a proposed clinical trial protocol for a second Phase III clinical trial to the FDA's Blood Product Advisory Committee, or BPAC. Although the BPAC agreed with the proposed trial design, safety endpoints and efficacy endpoints, we believe we will need to reach agreement with the FDA on the means necessary to satisfy the BPAC's request for more stringent safety margins than we had proposed. Satisfying that request will likely require assessing data from additional patients in the trial than what we had proposed. Until the final study size and design requirements are determined, we will not be able to assess the feasibility of a second Phase III trial. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. We have no plans to initiate such a trial unless adequate funding from partners or government agencies is secured. The additional Phase III clinical trial will need to be completed and data submitted to the FDA before we can complete our regulatory submission.

We have completed Phase IIIa, Phase IIIb and Phase IIIc clinical trials of the plasma system, in the United States, reports for which were filed with the FDA during 2005. We obtained a CE mark approval in Europe of the plasma system in November 2006 and final French approval in May 2007 based on data from those trials of the plasma system. We have not submitted any applications for regulatory approval of the plasma system in the United States or any other regions other than Europe. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by BPAC. BPAC would then make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily approve those products. If BPAC were to recommend 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.

If our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with Good Manufacturing Practice, or GMP, and ISO 13485, a quality management system standard applicable to the products we sell in Europe. The failure to comply with these requirements on an ongoing basis could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result in an enforcement action, which could harm our business. The current manufacturing sites we rely upon for producing the platelet and plasma system products for international distribution and sale are not FDA-qualified facilities.

The FDA will require, and other regulatory authorities may also require, post-marketing testing, which can involve significant expense. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

We have conducted many toxicology studies to demonstrate the INTERCEPT platelet and plasma systems' safety, and we have conducted and plan to conduct toxicology studies for the INTERCEPT red blood cell system

---

**Table of Contents**

throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay commercialization. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate our having to redesign our product or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. We believe the FDA and other regulatory authorities are likely to weigh the potential risks of using our pathogen inactivation products against the incremental benefits, which may be less compelling in light of improved safety in the blood supply. The FDA will require us to demonstrate a very low level of potential side effects in the proposed second Phase III trial of the platelet system. Trials of this type may be too large and expensive to be practical.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibody reactivity to red blood cells treated with the INTERCEPT red blood cell system in one patient in the chronic arm of the trials, we have been conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce the potential for antibody reactivity to treated red blood cells. Based upon an internal evaluation of the results from these additional research activities and after consulting with regulatory authorities, we initiated a new Phase I trial in 2006 in the United States using a modified red blood cell system before potentially progressing to later-stage clinical trials. We utilized a manual processing system in the Phase I trial conducted in 2006, which system is not in a commercially feasible form. Results of that Phase I trial suggested that the modified process in combination with a conventional additive solution results in conditions not suitable for long-term storage of red blood cells treated with the INTERCEPT system, adversely impacting their lifespan. Consequently, we conducted *in vitro* and *in vivo* studies and initiated a new Phase I clinical trial in the fourth quarter of 2008 to test further modifications to the red blood cell system. That new Phase I clinical trial has been completed, successfully meeting its primary endpoint of red cell recovery measured twenty-four hours after transfusion. In addition to red cell recovery, we also measured red cell lifespan, measured as the half-life of red cells circulating in transfusion recipients. INTERCEPT-treated red blood cells fell within the established normal reference range for red blood cells. Non-treated red cells were above the established normal reference range. Differences in the lifespan between INTERCEPT-treated red blood cells and non-treated red blood cells may inhibit our ability to obtain the necessary regulatory approvals or may impair market acceptance if the red blood cell system is successfully developed. A number of trial design, process and product design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials. While those clinical trials are being conducted and further clinical work is planned, we will need to develop a commercially feasible red blood cell system. In the aggregate, these activities will require significant funding beyond our current resources. We will not commence the next phase of clinical trial activities until we have secured adequate funds. We expect that we can continue some level of program advancement with minimal spending, by leveraging grant funding from the Department of Defense and existing and potential partners. A delay in completing such development activities could result in a delay in the timely progression to later stage trials. If we are unsuccessful in advancing a modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system program.

Regulatory delays can also materially impact our product development costs. If we experience delays in testing, conducting trials or approvals, our product development costs will increase. For example, we may need to repeat clinical trials to address regulatory or clinical questions. We may also need to retain third-party investigators and organizations in an attempt to facilitate regulatory review and approval. If the delays are significant, our financial results and the commercial prospects for our products will be harmed, and our ability to become profitable will be delayed.

Regulatory agencies may limit the uses, or indications, for which any of our products are approved. For example, we believe that the INTERCEPT Blood System products will be able to claim the inactivation of



## **Table of Contents**

particular pathogens only to the extent we have laboratory data to support such claims. After regulatory approval for the initial indications, further studies may be necessary to gain approval for the use of the product for additional indications.

In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the United States, Germany, Canada, and Australia, and other countries, applicable to our prospective customers of INTERCEPT Blood System products, the blood centers that process and distribute blood and blood products. In those countries, blood centers and other customers will be required to obtain approved license supplements from the appropriate regulatory authorities in each country before making available blood products processed with our pathogen inactivation systems to hospitals and transfusing physicians. For example, our customers in Germany must obtain separate regulatory approvals to manufacture and sell blood components treated with the INTERCEPT Blood System. Our customers may lack the resources or capability to obtain such regulatory approvals. These requirements or regulators' delays in approving license applications or supplements may deter some blood centers from using our products. Blood centers that do submit applications or supplements for manufacturing and sale may face disapproval or delays in approval that could provide further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

***We have limited experience operating a commercial organization. We rely on third parties to market, sell, and distribute our products and to maintain customer relationships in a certain countries.***

Since February 2006, we have been fully responsible for sales, marketing, distribution and regulatory support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties on a timely basis, our attempts to commercialize the INTERCEPT Blood System may be irreparably harmed.

We operate a small organization, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in geographies where the INTERCEPT platelet and plasma systems are approved or can be imported through the import license process. We will need to maintain and continue to increase our competence in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems. Many of these competencies require compliance with European Union and local standards and practices, with which we have limited experience.

We have entered into contracts, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our pathogen inactivation products directly. We have entered into geographical distribution agreements for distribution in Spain, Italy, Portugal, Chile, the Czech Republic, Slovakia, Russia, Poland, Greece, Kuwait, and Qatar. We rely on these distributors to market and sell the INTERCEPT Blood System, obtain any necessary in-country regulatory approvals, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. They may fail to sell product inventory they have purchased from us to end customers. Initial purchases of UVA illuminators or disposable kits by these third parties may not lead to follow-on purchases of disposable platelet and plasma system kits. We have limited visibility into the identity and requirements of blood banking customers these distributors may have. These third parties may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. We may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations.

---

**Table of Contents**

***Our product design and manufacturing supply chain is highly technical and exposes us to significant risks***

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. Fenwal has agreed, through an agreement signed with us in December 2008, to manufacture disposable kits for the platelet and plasma systems for us through the end of 2013. However, Fenwal may fail to manufacture an adequate supply of disposable kits or to do so on a cost effective basis, which would subject us to loss of revenue and reduced contribution margin. Fenwal may fail to coordinate or meet interdependent supply chain obligations, leading to a failure to manufacture an adequate supply of components or devices of the INTERCEPT Blood System, which would also subject us to the risks described below. We contract with independent suppliers, including NOVA Biomedical Corporation, or NOVA, for the manufacture of UVA illuminators and certain components of the INTERCEPT Blood System which are manufactured or assembled at facilities not owned by Fenwal or Baxter. NOVA has not manufactured UVA illuminators for a number of years. Should NOVA have difficulties manufacturing UVA illuminators, we may not be able to supply customer demand or provide replacement UVA illuminators to existing customers. Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons, causing at least temporary interruptions in supply. For our product components, including assembly, we do not have qualified suppliers beyond those on whom we currently rely, and we understand that Fenwal relies substantially on sole suppliers of certain materials for our products. If we need to or choose to identify and qualify alternate suppliers, the process will be time consuming and costly. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. If we conclude that supply of the INTERCEPT Blood System or components from Fenwal and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources and may cause our supply chain to be less efficient.

Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require us to identify and qualify replacement components and may require that we conduct additional studies, which could include clinical trials, to demonstrate equivalency or validate any required design or component changes. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. We will likely be required to redesign the illuminator used in the platelet and plasma systems to manage the risk of obsolete components. Such redesign may be expensive and lead to regulatory delays in obtaining approvals to market the redesigned device.

Fenwal manufactures our platelet and plasma systems in facilities that are not FDA-approved. In order to be sold in the United States, our systems would be required to be manufactured in FDA-approved facilities. FDA validation of manufacturing facilities, whether owned by Fenwal or by other parties, will be costly and time-consuming.

If we determine to establish alternate manufacturers, we will also be dependent on Fenwal to transfer know-how relevant to the manufacture of the INTERCEPT Blood System; however, certain of Fenwal's materials, manufacturing processes and methods are proprietary to Fenwal. We may be unable to establish alternate sources of supply to Fenwal, NOVA, or other suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review, which would delay our ability to commercialize the platelet and plasma systems. Fenwal is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Raw material and component suppliers may not meet quality specifications we have set, which would cause a disruption in supply and may lead to lost sales and irreparable damage to our customer relationships. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals.

---

## **Table of Contents**

In the event of a failure by Fenwal or other manufacturers to perform their obligations to supply components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Our supply agreements with Fenwal and NOVA, and supply agreements with others contain limitations on incidental and consequential damages that we may recover. A supplier's potential liability in the event of non-performance may not be sufficient to compel the supplier to continue to act in conformity with our agreements.

We are in the early stages of commercializing the INTERCEPT Blood System and may not accurately forecast demand for the INTERCEPT Blood System. In addition, we generally require our distributors to provide us with sales forecasts and binding purchase orders and as such, we may make inventory purchase decisions based on these forecasts. We have contracted with third parties to supply platelet and plasma systems and components to meet forecasted demand. However, such forecasts may prove to be either higher or lower than actual commercial demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. We have entered into certain public tenders, some which call for us to maintain certain minimum levels of inventory. If Fenwal or third-party manufacturers fail to produce components or our finished products satisfactorily, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non-compliance with certain public tenders which may in turn result in permanent harm to our customer relations or loss of customers. Our platelet and plasma system disposables have received regulatory approval for two-year shelf lives. We and our distributors may be unable to ship product to customers prior to the expiration of product shelf life, which would require that we destroy or consume the outdated inventory in product demonstration activities. Product expiration may in turn lead to elevated product demonstration costs or reduced gross margins.

***The platelet system is not compatible with some commercial platelet collection methods and platforms and platelet storage solutions.***

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the United States and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe, and the pooled random donor method, which is used in the United States.

Our system for platelets is designed to work with platelets collected and stored in storage solutions, called Intersol and SSP+, and for platelets suspended in plasma. For platelets collected by apheresis, the INTERCEPT platelet system is most compatible with Fenwal's apheresis platelet collection system, because it facilitates the use of Intersol. For platelets prepared from whole blood, our platelet system is most compatible with the buffy coat collection method. As a result, we have conducted most of our clinical studies using either Fenwal's equipment or buffy coat platelets. Fenwal may be required to obtain separate regulatory approval for Intersol in the United States and in countries which do not recognize CE mark approval before customers would be able to use Intersol with the INTERCEPT Blood System in those countries.

In order to address the entire market in the United States, we would need to develop and test additional configurations of the platelet system. Our efforts to develop the platelet system were initially focused on apheresis platelets collected on Fenwal's automated collection platform or using the buffy coat collection method. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. In order to gain regulatory approvals for a pathogen inactivation system compatible with random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product

---

## **Table of Contents**

configurations for the platelet and plasma systems. These development activities would increase our costs significantly, and may not be successful.

Fenwal has committed to us to make Intersol collection and pooling products and conversion kits available to customers. However, Fenwal may not make such products or its apheresis collection system available for sale timely or in certain countries and has elected to discontinue sales efforts for its apheresis collection system in Japan.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System compatible with their platforms. Attaining compatibility with collection platforms manufactured by others may require adaptations to either the INTERCEPT Blood System or to the collection platforms, which may be difficult to engineer, expensive to implement and test, require additional clinical trials, cause delays in regulatory approval and/or be commercially unattractive to pursue. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the INTERCEPT Blood System may be delayed until the system receives regulatory approval for use on such other equipment, if required.

***We have used prototype components in our preclinical studies and clinical trials of the INTERCEPT red blood cell system and have not completed the components commercial design. We will be required to identify and enter into agreements with third parties to manufacture the red blood cell system and related blood component storage solutions.***

Our red blood cell system that we used in our preclinical studies and recently completed Phase I red blood cell trial are prototypes of systems to be used in the final products. As a result, we expect regulatory authorities will require us to perform additional preclinical and clinical studies using the commercial versions of the systems to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial products, which may increase our expenses and delay the commercialization of our products. We may determine that although the modified red blood cell system may overcome technical issues encountered in the past, it may not be commercially feasible from potential customers' perspectives. If we fail to develop commercial versions of the INTERCEPT red blood cell system on schedule, our potential revenue would be delayed or diminished and our potential competitors may be able to bring products to market before we do.

In addition, the design and engineering effort required to complete the final commercial product will likely be substantial and time-consuming. As with any complex development effort, we expect to encounter design, engineering and manufacturing issues. Such issues have previously arisen, sometimes unexpectedly, and solutions to these issues have not always been readily forthcoming. Additional unforeseen design, engineering and manufacturing issues may arise in the future, which could increase the development cost and delay commercialization of our products.

We will need to identify and contract with parties to perform manufacturing related to our red blood cell system, including the chemical compounds used in the red blood cell system. It may be difficult to enter into these types of agreements on reasonable terms. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to commercialize the red blood cell system, even if we successfully complete clinical development. Any new or additional commercial manufacturer will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that its commercial scale manufacturing processes comply with government regulations and that its compounds are equivalent to originally licensed compounds in order for us to maintain commercial licensure of our products. It may be difficult or impossible to economically manufacture our products on a commercial scale.

---

**Table of Contents**

***BioOne may fail to take advantage of commercialization rights for our platelet and plasma systems in many Asian countries.***

Baxter and we licensed to BioOne rights to commercialize the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. BioOne is subject to similar risks in its territories regarding commercialization of the INTERCEPT Blood System as we are. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in countries where it holds licenses to commercialize the INTERCEPT platelet and plasma systems. BioOne is dependent on Fenwal and us for the manufacture and supply of the platelet and plasma systems. BioOne may be unable to qualify the platelet and plasma systems for sale in certain countries in its territory.

BioOne has made little progress to date in commercializing the platelet and plasma systems in Asian territories. Because we only have a minority investment interest in BioOne, we lack the ability to significantly influence BioOne, and are reliant on BioOne's performance to realize milestone and royalty revenue from commercialization of our platelet and plasma systems in those countries. In Japan, regulatory authorities may require our platelet and plasma systems to be widely adopted commercially in Europe or approved by the FDA before the platelet and plasma systems are considered for approval in Japan, which would delay or prevent BioOne from achieving significant product revenue. In July 2007, BioOne raised limited additional capital in order to fund curtailed operations. At these reduced operating levels, we expect that BioOne's ability to commercialize the platelet and plasma systems in its Asian territories is compromised. We understand that BioOne will need to raise additional capital to continue its operations beyond the near term and we do not know if it will be able to complete such a financing at or above our carrying value or at all. There is no assurance that BioOne will be able to attract additional required capital in the future to successfully commercialize those products licensed from Fenwal and us. Even if BioOne fails to commercialize the INTERCEPT Blood System in its territories, we may be unable to assert contractual rights to regain commercialization rights on satisfactory terms, if at all.

***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.***

We expect our products to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use, and may compete with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to medical and technological changes brought about by the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures.

Several companies have, or are developing, technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in platelets and plasma. These alternative strategies may be more effective in inactivating certain types of pathogens from blood products, including non-lipid-enveloped pathogens, such as hepatitis A virus, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, for which our products have not demonstrated a high level of inactivation. While our products can effectively inactivate a broad spectrum of pathogens in blood components, including more robust inactivation of many pathogens than has been shown by other companies, market acceptance of our products may be reduced if customers determine that competitor's products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. 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. CaridianBCT is developing a pathogen inactivation system for blood products and has been issued CE marks for a pathogen

---

## Table of Contents

reduction system for both platelets and plasma. We understand that CaridianBCT has also commenced trials on a pathogen inactivation system for whole blood, which if successful, may offer competitive advantages over our INTERCEPT Blood System.

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

***We may be liable and we may need to withdraw our products from the market if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials. Our insurance coverage may be inadequate to offset losses we may incur.***

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and pharmaceutical products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in clinical and preclinical testing could be discovered after a marketing approval has been received. For example, in cases where we have obtained regulatory approval for our products, we have demonstrated pathogen inactivation to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations would be harmed and we would incur unforeseen losses.

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

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

---

**Table of Contents**

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

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting studies and clinical development of our platelet and red blood cell systems, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We believe that our available cash balances will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect.

We may borrow additional capital from institutional and commercial banking sources to fund future growth on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to product revenues, our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us.

Our ability to raise additional capital by selling common stock is limited. All of our authorized common stock have been either issued or reserved for issuance in connection with convertible preferred stock, warrants, our employee stock purchase plan, and our equity incentive plan. Accordingly, in order to have shares available for future sale, we and our stockholders will need to approve an authorization to increase the number of shares that are issuable under our certificate of incorporation. Our ability to raise additional capital may also be adversely impacted by global, regional or national economic conditions. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms favorable to us or our stockholders. If we are unable to raise additional capital we may need to curtail planned development. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over development and commercialization of the red blood cell system and pursuit of regulatory approval of the platelet or plasma system in the United States.

Historically, we had received significant awards in funding under cooperative agreements with the DoD. Further funding awarded under Federal grants and cooperative agreements for the INTERCEPT Blood Systems may decline when compared to historic levels. Access to Federal grants and cooperative agreements is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. If we are unable to obtain Federal grant and cooperative agreement funding for future research and development activities at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs.

***We have only a limited operating history, and we expect to continue to generate losses.***

We may never achieve a profitable level of operations. Our development and selling, general, and administrative expenses have resulted in substantial losses each year since our inception with the exception of the

---

## **Table of Contents**

year ended December 31, 2005. At December 31, 2009, we had an accumulated deficit of approximately \$410.0 million. The platelet and plasma systems are not yet approved in the United States or in many other countries around the world. The red blood cell system is in early stage clinical development and may never emerge from the clinical development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which may reduce or altogether eliminate our gross profit on sales. At our present sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer the systems are in excess of revenue. Contribution from product sales is unlikely to exceed the costs we incur in research, development, and commercialization of the INTERCEPT Blood System for near-term. We expect our losses to continue at least until the INTERCEPT Blood System achieves more significant market acceptance. To the extent that we are able to secure funding from partners or government agencies for further development of the red blood cell system or an additional Phase III clinical trial of the platelet system in the United States, we will incur costs of such activities would extend the period during which we expect to operate at a loss.

***Our investment portfolio may become impaired by further deterioration of the capital markets.***

Our cash equivalent and short-term investment portfolio as of December 31, 2009 consisted primarily of high credit, high liquidity United States government agency securities, asset backed securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We follow an established investment policy and set of guidelines to monitor, manage and limit our exposure to interest rate and credit risk.

As a result of adverse financial market conditions, investments in some financial instruments, such as structured investment vehicles, sub-prime mortgage-backed securities, auction rate securities and collateralized debt obligations, may pose risks arising from liquidity and credit concerns. We have limited holdings of these investments in our portfolio; however, the current disruptions in the credit and financial markets have negatively affected investments in many industries, including those in which we invest. We did not recognize any other-than-temporary impairments on our investment portfolio during 2009. The recent global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

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

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



---

**Table of Contents**

*We do not anticipate receiving significant economic benefit from the spin-off of our immunotherapy business.*

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc. for preferred stock representing an equity interest of approximately 20% of Anza's preferred equity. We were informed that Anza had ceased operations by March 31, 2009. In July 2009, we and Anza's remaining stockholders agreed that we would relinquish our ownership in Anza and that Anza would transfer all of its intellectual property to Aduro BioTech Inc, or Aduro. In November, in exchange for the transfer, we received \$0.8 million in cash, preferred shares representing 10% of Aduro's capital and a royalty on any future sales resulting from the transferred technology. There is no assurance that the equity we have received in Aduro will have monetary value at or that we will receive any royalties from Aduro.

*We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.*

Our commercial success will depend, in part, on obtaining and maintaining patent protection on our products and successfully defending our products against third-party challenges. Our technology will be protected from unauthorized use only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to:

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, a United States patent issued to a third-party covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems, if and when those products are sold in the United States. Our key blood safety patents generally expire at various dates between 2012 and 2026. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fenwal to United States and foreign patents relating to the INTERCEPT Blood System, which expire from 2010 to 2023. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

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

We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings before the United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights.

## **Table of Contents**

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

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

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

Product sales of our blood safety products are typically made in Europe and generally are invoiced to customers in Euros. In addition, we purchase finished disposable kits for our platelet and plasma systems and incur operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of interest (expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

*The market price of our stock may be highly volatile.*

The market prices for our securities and those of other emerging medical device and biotechnology companies have been, and may continue to be, volatile. For example, during the period from January 1, 2007 to December 31, 2009, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of \$0.55 to a high of \$10.29. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

decisions regarding reimbursement and commercial adoption by customers, national blood services or governmental bodies;

biological or medical discoveries;

technological innovations discovered or new commercial services offered by us or our competitors;

developments concerning proprietary rights, including patents and litigation matters;

regulatory developments;

status of development partnerships;

dilution from future issuances of common stock, including through the exercise of vested stock options;

debt financings, with terms that may not be viewed favorably by stockholders;

public concern as to the safety of new technologies;

general market conditions;

comments made by analysts, including changes in analysts' estimates of our financial performance; and

quarterly fluctuations in our revenue and financial results.

Recently, the stock market has experienced extreme price and volume fluctuations due to the unprecedented turmoil and upheaval of the credit markets and the financial services industry, which have particularly affected

---

**Table of Contents**

the market prices for emerging biotechnology and medical device companies, and has adversely affected the market price of our common stock.

***Our stock price may not meet the minimum bid price for continued listing on The NASDAQ Global Market. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The NASDAQ Global Market or if we are unable to transfer our listing to another stock market.***

Our common stock is currently listed on The NASDAQ Global Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Global Market. These requirements include maintaining a minimum closing bid price of \$1.00 per share. If our common stock does not maintain a minimum closing bid price of \$1.00 per share, we may be subject to delisting by NASDAQ for failure to meet the continued listing requirements. Delisting from The NASDAQ Global Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of investor interest and fewer business development opportunities.

***We may fail to comply fully with elements of the Sarbanes-Oxley Act of 2002. Our failure to maintain effective internal controls in accordance with Section 404 of this Act could have a material adverse effect on our stock price.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accountants attesting to the effectiveness of our internal controls. These requirements extend to the operations of our subsidiary in Europe. If we fail to maintain the adequacy of our internal controls over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude in future periods that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

***Provisions of our charter documents, our stockholder rights plan and Delaware law could make it more difficult for a third party to acquire us, even if the offer may be considered beneficial by our stockholders.***

Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti-takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. In addition, Section 203 of the Delaware General Corporation Law, unless its application has been waived, provides certain default anti-takeover protections in connection with transactions between the company and an interested stockholder of the company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent stockholders. Our board of directors has also adopted a stockholder rights plan, or poison pill, which would significantly dilute the ownership of a hostile acquirer. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine.

**Table of Contents****Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

We lease both laboratory and general administrative space in Concord, California. These facilities are utilized for our main office and blood safety research. In addition to the leased space in Concord, we lease selling and administrative offices in Amersfoort, the Netherlands. We believe that our current facilities and available additional space, including after the expiration of those leases, will be adequate for the foreseeable future and do not plan on renewing any existing leases that expire in 2010. The following table depicts the functional nature of our leases, size, location, and term of our leased space.

Function	Location	Square Footage	Lease Expiration Date	Expiration if Renewal Options Exercised
Corporate Offices <sup>1</sup>	Concord, CA, USA	21,400	July 2010	July 2013
Sales & Administrative	Amersfoort, The Netherlands	7,300	January 2013	December 2013
Laboratories Blood Safety <sup>2</sup>	Concord, CA, USA	9,900	January 2010	
Laboratories Blood Safety	Concord, CA, USA	31,800	November 2019	November 2024

<sup>1</sup> Leases not expected to be renewed.

<sup>2</sup> Leasing 2,000 square feet on a month-to-month basis after January 2010.

**Item 3. Legal Proceeding**

None.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock is traded on the Nasdaq Global Market under the symbol CERS. The following table sets forth, for the periods indicated, the high and low sales prices for the common stock as reported by the Nasdaq Global Market:

	High	Low
<b>Year Ended December 31, 2008:</b>		
First Quarter	\$ 7.29	\$ 4.18
Second Quarter	7.24	4.09
Third Quarter	5.35	3.20
Fourth Quarter	4.37	.55
<b>Year Ended December 31, 2009:</b>		
First Quarter	\$ 1.12	\$ 0.59
Second Quarter	1.50	0.63
Third Quarter	3.57	0.81
Fourth Quarter	2.83	1.57

On February 18, 2010, the last reported sale price of our common stock on the Nasdaq Global Market was \$2.30 per share. On February 18, 2010, we had approximately 175 holders of record of common stock. We have not paid dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future.

**Table of Contents****Performance Measurement Comparison (1)**

The following graph shows the total stockholder return of an investment of \$100 in cash (and the reinvestment of any dividends thereafter) on December 31, 2004 for (i) our common stock, (ii) the NASDAQ Biotechnology Stocks Index, (iii) the Amex Biotech Index, and (iv) the NASDAQ Stock Market (United States) Index. Our stock price performance shown in the graph below is based upon historical data and is not indicative of future stock price performance.

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

	<b>December 31,</b>					
	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>
Cerus Corporation	\$ 100.00	\$ 344.07	\$ 198.64	\$ 220.68	\$ 23.73	\$ 67.46
NASDAQ Biotech Index	100.00	102.84	103.89	108.65	94.93	109.77
Amex Biotech Index	100.00	125.11	138.59	144.51	118.91	173.11
NASDAQ	100.00	101.37	111.03	121.92	72.49	104.26

- (1) The graph and other information furnished under this Part II Item 5 of this Form 10-K shall not be deemed to be soliciting material or to be filed with the Commission or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Exchange Act of 1934, as amended.

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

The following table summarizes certain selected financial data for the five years ended December 31, 2009. The information presented should be read in conjunction with the financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. The selected financial data for the periods prior to the financial statements included in this Annual Report on Form 10-K are derived from audited financial statements. The data presented below may not be indicative of future results.

	2009	2008	2007	2006	2005
	(in thousands, except per share data)				
<b>Statement of Operations Data: (1)</b>					
Product revenue	\$ 16,751	\$ 15,518	\$ 8,015	\$ 2,975	\$ 485
Other revenue	1,231	989	3,029	27,335	13,012
Total revenue	17,982	16,507	11,044	30,310	13,497
Cost of product revenue	12,580	9,668	5,228	1,541	
Gross profit	5,402	6,839	5,816	28,769	13,497
Operating expenses (gains):					
Research and development	6,372	10,205	14,957	16,036	10,660
Selling, general and administrative	21,867	27,164	24,575	15,082	10,785
Loss on long-term investments in related parties, net (2)	1,536		9,450		
Gain on operating settlement (3)	(1,381)				
Restructuring	841				
Total operating expenses	29,235	37,369	48,982	31,118	21,445
Loss from operations	(23,833)	(30,530)	(43,166)	(2,349)	(7,948)
Net interest and other income (expense)	(302)	1,349	4,066	4,701	22,405
Net income (loss) from continuing operations	\$ (24,135)	\$ (29,181)	\$ (39,100)	\$ 2,352	\$ 14,457
Discontinued operations:					
Loss from discontinued operations			(5,820)	(7,131)	(1,393)
Loss from sale of discontinued operations			(384)		
Net loss from discontinued operations			(6,204)	(7,131)	(1,393)
Net income (loss)	\$ (24,135)	\$ (29,181)	\$ (45,304)	\$ (4,779)	\$ 13,064
Net income (loss) from continuing operations per common share:					
Basic	\$ (0.69)	\$ (0.90)	\$ (1.23)	\$ 0.09	\$ 0.65
Diluted	\$ (0.69)	\$ (0.90)	\$ (1.23)	\$ 0.08	\$ 0.60
Net loss from discontinued operations per common share:					
Basic	\$	\$	\$ (0.19)	\$ (0.27)	\$ (0.06)
Diluted	\$	\$	\$ (0.19)	\$ (0.25)	\$ (0.06)
Net income (loss) per common share:					
Basic	\$ (0.69)	\$ (0.90)	\$ (1.42)	\$ (0.18)	\$ 0.58
Diluted	\$ (0.69)	\$ (0.90)	\$ (1.42)	\$ (0.17)	\$ 0.55
Weighted average common shares outstanding used for basic and diluted income (loss) per common share:					
Basic	34,750	32,430	31,870	26,870	22,350
Diluted	34,750	32,430	31,870	28,610	23,950
	2009	2008	2007	2006	2005
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 19,931	\$ 22,578	\$ 56,850	\$ 93,416	\$ 45,805
Working capital	19,446	29,145	55,582	87,929	27,690
Total assets	34,491	47,339	78,209	115,817	58,660
Loan and interest payable					4,826
Capital lease obligations, less current portion			2	32	68



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

Accumulated deficit	(410,042)	(385,907)	(356,726)	(311,422)	(306,643)
Total stockholders' equity	\$ 21,448	\$ 34,278	\$ 59,887	\$ 100,971	\$ 35,275

- (1) Statement of operations data for 2005, 2006 and 2007 has been restated to reflect the treatment of our former immunotherapy business as a discontinued operation. See Footnote 17 to Consolidated Financial Statements under Item IV to this Annual Report on Form 10-K;
- (2) Includes impairment of Company investment in BioOne Corporation and gain recognized from former immunotherapy business. See Footnote 1 to Consolidated Financial Statements under Item IV to this Annual Report on Form 10-K;
- (3) Settlement with Baxter regarding INTERCEPT commercialization transition. See Note 13 to Financial Statements in Section IV;

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

*This discussion and analysis should be read in conjunction with our consolidated financial statements and the accompanying notes included in this report and the audited consolidated financial statements and accompanying notes included in this Annual Report on Form 10-K for the year ended December 31, 2009. Operating results for the year ended December 31, 2009 are not necessarily indicative of results that may occur in future periods.*

*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 this 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 Systems, the successful completion of our research, development and clinical programs our ability to manage cost increases associated with pre-clinical and clinical development for the INTERCEPT Blood Systems, our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood Systems, 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. 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 above. 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.*

**Overview**

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of blood safety systems and, from 2001 until late 2007, immunotherapies for cancer and infectious disease. Our INTERCEPT platelet system, or the platelet system, and our INTERCEPT plasma system, or the plasma system, have received CE marks and are being marketed in Europe, Russia, the Middle East and selected countries in other regions around the world. We are pursuing regulatory approvals for the platelet and plasma systems in the United States and other countries. The INTERCEPT red blood cell system, or the red blood cell system, is in early stage clinical development.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting studies and clinical development of our platelet and red blood cell systems, timing and magnitude of payments under awards from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, meeting our long-term capital requirements is in

---

**Table of Contents**

large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We believe that cash received from product sales and our available cash balances will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect.

We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over pursuit of development and commercialization of the red blood cell system, or regulatory approval of the platelet or plasma systems in the United States.

We may borrow additional capital from institutional and commercial banking sources to fund future growth on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. All of our authorized common stock have been either issued or reserved for issuance in connection with convertible preferred stock, warrants, our employee stock purchase plan, and our equity incentive plan. Accordingly, in order to have shares available for future sale, we and our stockholders will need to approve an authorization to increase the number of shares that are issuable under our certificate of incorporation and we cannot guarantee that our stockholders would approve such an increase. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us. The credit markets and the financial services industry have continued to experience turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain and the terms less favorable to the companies seeking to raise financing. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the disruptions to the credit and financial markets in the United States and worldwide or other factors, we will need to curtail planned development and commercialization activities.

We recognize growing, but still relatively modest, product revenues from the sale of our platelet and plasma systems in Europe, Russia, the Middle East, and certain other countries around the world. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products that, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses at least until after our platelet and plasma systems gain widespread commercial acceptance in Europe, Russia, the Middle East, and selected countries in other regions around the world. Our ability to achieve a profitable level of operations in the future will depend on our ability to successfully commercialize and achieve market acceptance of our blood safety products. We may never achieve a profitable level of operations. Subject to the availability of adequate funding from partners, government grants, and/or capital markets, we also anticipate continuing our expenditures in support of preclinical and clinical trials and device development of our red blood cell system over the next several years.

We pay royalties to Fenwal on product sales, at rates of 10% of net 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 December 2008, we amended and extended our supply agreement with Fenwal for the manufacture of INTERCEPT finished disposable kits for the platelet and plasma systems through December 31, 2013. Under the amended manufacturing agreement, we pay Fenwal a set price per kit, which is established annually, plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead will be paid or refunded if actual manufacturing volumes are lower or higher than the annually estimated production volumes. Under the amended manufacturing

---

## Table of Contents

agreement, we are responsible for providing certain disposable kit components to Fenwal at no cost to Fenwal. This required us to enter into supply arrangements with certain other manufacturers for those components, some of which contain minimum purchase commitments. As a result, our supply chain for certain of these components, held as work-in-process on our consolidated balance sheet, can take over one year to complete production before being utilized in finished disposable kits.

We have worldwide commercialization rights for the INTERCEPT blood systems, except in certain parts of Asia. BioOne is responsible for commercializing the platelet and plasma systems, including regulatory efforts, in those certain parts of Asia. At December 31, 2009, we owned approximately 13% of the equity interest in BioOne and evaluate the carrying value of our investment in BioOne using a variety of criteria. These criteria included, but are 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.

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc., or Anza for preferred stock representing and equity interest of approximately 20% of Anza's preferred equity. We accounted for the immunotherapy business as a discontinued operation and restated our consolidated financial statements for 2007 and prior periods to reflect that accounting treatment. 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 and separate agreements with each of Anza and Aduro BioTech (collectively, the Assignment Agreements). In November 2009, Anza transferred all of its intellectual property to Aduro BioTech, or Aduro, pursuant to the terms of the Assignment Agreements. In exchange for agreeing to the transfer and for relinquishing our shares in Anza and releasing any claims against Anza, we received \$0.8 million in cash, preferred shares representing 10% of Aduro's capital and a 1% royalty on any future sales resulting from the transferred technology. Because Aduro's technology and efforts are in the very early stage of research and development, we have no basis to assign value to the equity we have received in Aduro or that such equity will have monetary value at such time we are allowed to sell it or that we will receive any royalties from Aduro.

Through December 31, 2009, in addition to the product revenues from sales of our platelet and plasma systems, we have recognized revenue from grants and cooperative agreements with the Armed Forces.

### **Critical Accounting Policies and Management Estimates**

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

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

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

Revenue related to product sales is generally recognized when we fulfill our obligations for each element of an agreement. For all sales of our INTERCEPT Blood System products, we use a binding purchase order and

**Table of Contents**

signed sales contract as evidence of a written agreement. We sell INTERCEPT Blood System for platelets and plasma directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, we evaluate whether the delivered elements have standalone value to the customer, whether the fair value of the undelivered elements is reliably determinable, and whether the delivery of the remaining elements is probable and within our control. When all of these conditions are met, we recognize the revenue on the delivered elements. If these conditions are not met, we defer revenue until such time as all of the conditions have been met or all of the elements have been delivered. Consideration received is allocated to elements that are identified as discrete units of accounting based on the relative fair market value method. Freight costs charged to customers are recorded as a component of revenue and value-added-taxes, or VAT, that we invoice to our customers and remit to governments are recorded on a net basis, which excludes such VAT from product revenue.

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

**Inventory** 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, can take over one year to complete production before being utilized in finished disposable kits. Under our manufacturing agreement with Fenwal, our carrying value of INTERCEPT disposable kits is dependent on an annually set price. In addition, at the end of each year, volume driven manufacturing overhead is either paid or refunded by or to us if manufacturing volumes are higher or lower than the anticipated manufacturing volumes at the time the price is established. As a result, at each interim period, manufacturing overhead can fluctuate and requires us to use judgment in accruing the manufacturing overhead. In addition, we use judgment in determining whether the manufacturing overhead is a cost of our inventory and recoverable when product is sold. We use significant judgment and evaluate manufacturing variances incurred during periods of abnormally low production by considering a variety of factors including the reasons for low production volumes, anticipated future production levels that correlate to and offset volumes experienced during abnormally low production cycles, and contractual requirements. We record manufacturing variances incurred during periods of abnormally low production volumes as a component of cost of product revenue when production volumes are abnormally low.

Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Our platelet and plasma system disposable kits generally have a two-year shelf life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. Our limited history selling the INTERCEPT Blood System limits the amount of historical data we have to perform this analysis. Generally, we write-down specifically identified obsolete, slow-moving, or known unsalable inventory that has no alternative use, using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts.

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

---

**Table of Contents**

**Stock-based compensation** We issue stock-based awards to our employees, members of our Board of Directors, our Scientific Advisory Board and certain contractors as strategic, long-term incentives. We recorded stock-based compensation expense for employee awards in accordance with ASC 505-50, Compensation Stock Compensation . We use the Black-Scholes option pricing model to determine the grant-date fair value of a stock award. We continue to apply the provisions of Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunctions with Selling, Goods or Services, for our non-employee stock-based awards. Under the provisions, the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of the non-employee awards in our consolidated statements of operations.

The Black-Scholes option pricing model calculates the grant-date fair value using certain variables. These variables are impacted by our stock price, award exercise behaviors, the risk free interest rate and our expected dividends and many of these variables require us to use significant judgment.

*Expected Term.* We estimate the expected term of options granted using a variety of factors. Where possible, we estimate the expected term of options granted by analyzing employee exercise and post-vesting termination behavior. To make this estimation, we analyze the population of options granted by discrete homogeneous groups. For those homogeneous groups where we are unable to obtain sufficient information to estimate the expected term in this manner, we estimate the expected term of the options granted by taking the average of the vesting term and the contractual term of the option. The expected term of employee stock purchase plan shares is the term of each offering period.

*Estimated Forfeiture Rate.* We estimate the forfeiture rate of options at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. We estimate the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

*Estimated Volatility.* We estimate the volatility of our common stock by using historical volatility of our common stock. We have used significant judgment in making these estimates and we will continue to monitor the availability of actively traded options on our common stock. If we determine that sufficient actively traded options on our common stock exist, we may consider a combination of historical and implied volatility, or solely implied volatility.

*Risk-Free Interest Rate.* We base the risk-free interest rate that we use in the option valuation model on United States Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Expected Dividend.* We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option valuation model.

If factors change and we utilize different assumptions in determining the grant-date fair value of stock compensation expense in the future, or if we utilize a different option pricing model in the future, then those results may differ significantly from what we have recorded in the current period and could materially affect our operating results. There is significant risk that the Black-Scholes option pricing model and the judgment we have used in ascertaining the variables will yield results that differ materially from the actual values realized upon the exercise, expiration, termination or forfeitures of the awards in the future. Historical results were utilized in deriving our variables, which may not be indicative of the future.

**Income Taxes** Since our inception, we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate

**Table of Contents**

that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carry forwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. We do not recognize tax positions that have a lower than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance is not an appropriate substitute for the derecognition of a tax position. We did not have any recorded liabilities for unrecognized tax benefits at December 31, 2009 or 2008. We recognize interest accrued and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our statements of operations, nor have we accrued for or made payments for interest and penalties. We continue to carry a full valuation allowance on all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed.

**Results of Operations***Years Ended December 31, 2009, 2008, and 2007**Revenue*

(in thousands, except percentages)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Product revenue	\$ 16,751	\$ 15,518	\$ 8,015	8%	94%
Government grant and cooperative agreements	1,231	989	3,029	24%	(67)%
<b>Total revenue</b>	<b>\$ 17,982</b>	<b>\$ 16,507</b>	<b>\$ 11,044</b>	<b>9%</b>	<b>49%</b>

Product revenue increased \$1.2 million to \$16.8 million during the year ended December 31, 2009, compared to \$15.5 million during the comparable period in the prior year. This increase was largely driven by an increase in the number of disposable platelet and plasma system kits sold to customers in Europe, Russia, and the Middle East. Notably, disposable kit sales to customers in France, Southern Europe and Belgium accounted for a significant portion of the increase in product revenue in 2009 from 2008. The increase was largely driven by an increase of \$2.4 million in sales of platelet and plasma disposable kits, offset by \$1.2 million decrease in product revenue from UVA illuminators. Product revenue increased \$7.5 million to \$15.5 million during the year ended December 31, 2008, compared to \$8.0 million during the comparable period in 2007. The increase was largely driven by an increase in the number of disposable platelet and plasma system kits sold to customers in Europe, Russia, and the Middle East. We anticipate product revenue for both the platelet and plasma systems will continue to increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway. Historical annual results may not be indicative of INTERCEPT Blood System revenue in the future.

We recognized \$1.2 million in revenue from government grants and cooperative agreements for the year ended December 31, 2009, compared to \$1.0 million for the comparable period in 2008. The increase was due primarily to an increase in the activities subject to reimbursement under current awards with the United States Department of Defense, or DoD. Of the total awarded amount during the year ended December 31, 2009 and 2008, the majority of the grant revenue came from reimbursement under a DoD award for development activities related to our red blood cell system. We recognized \$1.0 million in revenue from government grants and cooperative agreements for the year ended December 31, 2008, compared to \$3.0 million for the comparable period in 2007. The decrease was due primarily to the new DoD awards at reduced values for research activities for our INTERCEPT red blood cell system.

**Table of Contents****Cost of Product Revenue**

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

(in thousands, except percentage)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Cost of Product Revenue	\$ 12,580	\$ 9,668	\$ 5,228	30%	85%

Cost of product revenue increased \$2.9 million to \$12.6 million during the year ended December 31, 2009, compared to \$9.7 million during the comparable period in 2008. This increase in the cost of product revenue was due to the larger number of disposable platelet and plasma system kits sold, increased provisions for obsolete slow-moving and scrapped inventory, offset by lower illuminator sales during the year ended December 31, 2009, compared to the number sold during the prior year. In addition, royalties owed to Fenwal increased during the year ended December 31, 2009, compared to the same period in 2008, due to increased sales of both the platelet and plasma systems during the year ended December 31, 2009. Furthermore, cost of product revenue increased in 2009 compared to 2008 due to manufacturing and supply chain costs incurred as a result of the Company's decision to curtail manufacturing and optimize inventory levels, leading higher overhead absorption to the inventory units that were manufactured.

Similarly, cost of product revenue increased \$4.4 million to \$9.7 million during the year ended December 31, 2008, compared to \$5.2 million during the comparable period in 2007. This increase in the cost of product revenue was primarily due to the larger number of disposable platelet and plasma system kits sold during the year ended December 31, 2008, compared to the number sold during the year ended December 31, 2007, and the increased royalties owed to Fenwal as a result of increased sales of both the platelet and plasma systems during the year ended December 31, 2008. Finally, cost of product revenue increased in 2008 compared to 2007 due to a non-cash charge of \$0.4 million for potentially unusable work-in-progress inventory.

We anticipate that our cost of product revenue will continue to increase in the future as we continue to increase product sales volume. Our realized gross margins on product sales were 25% in 2009, down from 38% in 2008, and down from 35% in 2007. The changes in our gross margins are affected by various factors, including manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which product is sold. Generally, we offer our distributors tiered volume discounts of varying magnitudes, depending on their purchase commitments, which depending on sales volumes to those distributors receiving tiered volume discounts, may impact our gross margins.

We expect to maintain inventory levels that will be sufficient to meet forecast demand for a relatively short time period and plan to manufacture at levels above those produced in 2009. Manufacturing at levels above the levels produced in 2009 should result in a lower per unit cost of goods sold when the product is ultimately sold.

**Research and Development Expenses**

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

(in thousands, except percentages)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Research and development	\$ 6,372	\$ 10,205	\$ 14,957	(38)%	(32)%



**Table of Contents**

Research and development expenses decreased \$3.8 million to \$6.4 million for the year ended December 31, 2009, compared to \$10.2 million during the comparable period in 2008. This decrease in our research and development expenses was the result of reduced research and development activities driven primarily by our March 2009 restructuring plan and the associated reduction in force.

Research and development expenses decreased \$4.8 million to \$10.2 million for the year ended December 31, 2008, compared to \$15.0 million during the comparable period in 2007. This decrease in our research and development expenses was the result of reduced development activities regarding our plasma system and lower clinical trial costs associated with our red blood cell system.

We anticipate our research and development spending will continue at approximately the current level and at times may increase as a result of ongoing and later stage clinical trials and development activities. Because of the numerous risks and uncertainties associated with research and development activities, including but not limited to, the development of the red blood cell system, the time and cost involved in obtaining regulatory approval and subsequent launch of our platelet and plasma systems in the United States, and other development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that may ultimately be associated with our current and anticipated clinical trials and other research and development activities. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, including the risks described in *Risk Factors* in Part I, Item 1A above.

***Selling, General, and Administrative Expenses***

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, non-cash stock based compensation, expenses for our commercialization efforts in Europe and elsewhere, expenses for accounting, tax, and internal control, legal and facility related expenses, and insurance premiums.

(in thousands, except percentage)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Selling, general and administrative	\$ 21,867	\$ 27,164	\$ 24,575	(20)%	11%

Selling, general, and administrative expenses decreased \$5.3 million to \$21.9 million for the year ended December 31, 2009, compared to \$27.2 million during the comparable period in 2008. Overall, this decrease in selling, general and administrative expenses was primarily due to decreased personnel costs and lower marketing and public affairs costs driven primarily by our March 2009 restructuring plan and the associated reductions in force.

Selling, general, and administrative expenses increased \$2.6 million to \$27.2 million for the year ended December 31, 2008, compared to \$24.6 million during the comparable period in 2007. Overall, this increase in selling, general and administrative expenses was primarily due to expansion of our commercial operations in Europe, including increases in personnel costs, and to a lesser extent, increased marketing activities.

Of the total selling, general, and administrative expenses incurred, non-cash stock based compensation represented \$1.6 million, \$1.6 million, and \$1.4 million for the years ended December 31, 2009, 2008, and 2007.

We anticipate that we will be focused on maintaining our selling, general, and administrative spending around the current levels over the next year, as part of a larger effort to lower operating expenses and conserve cash.

**Table of Contents****Restructuring**

Restructuring costs during the year ended December 31, 2009, include one-time termination benefits, facility consolidation and related moving costs.

(in thousands, except percentage)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Restructuring	\$ 841	\$	\$	100%	

In March 2009, pursuant to the Board of Directors' approval, we began implementing a plan to focus resources on commercializing the INTERCEPT Blood System in Europe, to consolidate facilities, and to reduce our cost structure. During the year ended December 31, 2009, we incurred costs for one-time termination benefits for employee positions that were eliminated under the restructuring plan. During the year ended December 31, 2009, we also incurred costs associated with consolidating facilities and certain other costs associated with the restructuring plan. Most costs accrued as one-time termination benefits as of March 31, 2009 were paid by December 31, 2009. The balance of \$0.1 million left at December 31, 2009 will be paid over an extended period of time, into 2010. As a result of the restructuring, Cerus expects that annualized operating expenses may be reduced by about \$10 million compared to operating expenses in 2008.

**Loss from Long-term Investment in Related Parties, Net**

During the year ended December 31, 2009, we owned certain equity interests in two companies, BioOne Corporation and Anza Therapeutics, both accounted for under the cost method of accounting. During 2009, we recorded the following gains and losses on these investments.

(in thousands, except percentage)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Gain from long term investment in related party Anza Therapeutics	\$ (804)	\$	\$	100%	%
Impairment of long-term investment in related party BioOne	2,340		9,450	100%	(100)%
Total	\$ 1,536	\$	\$ 9,450	100%	(100)%

During the year ended December 31, 2009, Anza transferred all of its intellectual property to Aduro BioTech, or Aduro. In exchange for agreeing to the transfer and for relinquishing our shares in Anza and releasing any claims against Anza, we received \$0.8 million in cash. As such, a gain of \$0.8 million was recognized.

We also recorded an impairment to the carrying value on our investment in BioOne of \$2.3 million. The charge was taken as a result of our evaluation of the factors used to support our position in BioOne and the Company determined that the investment was not recoverable.

**Gain on Operating Settlement**

(in thousands, except percentage)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Gain on operating agreement settlement	\$ 1,381	\$	\$	100%	%

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



## **Table of Contents**

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.

### ***Interest Income (Expense) and Other, Net***

Interest income (expense) and other, net consists of interest earned from our short-term investment portfolio, foreign exchange gain (loss), and other non-operating gains and losses.

(in thousands, except percentage)	Years Ended December 31,			% Change	% Change
	2009	2008	2007	2009 to 2008	2008 to 2007
Interest Income (Expense) and Other, Net	\$ (302)	\$ 1,349	\$ 4,066	(122)%	(67)%

Interest income (expense) and other, net, was a net expense of \$0.3 million for the year ended December 31, 2009, compared to \$1.3 million in income during the comparable period in 2008. This decrease in income was primarily due to lower interest income resulting from lower cash and short-term investment balances and lower yields on those balances and foreign currency exchange rate differences between the United States dollar and the Euro, during the year ended December 31, 2009, compared to the year ended December 31, 2008.

Interest income and other, net, was \$1.3 million for the year ended December 31, 2008, compared to \$4.1 million in income during the comparable period in 2007. This decrease in income was primarily due to lower interest income resulting from lower cash and short-term investment balances and lower yields on those balances and foreign currency exchange rate differences between the United States dollar and the Euro, during the year ended December 31, 2008, compared to the year ended December 31, 2007. In addition, during the year ended December 31, 2008, we recorded other-than-temporary impairments totaling \$0.3 million to our investment portfolio as a result of market deterioration due to the tightening global credit crisis.

We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. We generally hold such investments until such time as we liquidate them to meet an operating cash need. Interest paid on our investment portfolio may decrease and the value of certain securities we hold may decline, which could negatively affect our financial condition, cash flow and reported earnings. In August 2009, we completed a public offering of our common stock, netting proceeds of approximately \$12.1 million. We invested these proceeds in marketable securities pursuant to our investment policy, and generally hold such investments until such time as we liquidate them to meet an operating cash need.

### **Liquidity and Capital Resources**

In recent years, our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, payments received under our agreements with BioOne, United States government grants and cooperative agreements, and, contribution from product sales net of expenses and interest income.

At December 31, 2009, we had cash, cash equivalents and short-term investments of \$19.9 million. Net cash used in operating activities was \$14.7 million for the year ended December 31, 2009, compared to \$34.4 million during the comparable period in 2008. The decrease in net cash used in operating activities was primarily due to higher revenues and lower operating expenses, coupled with changes in our operating assets and liabilities, notably inventory which we sold down in 2009, as well as higher accrued expenses. Cash used in operating activities during the year ended December 31, 2008, was \$34.4 million compared to \$37.3 million during the comparable period in 2007. The decrease in net cash used in operating activities was primarily due to changes in

---

**Table of Contents**

our operating assets and liabilities, notably decreases in our accrued expenses and increases in our inventory balances, offset by decreases in our accounts receivable balances. Net cash provided by investing activities during the year ended December 31, 2009, was \$9.4 million compared to \$23.8 million during the comparable period in 2008. The decrease was primarily due to fewer maturities of short-term investments in 2009 compared to 2008. Net cash provided by investing activities during the year ended December 31, 2008, was \$23.8 million compared to \$9.2 million during the comparable period in 2007. The increase was primarily due to fewer purchases of short-term investments in 2008, offset by the sales and maturities of short-term investments. The cash provided by financing activities in 2009 was primarily due to cash received from net proceeds raised from our registered direct public offering of common stock and warrants, while cash provided by financing activities in 2008 was primarily due to cash received from the exercise of stock options. Working capital decreased to \$19.4 million at December 31, 2009, from \$29.1 million and \$55.6 million at December 31, 2008 and 2007, respectively primarily due to lower cash, cash equivalents and short-term investments and partially offset by increased accounts receivable and inventory balances, net of accounts payable balances.

Our near-term capital requirements are dependent on various factors, including operating costs and capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting clinical trials of our red blood cell system, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world, over the pursuit of regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system. Because of the numerous risks and uncertainties associated with the commercialization of the platelet and plasma systems, the time and cost involved in obtaining regulatory approval and subsequent launch of our platelet and plasma systems in the United States, and the development of the red blood cell system and other development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that may ultimately be associated with our anticipated clinical trials and other research and development activities.

We may borrow additional capital from institutional and commercial banking sources to fund future growth on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. All of our authorized common stock have been either issued or reserved for issuance in connection with convertible preferred stock, warrants, our employee stock purchase plan, and our equity incentive plan. Accordingly, in order to have shares available for future sale, we and our stockholders will need to approve an authorization to increase the number of shares that are issuable under our certificate of incorporation and we cannot guarantee that our stockholders would approve such an increase. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or product, or grant licenses on terms that are not favorable to us. The credit markets and the financial services industry continued to experience turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms reasonable to us or our stockholders.

**Table of Contents**

Historically, we had received significant awards in funding under cooperative agreements with the DoD for the INTERCEPT Blood System. Further funding awarded under Federal grants and cooperative agreements for the INTERCEPT Blood Systems may decline when compared to historic levels. Any such funding is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. The general economic environment, coupled with tight Federal budgets, has led to a general decline in the amount of government funding. If we are unable to obtain Federal grant and cooperative agreement funding for the continued development of the INTERCEPT system in the United States at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs.

In late October 2008 we filed a shelf registration statement on Form S-3 to offer and sell up to \$200.0 million of common stock, preferred stock, warrants, and/or debt securities. This shelf registration statement was declared effective by the SEC in December 2008. In August 2009, we completed a registered direct offering under our shelf registration, netting proceeds of approximately \$12.1 million. We will not be able to issue common stock under this shelf registration statement until we and our stockholders approve an increase to the number of authorized shares that are issuable under our certificate of incorporation.

**Commitments and Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements.

*Commitments*

Our commitments are as follows (in thousands):

	Payments Due by Period from December 31, 2009				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
<b>Contractual obligations:</b>					
Minimum purchase requirements	\$ 2,133	\$ 664	\$ 1,469	\$	\$
Operating leases	3,307	971	1,466	870	
Other commitments	306	259	45	2	
<b>Total contractual cash obligations</b>	<b>\$ 5,746</b>	<b>\$ 1,894</b>	<b>\$ 2,980</b>	<b>\$ 872</b>	<b>\$</b>

*Minimum Purchase Requirements*

Our minimum purchase commitments include certain components of our INTERCEPT blood safety system that we purchase from third party manufacturers and supply to Fenway for use in manufacturing finished disposable kits.

*Operating Leases*

We generally lease our office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. On December 10, 2009 we exercised a ten year extension option to extend the term of our lease relating to 2550 Stanwell Drive in Concord, California. By exercising this extension option, our lease payments for that building will be increased. Our facility leases qualify as operating leases under FASB ASC Topic 840, Leases and as such, are not included on our balance sheet.

*Other Commitments*

Our other commitments consist of financing obligations for payment of certain insurance premiums which expire in 2010. In addition, we financed certain of our leasehold buildouts relating to our Amersfoort office.



---

## **Table of Contents**

Under the terms of the financing arrangement, we are obligated to pay for these leasehold buildouts on a monthly basis through the remaining lease term.

### *Royalties*

We are obligated to pay royalties on certain INTERCEPT product sales based on a percentage of net sales generated. The royalty rates vary by product, with rates of 10% of net sales for the platelet system, 3% for the plasma system, 5% for the red blood cell system, and 6.5% for UVA illuminators. As future product sales cannot be estimated, this royalty obligation is not included in the table above.

### **Financial Instruments**

We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of stockholders equity. Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. Unrealized gains at December 31, 2009, 2008, and 2007, totaled \$0.1 million, \$0.2 million, and \$0.1 million, respectively.

We invest our cash, cash equivalents and short-term investments in a variety of financial instruments, consisting primarily of high credit, high liquidity United States government agency securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. Certain of the investments in our portfolio are subject to general market risk and more specifically, the United States mortgage industry and financial institutions. As a result, during the years ended December 31, 2008 and 2007, we recognized other than temporary impairments for certain investments in our portfolio totaling \$0.3 million and \$0.2 million, respectively. We did not recognize any other than temporary impairments during the year ended December 31, 2009. The current global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. There can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

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

Of our cash, cash equivalent, and short-term investments balance of \$19.9 million at December 31, 2009, approximately 87% had original maturity dates of less than 90 days, and the remaining 13% had original maturities more than one year. We do not believe our exposure to interest rate risk to be material given the short-term nature of our investment portfolio and the relatively flat yields in high credit, fixed-income investments and the consistent yields we have experienced and anticipate experiencing across our portfolio, regardless of maturity date.

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. By policy, we place our investments with high quality debt security issuers, limit the amount of credit exposure to any one issuer and limit duration by restricting the term for single securities and for the portfolio as a whole. Our investments are held and managed by a third-party capital management adviser that in turn, utilizes a combination of active market quotes and where necessary, proprietary pricing models as well as a subscribed pricing service, in order to estimate fair value.



**Table of Contents**

We invest our cash, cash equivalents and short-term investments in a variety of financial instruments, consisting primarily of high credit, high liquidity United States government agency securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. Certain of the investments in our portfolio are subject to general market risk and to a lesser extent, the United States mortgage industry. While we believe that we will be able to recognize the fair value of these instruments when they mature or we sell them, there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations.

We account for our short-term investments in accordance with ASC 320, Investments – Debt and Equity Securities. Our cash, cash equivalents and short-term investments are all recorded as current assets on our consolidated balance sheets as they are classified as available-for-sale. Securities with remaining maturities at purchase date of less than 90 days are classified as cash equivalents. The table below presents the amounts and weighted interest rates of our cash, cash equivalents and marketable securities at December 31, 2009 (dollar amounts in thousands):

	Fair Value	Weighted Average Interest Rate
Cash and Cash equivalents (0 – 90 days <sup>(1)</sup> )	\$ 17,287	0.09%
Short-term investments (91 days – 1 year <sup>(1)</sup> )		%
Short-term investments (1 – 3 years <sup>(1)</sup> )	2,644	4.43%
Total investments	\$ 19,931	0.66%

(1) Based on original contractual maturity date

**Foreign Currency Risk**

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

Product sales for our blood safety products are predominantly made in Europe and generally are invoiced to customers in Euros. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems. These inventory purchases and operating expenses are generally paid in Euros and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support of our international operations. Foreign exchange rate fluctuations are recorded as a component of Interest income (expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

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

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

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

None.

**Table of Contents**

**Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* Our chief executive officer and chief accounting officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e), promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of December 31, 2009, our chief executive officer and chief accounting officer have concluded that our disclosure controls and procedures were effective.

*Changes in Internal Control over Financial Reporting.* During the last quarter of our fiscal year ended December 31, 2009, there were no changes in our internal control over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

*Management's Assessment of Internal Control.* Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2009, is discussed in the Management's Report on Internal Control over Financial Reporting included on page 54.

**Item 9B. Other Information**

None.

**Table of Contents**

**PART III**

**Item 10. *Directors and Executive Officers of the Registrant***

Information regarding our directors and officers, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, will be set forth under the captions Election of Directors, Management, Section 16(a) Beneficial Ownership Reporting Compliance and Code of Ethics in our definitive proxy statement, or proxy statement, for use in connection with the annual meeting of stockholders to be held on June 2, 2010, and is incorporated herein by reference. We intend to file the Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our 2009 fiscal year.

**Item 11. *Executive Compensation***

The information required by this item is incorporated herein by reference to the information set forth under the caption Executive Compensation and Other Information in the proxy statement.

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

The information required by this item is incorporated herein by reference to the information set forth under the captions Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information in the proxy statement.

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

The information required by this item is incorporated herein by reference to the information set forth under the caption Certain Related-Person Transactions and Proposal No. 1 Election of Directors in the proxy statement.

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

The information required by this item is incorporated herein by reference to the information set forth under the captions Independent Registered Public Accounting Firm Fees And Services and Pre-Approval Policies and Procedures in the proxy statement.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules**

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

(a) *Financial Statements.*

	<b>Page</b>
<u>Management's Report on Internal Control Over Financial Reporting</u>	54
<u>Reports of Ernst &amp; Young LLP, Independent Registered Public Accounting Firm</u>	55
<u>Consolidated Balance Sheets as of December 31, 2008, and 2009</u>	57
<u>Consolidated Statements of Operations for the three years ended December 31, 2009</u>	58
<u>Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2009</u>	59
<u>Consolidated Statements of Cash Flows for the three years ended December 31, 2009</u>	60
<u>Notes to Consolidated Financial Statements</u>	61

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

(b) *Exhibits.***Exhibit**

<b>Number</b>	<b>Description of Exhibit</b>
3.1.1(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2(17)	Bylaws of Cerus Corporation.
4.2(1)	Specimen Stock Certificate.
4.3(27)	Stockholder Rights Plan, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
4.4(28)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
4.5(26)	Form of Registered Direct Common Warrant.
10.1(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.2(1)*	1996 Equity Incentive Plan.
10.3(1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.4(1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.5(1)*	1996 Employee Stock Purchase Plan Offering.
10.6(1)	Industrial Real Estate Lease, dated October 1, 1992, between Cerus Corporation and Shamrock Development Company, as amended on May 16, 1994 and December 21, 1995.
10.7(1)	Real Property Lease, dated August 8, 1996, between Cerus Corporation and S.P. Cuff.
10.8(1)	Lease, dated February 1, 1996, between Cerus Corporation and Holmgren Partners.

Edgar Filing: CERUS CORP - Form 10-K

- 10.9(2) License Agreement, dated as of November 30, 1992, by and among Cerus Corporation, Miles Inc. and Diamond Scientific Corporation.

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Exhibit</b>
10.10(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus Corporation and Baxter Healthcare Corporation.
10.11(5)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.12(6)*	Amended and Restated Employment Agreement with Howard G. Ervin, dated December 22, 2008.
10.13(8)	Lease, dated December 17, 1999 between Cerus Corporation and Redwoods Office Center, L.P.
10.14(8)	Lease, dated October 12, 2001 between Cerus Corporation and California Development, Inc. (the Lease )
10.15(11)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008.
10.16(30)	Letter to California Development, Inc. exercising option to extend Lease
10.17(9)	Loan and Security Agreement, dated November 15, 2002, between Cerus Corporation and Baxter Capital Corporation.
10.18(10)*	1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.
10.19(6)*	Amended and Restated Employment Agreement with Claes Glassell, dated December 19, 2008.
10.20(13)*	Amended and Restated Employment Agreement with William J. Dawson, dated January 16, 2009.
10.21(30)	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.22(30)	License Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.23(14)	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.24(29)*	Bonus Plan for Senior Management of Cerus Corporation, as amended February 4, 2010.
10.25(15)	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.26(16)	Offer Letter to Gail Schulze, dated October 15, 2007.
10.27(18)	2008 Equity Incentive Plan
10.28(19)	Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Puro-lite Company.
10.29(19)	Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus Corporation and Porex Corporation.
10.30(12)	Credit Agreement, dated as of June 18, 2008, by and between Cerus Corporation and Wells Fargo Bank, National Association
10.31(12)	Security Agreement, dated as of June 18, 2008, by and between Cerus Corporation and Wells Fargo Bank, National Association.
10.32(20)	Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus Corporation and Fenwal, Inc.

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description of Exhibit</b>
10.33(20)	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.34(20)*	Non-Employee Director Compensation Policy.
10.35(21)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.36(21)*	Form of Restricted Stock Unit Agreement under the 1999 Equity Incentive Plan, as amended.
10.37(22)*	Form of Indemnity Agreement, adopted April 24, 2009.
10.38(23)*	Employment Letter for Kevin D. Green dated May 1, 2009.
10.39(24)*	Form of Severance Benefits Agreement.
10.40(25)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.41(26)	Form of Subscription Agreement.
10.42(30)*	Base Salaries for Fiscal Year 2009 for Named Executive Officers.
21.1	List of Registrant's subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
31.1	Certification of the Chief Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Accounting Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

Registrant has requested confidential treatment for portions of this exhibit.

\* Compensatory Plan.

- (a) Previously filed.
- (1) Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
  - (2) Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 1997.
  - (3) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on July 22, 1998.
  - (4) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on November 12, 1999.
  - (5) Incorporated by reference to Cerus Registration Statement on Form S-8, dated August 4, 1999.
  - (6) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on December 23, 2008.
  - (7) Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2001.
  - (8) Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2001.
  - (9) Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2002.
  - (10) Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2003.
  - (11) Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended September 30, 2008.
  - (12) Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended June 30, 2008.
  - (13) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on January 16, 2009.
  - (14) Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2005.
  - (15) Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2006.
  - (16) Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2007.

**Table of Contents**

(17)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on June 19, 2008.
(18)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on June 6, 2008.
(19)	Incorporated by reference to Cerus	Quarterly Report on Form 10-Q, for the quarter ended March 31, 2008.
(20)	Incorporated by reference to Cerus	Annual Report on Form 10-K, for the year ended December 31, 2008.
(21)	Incorporated by reference to Cerus	Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
(22)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on April 30, 2009.
(23)	Incorporated by reference to Cerus	Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.
(24)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on June 1, 2009.
(25)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on July 30, 2009.
(26)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on August 20, 2009.
(27)	Incorporated by reference to Cerus	Quarterly Report on form 10-Q, for the quarter ended June 30, 2009.
(28)	Incorporated by reference to Cerus	Current Report on Form 8-K, filed with the SEC on October 30, 2009.
(29)	Incorporated by reference to Cerus	Current Report on form 8-K, filed with the SEC February 10, 2010.
(30)	Filed herewith	



**Table of Contents**

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

Management is responsible for establishing and maintaining effective internal control over the Company's financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ) in *Internal Control - Integrated Framework*. Based on this assessment, management has concluded that, as of December 31, 2009, the Company's internal control over financial reporting is effective.

The Company's independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of internal control over financial reporting as of December 31, 2009. Ernst and Young's attestation report on internal control over financial reporting is included at page 55.

The Company's internal control system was designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Accordingly, our internal control systems are designed to provide reasonable, not absolute, assurance that the objectives of our internal control systems are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our internal control over financial reporting was effective. To provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles, we continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

The Board of Directors and Stockholders of Cerus Corporation

We have audited Cerus Corporation's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cerus Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Cerus Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cerus Corporation as of December 31, 2009, and 2008, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009, and our report dated March 11, 2010, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Jose, California

March 11, 2010

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Cerus Corporation

We have audited the accompanying consolidated balance sheets of Cerus Corporation as of December 31, 2009, and 2008, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cerus Corporation at December 31, 2009, and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with United States generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cerus Corporation's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2010 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Jose, California

March 11, 2010

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

	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,287	\$ 10,303
Short-term investments	2,644	12,275
Accounts receivable, net of allowance of \$66 and \$180 at December 31, 2009 and 2008, respectively	3,625	7,152
Inventories	7,707	11,109
Prepaid and other current assets	1,096	1,204
<b>Total current assets</b>	<b>32,359</b>	<b>42,043</b>
Property and equipment, net	1,217	1,844
Long-term investment in related party		2,329
Restricted cash	332	315
Other assets	583	808
<b>Total assets</b>	<b>\$ 34,491</b>	<b>\$ 47,339</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,423	\$ 7,963
Accrued liabilities	5,286	4,490
Accrued restructuring	113	
Warrant liability	2,737	
Deferred revenue	345	445
Current portion of capital lease obligations	9	
<b>Total current liabilities</b>	<b>12,913</b>	<b>12,898</b>
Long term portion of capital lease obligations	15	
Other long-term liabilities	115	163
<b>Total liabilities</b>	<b>13,043</b>	<b>13,061</b>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, issuable in series; 3 shares issued and outstanding at December 31, 2009, and 2008; aggregate liquidation preference of \$9,496 at December 31, 2009, and 2008	9,496	9,496
Common stock, \$0.001 par value; 50,000 shares authorized: 38,678 and 32,544 shares issued and outstanding at December 31, 2009, and 2008, respectively	39	33
Additional paid-in capital	421,897	410,444
Accumulated other comprehensive income	58	212
Accumulated deficit	(410,042)	(385,907)
<b>Total stockholders' equity</b>	<b>21,448</b>	<b>34,278</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 34,491</b>	<b>\$ 47,339</b>

See accompanying notes.

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

(in thousands, except per share amounts)

	Years Ended December 31,		
	2009	2008	2007
<b>Revenue:</b>			
Product revenue	\$ 16,751	\$ 15,518	\$ 8,015
Government grants and cooperative agreements	1,231	989	3,029
<b>Total revenue</b>	<b>17,982</b>	<b>16,507</b>	<b>11,044</b>
Cost of product revenue	12,580	9,668	5,228
<b>Gross profit</b>	<b>5,402</b>	<b>6,839</b>	<b>5,816</b>
<b>Operating expenses (gains):</b>			
Research and development	6,372	10,205	14,957
Selling, general, and administrative	21,867	27,164	24,575
Restructuring	841		
Gain on operating settlement	(1,381)		
Loss on long-term investment in related parties, net	1,536		9,450
<b>Total operating expenses</b>	<b>29,235</b>	<b>37,369</b>	<b>48,982</b>
<b>Loss from operations</b>	<b>(23,833)</b>	<b>(30,530)</b>	<b>(43,166)</b>
Interest income (expense) and other, net	(302)	1,349	4,066
<b>Net loss from continuing operations</b>	<b>(24,135)</b>	<b>(29,181)</b>	<b>(39,100)</b>
<b>Discontinued operations:</b>			
Loss from discontinued operations			(5,820)
Loss from sale of discontinued operations			(384)
<b>Net loss from discontinued operations</b>			<b>(6,204)</b>
<b>Net loss</b>	<b>\$ (24,135)</b>	<b>\$ (29,181)</b>	<b>\$ (45,304)</b>
<b>Net loss from continuing operations per common share:</b>			
Basic	\$ (0.69)	\$ (0.90)	\$ (1.23)
Diluted	\$ (0.69)	\$ (0.90)	\$ (1.23)
<b>Net loss from discontinued operations per common share:</b>			
Basic	\$	\$	\$ (0.19)
Diluted	\$	\$	\$ (0.19)
<b>Net loss per common share:</b>			
Basic	\$ (0.69)	\$ (0.90)	\$ (1.42)
Diluted	\$ (0.69)	\$ (0.90)	\$ (1.42)
<b>Weighted average common shares outstanding used for basic and diluted net income (loss) per share:</b>			
Basic	34,750	32,430	31,870
Diluted	34,750	32,430	31,870

See accompanying notes.



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

(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Shares	Amount					
Balances at December 31, 2006	3	\$ 9,496	31,734	\$ 32	\$ 402,888	\$ (23)		\$ (311,422)	\$ 100,971
Issuance of common stock under stock option and employee stock purchase plans			378		1,522				1,522
Stock-based compensation					2,600				2,600
Net change in unrealized gain on investments						98	\$ 98		98
Net loss							(45,304)	(45,304)	(45,304)
Total comprehensive loss							\$ (45,206)		
Balances at December 31, 2007	3	\$ 9,496	32,112	\$ 32	\$ 407,010	\$ 75		\$ (356,726)	\$ 59,887
Issuance of common stock under stock option and employee stock purchase plans			432	1	1,289				1,290
Stock-based compensation					2,145				2,145
Net change in unrealized gain on investments						137	\$ 137		137
Net loss							(29,181)	(29,181)	(29,181)
Total comprehensive loss							\$ (29,044)		
Balances at December 31, 2008	3	\$ 9,496	32,544	\$ 33	\$ 410,444	\$ 212		\$ (385,907)	\$ 34,278
Issuance of common stock, net of expenses of \$3,865			6,000	6	9,329				9,335
Issuance of common stock under stock option restricted stock and employee stock purchase plans			134		78				78
Stock-based compensation					2,046				2,046
Net change in unrealized gain on investments						(154)	\$ (154)		(154)
Net loss							(24,135)	(24,135)	(24,135)
Total comprehensive loss							\$ (24,289)		
Balances at December 31, 2009	3	\$ 9,496	38,678	\$ 39	\$ 421,897	\$ 58		\$ (410,042)	\$ 21,448

See accompanying notes.



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

(in thousands)

	Years Ended December 31,		
	2009	2008	2007
<b>Operating activities</b>			
Net loss	\$ (24,135)	\$ (29,181)	\$ (45,304)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	915	651	774
Stock-based compensation	2,046	2,145	2,600
Unrealized (gain) loss on securities	(154)	137	98
Loss (gain) on sale of equipment	109	(34)	231
Impairment of long-term investment in related party	2,329		9,450
Gain from revaluation of warrant liability	(63)		
Gain from operating settlement	(1,381)		
Changes in operating assets and liabilities:			
Accounts receivable	696	660	(2,493)
Inventories	3,367	(4,047)	(5,229)
Other assets	145	572	(991)
Accounts payable	102	(2,145)	3,442
Accrued liabilities	1,460	(2,107)	(800)
Deferred gain			(586)
Deferred revenue	(100)	(1,059)	1,504
Net cash used in operating activities	(14,664)	(34,408)	(37,304)
<b>Investing activities</b>			
Purchases of furniture and equipment	(191)	(1,194)	(700)
Purchases of short-term investments	(499)	(2,285)	(44,481)
Sales of short-term investments	499	4,954	1,601
Maturities of short-term investments	9,631	22,281	52,784
Net cash provided by investing activities	9,440	23,756	9,204
<b>Financing activities</b>			
Net proceeds from issuance of common stock	78	1,290	1,522
Net proceeds from public offering	12,135		
Issuance cost for credit facility		(25)	
Proceed from note payable		97	
Payments on capital lease obligations	(5)	(32)	(84)
Net cash provided by financing activities	12,208	1,330	1,438
Net increase (decrease) in cash and cash equivalents	6,984	(9,322)	(26,662)
Cash and cash equivalents, beginning of period	10,303	19,625	46,287
Cash and cash equivalents, end of period	\$ 17,287	\$ 10,303	\$ 19,625

See accompanying notes.



---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2009**

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

Cerus Corporation, or the Company, was incorporated on September 19, 1991, and is developing and commercializing the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen inactivation. The Company has licensed commercialization rights for its platelet and plasma systems in parts of Asia to BioOne Corporation, or BioOne.

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

**2. Summary of Significant Accounting Policies**

**Principles of Consolidation**

The accompanying audited consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (collectively hereinafter Cerus or the Company) after elimination of all intercompany accounts and transactions. Results of the Company's immunotherapy business, which was sold to a newly-formed company in November 2007, are recorded as a discontinued operation in the accompanying consolidated statements of operations for the year ended December 31, 2007. As such, results previously reported have been restated to reflect the discontinued operation treatment of the immunotherapy business. In addition, the Company reclassified the unrealized gain (loss) on available for sale investments on the consolidated statements of cash flows for the years ended December 31, 2008 and 2007.

**Use of Estimates**

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

**Revenue**

The Company recognizes revenue in accordance with the FASB ASC Topic 605-25, Revenue Recognition Arrangements with Multiple Deliverables, as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

The Company's main sources of revenues for the three years ended December 31, 2009 were product revenue from sales of the INTERCEPT Blood System, research and development activities and agreements, United States government grants and awards, and commercialization agreements.

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all INTERCEPT Blood System sales, the Company uses a binding purchase order

---

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

and signed sales contract as evidence of written agreement. The Company sells INTERCEPT Blood System directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective product. Deliverables and the units of accounting vary according to the provisions of the purchase order or sales contract. For revenue arrangements with multiple elements, the Company evaluates whether the delivered elements have standalone value to the customer, whether the fair value of the undelivered elements is reliably determinable, and whether the delivery of the remaining elements is probable and within the Company's control. When all of these conditions are met, the Company recognizes the revenue on the delivered elements. If these conditions are not met, the Company defers revenue until such time as all of the conditions have been met or all of the elements have been delivered. Consideration received is allocated to elements that are identified as discrete units of accounting based on the relative fair value method. At December 31, 2009 and December 31, 2008, the Company had \$0.3 million and \$0.4 million of short-term deferred revenue on its consolidated balance sheets, respectively. Freight costs charged to customers are recorded as a component of revenue under FASB ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs*. Value-added-taxes, or VAT, that the Company invoices to its customers and remits to governments, are recorded on a net basis, and are excluded from product revenue.

**Research and Development Expenses**

The Company receives certain United States government grants that support the Company's efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In accordance with FASB ASC Topic 730, *Accounting for Research and Development Expenses*, research and development expenses are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

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

**Cash, Cash Equivalents and Short-Term Investments**

The Company considers all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments.

In accordance with FASB ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities*, the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at estimated fair value based on quoted market prices. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income (expense) and other, net. The Company's available-for-sale securities consist primarily of United States government agency securities and corporate debt securities.

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2009**

Unrealized gains and losses at December 31, 2009, and 2008, are reported in accumulated other comprehensive income (loss) on the Company's consolidated balance sheets. The Company reviews all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. During the years ended December 31, 2009, and 2008, the Company recognized losses totaling zero and \$0.3 million, respectively, associated with investments experiencing an other-than-temporary decline in fair value. These investments experienced an other-than-temporary decline in fair value primarily relate to fixed income securities. At December 31, 2009, the Company recorded the fair value of these investments on its consolidated balance sheet which have become the Company's basis for recording prospective unrealized gains and losses. The cost of securities sold is based on the specific identification method.

As of December 31, 2009, the Company also maintained a certificate of deposit for approximately \$0.2 million with a domestic bank. The Company holds this certificate of deposit for any potential decommissioning resulting from the Company's possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded as restricted cash on its consolidated balance sheets at December 31, 2009, and 2008.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, short-term investments and accounts receivable.

Substantially all of the Company's cash, cash equivalents and short-term investments are maintained pursuant to the Company's investment policy at a major financial institution of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and type of investments that exist within its investment portfolio. All of the Company's investments carry high credit quality ratings, in accordance with its investment policy. At December 31, 2009, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

Concentrations of credit risk with respect to trade receivables exist to the full extent of amounts presented in the consolidated financial statements. On a regular basis, including the point of sale, the Company performs credit evaluations of its customers. Generally, the Company does not require collateral from its customers to secure accounts receivable. To the extent that the Company determines specific invoices or customer accounts may be uncollectible, the Company reserves against the accounts receivable on its balance sheet and records a charge on its statement of operations. The Company had recorded allowances for potentially uncollectible accounts receivable of approximately \$0.1 million and \$0.2 million at December 31, 2009 and 2008, respectively. For the year ended December 31, 2009, the Company did not incur any material write-off. Actual collection losses may differ from management's estimate, and such differences could be material to the Company's financial position and results of operations.

The Company had four and three customers each accounting for more than 10% of the Company's outstanding trade receivables and aggregating approximately 73% and 60% of outstanding trade receivables at December 31, 2009 and December 31, 2008, respectively. To date, the Company has not experienced collection difficulties from these customers.

**Inventories**

At December 31, 2009 and December 31, 2008, inventory consisted of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the

---

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

illumination devices. The Company's supply chain for certain of these components, held as work-in-process on its consolidated balance sheet, can take in excess of one year for production to be complete before the work-in-process is utilized in finished disposable kits. Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Platelet and plasma system disposable kits generally have two-year lives from date of manufacture. The Company frequently reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise unsalable items. To the extent unsalable items are observed and there is no alternative use, the Company will record a write-down to net realizable value in the period that the impairment is first recognized. The Company records the manufacturing variances incurred during periods of abnormally low production volumes as a period cost in its cost of product revenue. At December 31, 2009, and December 31, 2008, the Company had written down approximately \$0.3 million and \$0.1 million, respectively, associated with potentially obsolete or expiring product.

**Property and Equipment, net**

Property and equipment is comprised of furniture, equipment, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated on a straight-line basis over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements.

The Company evaluates its long-lived assets for impairment in accordance with ASC Topic 360, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The Company continually monitors events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the future undiscounted cash flows are less than the carrying amount of these assets, the Company recognizes an impairment loss based on the excess of the carrying amount over the fair value of the assets. The Company did not recognize impairment charges related to its long-lived assets in 2009, 2008 or 2007.

**Long-Term Investment in Related Party**

At December 31, 2009 and December 31, 2008, the Company held an approximate 13% interest in the voting securities of BioOne Corporation, or BioOne, and accounted for its investment in BioOne under the cost method. The Company's investment in BioOne is included in long-term investments in related party on its consolidated balance sheets. On an ongoing basis, the Company evaluates several criteria to determine whether facts and circumstances support the carrying value of its investment in BioOne. These criteria include, but are not limited to: third-party investor interest and participation in recent equity offerings at current pricing, business outlook of BioOne and available financial information. The Company periodically re-evaluates the carrying value of its investment in BioOne's equity, and to the extent that the criteria used to support the carrying value change.

The Company understands that BioOne has reduced its operations considerably in order to conserve cash. To date, BioOne has not made significant progress commercializing the INTERCEPT rights in its territories. At December 31, 2009, the Company evaluated the criteria used to support the carrying value of its investment in BioOne. As a result of its evaluation of the criteria used to support its position in BioOne, the Company determined that there were no factors to support any carrying value of its investment in BioOne. As a result, at December 31, 2009, the Company completely impaired its investment in BioOne and recorded a \$2.3 million

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2009**

charge as a component of loss from long term investments in related parties, net on its 2009 consolidated statement of operations.

**Foreign Currency Remeasurement**

The functional currency of the Company's foreign subsidiary is the United States Dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in United States Dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in United States Dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company's consolidated statements of operations as a component of interest income and other, net. The Company recorded foreign currency losses of \$0.6 million and gains of \$0.5 million during the years ended December 31, 2009, and 2008, respectively, and foreign currency gains of \$0.7 million during the year ended December 31, 2007.

**Stock-Based Compensation**

The Company maintains an equity incentive plan to provide long-term incentives for employees, contractors, members of the Board of Directors, and Scientific Advisory Board. The plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. The Company also maintains an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code.

The Company accounts for stock-based compensation in accordance with ASC Topic 505-50, Compensation—Stock Compensation. Under the fair value recognition provisions, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being met.

For its non-employee stock-based awards the Company considers the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of 1) the date at which a commitment for performance by the counter party to earn the equity instrument is reached or 2) the date at which the counter party's performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee awards in its consolidated statements of operations.

See Note 12 for further information regarding our stock-based compensation assumptions and expenses.

**Warrant Liability**

In August 2009, the Company issued warrants to purchase an aggregate of 2.4 million shares of common stock of the Company in connection with a registered direct offering. The outstanding warrants are classified as a liability, and as such the fair value of the warrants is recorded on the consolidated balance sheet at inception of such classification and adjusted to fair value at each financial reporting date. The changes in fair value of the warrants are recorded in the consolidated statements of operations as a component of other income (expense). The fair value of the warrants is estimated using the binomial-lattice option-pricing model. During the year ended December 31, 2009, the Company recorded gains of \$0.1 million associated with changes in the fair value of the

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

warrants. The warrants will continue to be reported as a liability until such time as the instruments are exercised or are otherwise modified to remove the provisions which require this treatment, at which time the warrants are adjusted to fair value and reclassified from liabilities to stockholders' equity. If the warrants are reclassified as permanent equity, the fair value of the warrants would be recorded in stockholders' equity and no further adjustment would be made in subsequent periods.

See Note 11 for further information regarding our warrant liability valuation.

**Other Comprehensive Income (Loss)**

The components of comprehensive income (loss) include net income (loss) and other comprehensive income (loss). The Company's only component of other comprehensive income (loss) for the years ended 2009, 2008, and 2007 consisted of unrealized gains or losses from the Company's available-for-sales short-term investments. Other comprehensive income (loss) is reported as a separate component of stockholders' equity.

**Income Taxes**

The Company accounts for income taxes in accordance with Accounting for Income Taxes, ASC Topic 740. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Effective January 1, 2007, Accounting for Uncertainty in Income Taxes, ASC Topic 740 became effective for the Company, which requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in ASC 740 is not an appropriate substitute for the derecognition of a tax position. The Company did not have any recorded liabilities for unrecognized tax benefits at December 31, 2009, or 2008. The Company recognizes interest accrued and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its statements of operations, nor has its accrued for or made payments for interest and penalties. The adoption of Topic ASC 740 has not resulted in any significant impact to the Company. The Company continues to carry a full valuation allowance on all of its deferred tax assets. The tax years 2005 through 2009 remain subject to examination by the taxing jurisdictions to which the Company is subject.

**Net Income (Loss) Per Share - Basic and Diluted**

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per share reflects the assumed conversion of all dilutive securities, such as options, restricted stock units and convertible preferred stock.

The following table sets forth the reconciliation of the denominator used in the computation of basic and diluted net income (loss) per common share (in thousands, except per share amounts):

	2009	2008	2007
Denominator:			
Basic weighted average number of common shares outstanding	34,750	32,430	31,870
Effect of dilutive potential common shares resulting from stock options, unvested restricted common stock and ESPP shares			
Diluted weighted average number of common shares outstanding	34,750	32,430	31,870





**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

The table below presents stock options, preferred stock and restricted stock units that are excluded from the diluted net income (loss) per common share due to their anti-dilutive effect (shares in thousands):

	2009	2008	2007
Antidilutive securities weighted average shares	6,772	5,374	5,649

**Guarantee and Indemnification Arrangements**

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

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become probable and estimable. There have been no warranty costs incurred through December 31, 2009. Accordingly, at December 31, 2009, the Company has not accrued for any potential future warranty costs.

**Fair Value of Financial Instruments**

The Company adopted the provisions of ASC Topic 820-10-65-4, *Fair Value Measurements*, on January 1, 2008, relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities. The carrying amounts and fair value of the Company's short term investments and long term investments in related parties are described elsewhere in the notes to the consolidated financial statements.

**New Accounting Pronouncements**

Statement of Financial Accounting Standards, or FAS, 157, *Fair value Measurements*, which is codified in FASB ASC Topic 820-10-65-4, defines fair value as the price that would be received to sell the asset or transfer the liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. FASB ASC Topic 820 provided additional guidance on identifying circumstances when a transaction may not be considered orderly. In April 2009, the FASB issued three amendments to the fair value measurement, disclosure and other-than-temporary impairment standards:

FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions that are Not Orderly*, which is codified in FASB ASC Topics 820-10-35-51 and 820-10-50-2.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, which is codified in FASB ASC Topic 320-10.

FAS 107 and Accounting Principles Bulletin, or APB, 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, which is codified in FASB ASC Topic 825-10-50.

FAS 107-1 and APB 28-1 amends FAS 107, *Disclosures about Fair Value of Financial Instruments*, which are codified in FASB ASC Topic 825-10-50, require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FAS 107-1 also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. The adoption did not have a material impact on the Company's consolidated financial statements.

On May 28, 2009, the FASB issued SFAS No. 165, *Subsequent Events*, or FAS 165, codified in FASB ASC Topic 855-10, which requires companies to evaluate events and transactions that occur after the balance sheet date but before the date the financial statements are issued, or available to be issued in the case of non-public entities. FAS 165 requires entities to recognize in the financial statements the effect of all events or transactions that provide additional evidence of conditions that existed at the balance sheet date, including the estimates inherent in the financial preparation process. Entities shall not recognize the impact of events or transactions that provide evidence about conditions that did not exist at the balance sheet date but arose after that date. FAS 165 was effective for interim and annual reporting periods ending after September 15, 2009. The Company adopted the provisions of FAS 165 for the year ended December 31, 2009, as required, and adoption did not have a material impact on the Company's consolidated financial statements.

**Note 3. Financial Instruments**

The Company measures and records certain financial assets at fair value on a recurring basis, including its available-for-sale short-term investments. The Company's available-for-sale short-term investments consist of fixed income corporate bonds and United States government agency securities. The Company classifies investments with original maturities of three months or less at the date of purchase, as cash equivalents. Cash equivalents consist of money market funds, for which the carrying amount is a reasonable estimate of fair value.

At December 31, 2009, the fair values of certain of the Company's financial assets and liabilities were determined using the following inputs (in thousands):

Fixed income available-for-sale-securities	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds <sup>(1)</sup>	\$ 11,059	\$ 11,059	\$	\$
Corporate bonds <sup>(2)</sup>	657		657	
United States government agency securities <sup>(2)</sup>	1,987		1,987	
	\$ 13,703	\$ 11,059	\$ 2,644	\$
Warrant Liability <sup>(3)</sup>	\$ 2,737	\$	\$	\$ 2,737



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

At December 31, 2008, the fair values of certain of the Company's financial assets and liabilities were determined using the following inputs (in thousands):

Fixed income	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>available-for-sale-securities</b>				
Money market funds <sup>(1)</sup>	\$ 7,183	\$ 7,183	\$	\$
Corporate bonds <sup>(2)</sup>	8,813		8,813	
United States government agency securities <sup>(2)</sup>	3,462		3,462	
	\$ 19,458	\$ 7,183	\$ 12,275	\$

(1) Included in cash and cash equivalents on our consolidated balance sheet.

(2) Included in short-term investments on our consolidated balance sheet.

(3) Included in current liabilities on consolidated balance sheet. For further discussion, see Note 11.

The Company classifies investments within Level 1 if quote prices are available in active markets. The Company classifies items in Level 2 if the investments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. These investments include: United States government agencies and corporate bonds. Investments are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs to models which vary by asset class. The Company did not hold financial assets which were recorded at fair value in the Level 3 category, which defines that one or more significant inputs or significant value drivers are unobservable, as of December 31, 2009 and December 31, 2008. The Company's warrant liability is recorded at fair value and classified in the Level 3 category. For further discussion, see Note 11.

**Note 4. Cash, Cash Equivalents and Short-Term Investments**

The following is a summary of cash, cash equivalents and short-term investments at December 31 (in thousands):

	Carrying Value	2009 Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	\$ 6,228	\$	\$ 6,228
Money Market funds	11,059		11,059
Total cash and cash equivalents	\$ 17,287	\$	\$ 17,287

Edgar Filing: CERUS CORP - Form 10-K

Short-term investments			
Corporate debt securities	\$ 629	\$ 28	\$ 657
United States government agency securities	1,957	30	1,987
Total short-term investments	\$ 2,586	\$ 58	\$ 2,644
	\$ 19,873	\$ 58	\$ 19,931

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

	Carrying Value	2008 Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	\$ 3,120	\$	\$ 3,120
Money Market funds	7,183		7,183
Total cash and cash equivalents	\$ 10,303	\$	\$ 10,303
Short-term investments			
Corporate debt securities	\$ 8,741	\$ 72	\$ 8,813
United States government agency securities	3,322	140	3,462
Total short-term investments	12,063	\$ 212	12,275
	\$ 22,366	\$ 212	\$ 22,578

Short-term investments and cash equivalents consisted of the following by original contractual maturity (in thousands):

	2009	2008
Due in one year or less	\$ 11,059	\$ 7,183
Due greater than one year and less than three years	2,644	12,275
Total	\$ 13,703	\$ 19,458

Gross proceeds from the sale of available-for-sale investments totaled \$0.5 million and there were no realized losses from the sale during the year ended December 31, 2009. Gross proceeds and the realized losses from the sale of available-for-sale investments totaled \$4.6 million and \$0.3 million, respectively, during the year ended December 31, 2008. Gross proceeds and the realized losses from the sale of available-for-sale investments totaled \$1.4 million and \$0.2 million, respectively, during the year ended December 31, 2007. Realized losses for other-than-temporary declines in market value totaled \$0.3 million and \$0.2 million during the years ended December 31, 2008, and 2007, respectively. The Company did not record any other-than temporary declines in market value during the year ended December 31, 2009. Realized gains and losses from the sale of available-for-sale investments and from other-than-temporary declines in market value are recorded in Interest income (expense) and other, net.

**Note 5. Inventories**

Inventories consisted of the following (in thousands):

	December 31,	
	2009	2008
Work in progress	\$ 3,638	\$ 3,750
Finished goods	4,069	7,359
	\$ 7,707	\$ 11,109

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

The Company's inventory at December 31, 2009, and 2008, consisted of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

illumination devices. The Company is responsible for supplying Fenwal with certain components for assembly into finished INTERCEPT disposable kits. The Company accounts for these components as work-in-process until such time as the components are used in the production of finished INTERCEPT disposable sets. The Company's work-in-process components are manufactured over a protracted length of time before being incorporated into the finished disposable kits. As a result, work-in-process costs accumulate for a period of time which can exceed one year.

**Note 6. Property and Equipment, net**

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2009	2008
Leasehold Improvements	\$ 6,498	\$ 7,999
Machinery and Equipment	1,922	2,530
Demonstration Equipment	104	94
Office Furniture	962	1,124
Computer Equipment	598	642
Computer Software	1,105	710
Consigned demonstration equipment	335	420
Construction-in-Progress	61	325
	11,585	13,844
Less accumulated depreciation and amortization	(10,368)	(12,000)
	\$ 1,217	\$ 1,844

**Note 7. Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2009	2008
Accrued compensation and related	\$ 942	\$ 636
Accrued inventory	2,366	2,121
Other accrued expenses	1,978	1,733
	\$ 5,286	\$ 4,490

**Note 8. Restructuring**

In March 2009, pursuant to the Board of Directors' approval, the Company began implementing a plan to focus on commercializing the INTERCEPT Blood System in Europe, to consolidate facilities, and to reduce its cost structure. During the year ended December 31, 2009, the Company incurred costs for one-time termination benefits for employee positions that were eliminated under the restructuring plan,

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

consolidation of facility and related moving costs. Affected employees received severance consideration and continuation of benefits, as well as transition assistance. Certain of these costs will be paid through April 30, 2010.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

A summary of the Company's restructuring costs is as follows (in thousands):

	Balance at December 31, 2008	Restructuring Charge	Cash Payments	Balance at December 31, 2009
One-time termination benefits	\$	\$ 712	\$ (599)	\$ 113
Other		129	(129)	
<b>Total</b>	<b>\$</b>	<b>\$ 841</b>	<b>\$ (728)</b>	<b>\$ 113</b>

**Note 9. Commitments and Contingencies**

The Company leases its office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised.

Future minimum payments under operating leases are as follows (in thousands):

Year ending December 31,	
2010	\$ 971
2011	738
2012	728
2013	449
2014	421
Thereafter	
<b>Total minimum lease payments</b>	<b>\$ 3,307</b>

Rent expense for office facilities, net of rental income, was \$1.4 million, \$1.4 million and \$1.5 million for the years ended December 31, 2009, 2008, and 2007, respectively.

The Company's total non-cancelable commitments at December 31, 2009 are as follows (in thousands):

	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Minimum purchase requirements	\$ 2,133	\$ 664	\$ 1,469	\$	\$
Operating leases	3,307	971	1,466	870	
Other commitments	306	259	45	2	
<b>Total contractual obligations</b>	<b>\$ 5,746</b>	<b>\$ 1,894</b>	<b>\$ 2,980</b>	<b>\$ 872</b>	<b>\$</b>

Minimum purchase commitments include certain components of INTERCEPT blood safety system which the Company purchases from third party manufacturers and supplies to Fenwal for use in manufacturing finished disposable kits. The Company has paid \$1.2 million, \$1.1 million, and \$0.9 million, for goods under contracts which are subject to minimum purchase commitments during the years ended December 31, 2009, 2008, and 2007, respectively.

---

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009****Note 10. Credit Agreement**

In June 2008, the Company entered into a senior secured revolving credit facility with Wells Fargo Bank, N.A., or the Facility, which allowed the Company to borrow up to \$10.0 million for working capital and general operating needs. In December 2008, the Company amended the terms of the Facility. The initial term of the Facility was one year. The Facility expired in June 2009, with no amounts drawn against the Facility.

**Note 11. Stockholders' Equity***Series B Preferred Stock*

Baxter holds 3,327 shares of the Company's Series B preferred stock. The holder of Series B preferred stock has no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B preferred stock as to voting, liquidation or conversion or with respect to the determination of fair market value of non-publicly traded shares received by the holder of Series B stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder may convert each share of Series B preferred stock into 100 shares of the Company's common stock. If all shares of Series B preferred stock were converted to common stock, 332,700 shares of common stock would be issued, which represents approximately 1% of the outstanding common shares of the Company at December 31, 2008. The Company has the right to redeem the Series B preferred stock prior to conversion for a payment of \$9.5 million.

*Common Stock and Warrant Liability*

In August 2009, the Company received net proceeds of approximately \$12.1 million in a registered direct offering of units, made pursuant to its shelf registration statement on Form S-3, after deducting placement agent's fees and stock issuance costs of approximately \$1.1 million, from the sale of 6.0 million units. Each unit sold consisted of one share of common stock and a warrant to purchase 4/10 of a share of common stock. Each unit was sold for \$2.20, resulting in the issuance of 6.0 million shares of common stock and warrants to purchase 2.4 million shares of common stock, exercisable at an exercise price of \$2.90 per share. The warrants contain certain provisions that, under certain circumstances which may be out of the Company's control, could require the Company to pay cash to settle the exercise of the warrants or may require the Company to redeem the warrants.

The offering was made pursuant to the Company's shelf registration statement on Form S-3. These warrants are exercisable beginning on February 25, 2010 and are exercisable for a period of five years thereafter. The fair value on the date of issuance of the warrants was determined to be \$2.8 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 2.48%, (ii) an expected term of 5.0 years, (iii) no dividend yield and (iv) a volatility of 77%. The warrants are classified as a liability pursuant to *Accounting for Derivative Instruments and Hedging Activities* and *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* Topics of FASB ASC. Therefore, the fair value of the warrants is recorded on the consolidated balance sheet as a liability and will be adjusted to fair value at each financial reporting date thereafter until the earlier of exercise or expiration. At December 31, 2009, the fair value of the warrants was determined to be approximately \$2.7 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 2.69%, (ii) an expected term of 4.65 years, (iii) no dividend yield and (iv) a volatility of 82%. For the year ended December 31, 2009, due to the decrease in fair value of the warrants, the Company recorded a \$0.1 million gain to other income (expense), net.

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2009**

*Stockholder Rights Plan*

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

**Note 12. Stock-Based Compensation**

*2008 Equity Incentive Plan*

The Company maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors and Scientific Advisory Board. The Company currently grants awards from one plan, the 2008 Equity Incentive Plan, or the 2008 Plan. The 2008 Plan allows for the granting of stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. The 2008 Plan has 1.7 million shares available for grant. Awards under the 2008 Plan generally have a maximum term of 10 years from the date of the award. Employee options granted under the 2008 Plan generally vest over four years. The 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Performance-based stock options granted under the 2008 Plan are limited to either 500,000 shares or \$1.0 million, in the case of performance based cash awards, per recipient per calendar year. During the year ended December 31, 2008, the Company granted performance based stock options totaling 50,000 shares which remain outstanding at December 31, 2009.

*Employee Stock Purchase Plan*

The Company also maintains an Employee Stock Purchase Plan, or the Purchase Plan. The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. The offering period for any offering will be no more than 27 months.

*Restricted Stock Units*

The Company has granted restricted stock units to the Chief Executive Officer, Senior Vice Presidents, and Vice Presidents in accordance with the Bonus Plan for Senior Management of Cerus Corporation. Subject to each grantee's continued employment shares underlying the grants vest in three annual installments and are issuable at the end of the three-year vesting term.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

Restricted stock unit grants made in connection with the Bonus Plan for Senior Management of Cerus Corporation are presented in the following table:

	Number of RSUs	Weighted Average Exercise Price per Share (\$)
Balances at December 31, 2006	37,098	\$ 10.32
Granted	60,620	5.54
Cancelled	(12,772)	7.20
Vested	(12,366)	10.32
Balances at December 31, 2007	72,580	\$ 6.88
Granted	43,086	6.99
Cancelled	(3,430)	6.78
Vested	(27,581)	7.30
Balances at December 31, 2008	84,655	\$ 6.80
Granted		
Cancelled	(6,484)	6.41
Vested	(40,306)	7.19
Balances at December 31, 2009	37,865	\$ 6.45

*Stock-based Compensation*

The Company currently uses the Black-Scholes option pricing model to determine the fair value of stock options and employee stock purchase plan shares. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables. The variables used to calculate the fair value of stock based payment awards using the Black-Scholes option pricing model, include the Company's expected stock price volatility, actual and projected employee stock option exercise behaviors, including forfeitures, the risk-free interest rate and expected dividends.

The Company does not recognize stock based compensation on stock options that contain performance conditions, until such time as the performance criteria are probable of being achieved. As such, for the year ended December 31, 2009, the Company had not recorded any such stock based compensation for the 50,000 performance-based stock options granted during such period.

*Expected Term*

The Company estimates the expected term of options granted using a variety of factors. Where possible, the Company estimates the expected term of options granted by analyzing employee exercise and post-vesting termination behavior. To make this estimation, the Company analyzes the population of options granted by discreet, homogeneous groups. If the Company is unable to obtain sufficient information to estimate the expected term for a particular group, it estimates the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in SAB 107 and SAB 110. The expected term of employee stock purchase plan shares is the term of each purchase period.





**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009***Estimated Forfeiture Rate*

The Company estimates the forfeiture rate of options at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. The Company estimates the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

*Estimated Volatility*

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

*Risk-Free Interest Rate*

The Company bases the risk-free interest rate that it uses in the option valuation model on United States Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Expected Dividend*

The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model.

The assumptions used to value option grants for three years ended December 31:

	2009	2008	2007
Expected term (in years)	4.34-6.25	5.25-6.50	4.16-6.73
Volatility	72.0-136.0%	59.1%-84.1%	59.1%-64.3%
Risk free interest rate	2.80%-4.03%	2.80%-4.03%	4.03%-4.62%

The assumptions used to value employee stock purchase rights for the three years ended December 31:

	2009	2008	2007
Expected term (in years)	0.50	0.50	0.50
Volatility	148.8%-150.0%	54.6%-78.8%	54.6%-57.1%
Risk free interest rate	2.0%	2.0%-4.4%	4.4%-4.8%

Total stock-based compensation recognized on the Company's consolidated statements of operations for the years ended December 31, 2009, 2008, and 2007, was as follows (in thousands):

Edgar Filing: CERUS CORP - Form 10-K

	<b>2009</b>	<b>2008</b>	<b>2007</b>
Research and development	\$ 494	\$ 531	\$ 1,160
Selling, general and administrative	1,563	1,614	1,440
	\$ 2,057	\$ 2,145	\$ 2,600

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

Activity under the Company's stock option plans is set forth below (in thousands except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price per Share (\$)
Balances at December 31, 2006	5,255	\$ 12.06
Granted	895	7.90
Cancelled	(654)	9.79
Exercised	(323)	3.92
Balances at December 31, 2007	5,173	\$ 12.13
Granted	941	4.45
Cancelled	(652)	21.17
Exercised	(399)	2.86
Balances at December 31, 2008	5,063	\$ 10.27
Granted	2,229	1.11
Cancelled	(723)	8.27
Exercised	(4)	2.39
Balances at December 31, 2009	6,565	\$ 7.38

The weighted average fair value of options granted during the years ended December 31, 2009, 2008, and 2007, was \$2.93, \$2.88 and \$4.34 per share, respectively. The intrinsic value of options exercised the years ended December 31, 2009, 2008, and 2007 was \$0.0 million, \$1.1 million, and \$1.3 million per share, respectively.

Information regarding the stock options outstanding at December 31, 2009, 2008, and 2007 is set forth below (in thousands except per share amounts and years):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
<b>2009</b>				
Shares Outstanding	6,565	\$ 7.38	6.37	\$
Shares vested and expected to vest	6,165	\$ 7.74	6.18	\$
Shares exercisable	3,901	\$ 10.77	4.62	\$
<b>2008</b>				
Shares Outstanding	5,063	\$ 10.27	6.32	\$
Shares vested and expected to vest	4,802	\$ 10.54	6.18	\$
Shares exercisable	3,503	\$ 12.26	5.25	\$
<b>2007</b>				
Shares Outstanding	5,173	\$ 12.13	5.61	\$ 7,516

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

Shares vested and expected to vest	5,016	\$ 12.28	5.54	\$ 7,439
Shares exercisable	3,527	\$ 14.68	4.70	\$ 5,943

In 2007, the Company modified stock options for two employees of its former immunotherapy business. The modifications extended the expiration date of vested options and resulted in additional stock based-compensation of \$0.1 million in 2007. None of these options remained outstanding at December 31, 2009. As of

---

**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2009**

December 31, 2009, the Company had stock-based compensation expense of \$3.5 million related to non-vested stock options not yet recognized, which is expected to be recognized over an estimated weighted average period of 2.9 years.

**Note 13. Development and License Agreements**

**Agreements with Baxter and Fenwal**

In connection with the transfer of commercialization rights to the Company in February 2006, Baxter agreed to supply, at the Company's expense, certain transition services, including regulatory, technical and related administrative support through December 31, 2006. During that 2006 transition period, the Company recorded receivables of \$2.8 million from Baxter and payables of \$4.7 million to Baxter, associated with those transition services. The Company and Baxter have disputed the amounts owed and due since 2006. As such, since 2006, the Company has recorded the transition service receivables and payables on its consolidated balance sheets. In December 2009, the Company and Baxter entered into a settlement agreement with both parties waiving all rights and obligations associated with the 2006 transition services. In consideration for agreeing to the settlement, the Company agreed to pay Baxter \$0.5 million which was recorded as a payable on its 2009 consolidated balance sheet, along with a gain of \$1.4 million which was recorded as an operating gain on its year ended December 31, 2009 consolidated statement of operations.

As a result of Baxter's sale of its transfusion therapies division in 2007 to Fenwal, the Company has certain agreements with Fenwal which require the Company to pay royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system.

In December 2008, the Company extended its agreement with Fenwal to manufacture finished disposable kits for the platelet and plasma systems through December 31, 2013. Under the amended manufacturing agreement, the Company pays Fenwal a set price per kit, which is established annually plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead is to be paid or refunded if actual manufacturing volumes are lower or higher than the annually estimated production volumes.

**Agreements with BioOne**

BioOne was formed in 2004 to develop technologies to improve the safety of blood products in Asia, and is funded by equity investments from Japanese venture capital firms, other corporations and individual investors. At December 31, 2009, the Company held 13% of the voting rights in BioOne. See Note 1 for additional information regarding the Company's investment in BioOne.

*Platelet Agreement*

In September 2004, Baxter and the Company entered into an agreement with BioOne for commercialization of the INTERCEPT Blood System for platelets in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for platelets in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. The agreement provides for contingent milestone payments and royalties on future product sales, which generally would be shared equally by Fenwal (Baxter's assignee) and the Company. The Company did not recognize any revenue under this agreement during the three years ended December 31, 2009.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009***Plasma Agreement*

A definitive agreement with BioOne for the plasma system was signed by Baxter and the Company in September 2005 for the commercialization of the INTECEPT Blood System for plasma in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for plasma in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. The agreement provides for contingent milestone payments and royalties on future product sales, which generally would be shared equally by Fenwal (Baxter's assignee) and the Company. The Company did not recognize any revenue under this agreement during the three years ended December 31, 2009.

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

Since February 2001, the Company has received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received these awards in order to develop its pathogen inactivation technologies for the improved safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the conditions of the agreements, the Company is conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that are of concern to the United States Armed Forces. This funding supports advanced development of the Company's red blood cell system. The Company recognized \$1.2 million, \$1.0 million, \$3.0 million, of revenue under these agreements during the years ended December 31, 2009, 2008, and 2007, respectively.

**Note 14. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2009	2008
Net operating loss carryforward	\$ 123,900	\$ 110,000
Research and development credit carryforward	32,000	33,200
Realized loss from cost basis investment		3,800
Inventory reserve	100	
Capitalized inventory cost	700	400
Realized loss on other-than-temporary impairments of marketable securities		100
Capitalized research and development	18,200	22,500
Certain expenses not currently deductible for tax purposes	1,200	1,600
Accrued liabilities	3,000	2,600
Stock-based compensation	100	2,600
Other	2,900	2,800
Gross deferred tax assets	182,100	179,600
Valuation allowance	(182,100)	(179,600)
Net deferred tax assets	\$	\$



**Table of Contents**

**CERUS CORPORATION**

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

**December 31, 2009**

The valuation allowance increased by \$2.5 million, \$9.5 million, and \$18.4 million for the years ended December 31, 2009, 2008, and 2007, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a full valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization, expected near-term future losses and the absence of taxable income in prior carryback years. The Company expects to maintain a full valuation allowance until circumstances change. Undistributed earnings of the Company's foreign subsidiary, Cerus Europe B.V., amounted to approximately \$0.3 million at December 31, 2009. The earnings are considered to be permanently reinvested and accordingly, no deferred United States income taxes have been provided thereon. Upon distribution of those earnings in the form of dividend or otherwise, the Company would be subject to United States income tax. At the Federal statutory income tax rate of 35%, this would result in taxes of approximately \$0.1 million.

For the year ended December 31, 2009, the Company reported net losses of \$24.1 million on its consolidated statement of operations and calculated taxable losses for both federal and state taxes. The difference between reported net loss and taxable loss are due to temporary differences between United States GAAP and the respective tax laws.

At December 31, 2009, the Company had net operating loss carryforwards of approximately \$311.1 million for federal and \$301.4 million for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately \$21.7 million for federal income tax purposes and approximately \$15.5 million for state income tax purposes at December 31, 2009. The federal net operating loss and tax credit carryforwards expire between the years 2010 and 2029. The state net operating loss carryforwards expire between the years 2012 and 2029. The state research and development credits do not expire.

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

**Note 15. Retirement Plan**

The Company maintains a defined contribution savings plan, or the 401(k) Plan, that qualifies under the provisions of Section 401(k) of the Internal Revenue Code and covers all employees of the Company. Under the terms of the 401(k) Plan, employees may contribute varying amounts of their annual compensation. The Company may contribute a discretionary percentage of qualified individual employee's salaries, as defined, to the 401(k) Plan. The Company did not contribute to the 401(k) Plan in the years ended December 31, 2009, 2008, and 2007.

**Note 16. Segment Information and Geographic Information**

At December 31, 2009, and 2008, the Company operated only one segment, blood safety. Prior to its November 2007 sale of its former immunotherapy business to Anza Therapeutics, the Company operated two segments: blood safety and Immunotherapy. Results for the year ended December 31, 2007 have been restated to show the Company's former immunotherapy segment as a discontinued operation. Results for the Company's



**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

remaining segment, the blood safety segment, are the same as its consolidated results. The Company's chief executive officer is the chief operating decision maker who evaluates performance based on the net revenues and operating income (loss) of the blood safety segment.

The Company's operations outside of the United States include a wholly-owned subsidiary headquartered in Europe. The Company's operations in the United States are responsible for the research and development and global commercialization of the INTERCEPT Blood System, while operations in Europe are responsible for the commercialization efforts of the platelet and plasma systems in Europe and the Middle East. Essentially all of the Company's long-lived assets are in the United States. Revenues are attributed to each region based on the location of the customer, and in the case of non-product revenues, on the location of the collaboration partner.

During the years ended December 31, 2009, 2008 and 2007, we had the following significant customers, listed as a percentage of product revenue:

	2009	2008	2007
Customer			
Movaco, S.A. (Spain and other EU countries)	25%	33%	12%
Etablissement Francais du Sang (France)	24%	18%	33%
Service Francophone du Sang (Belgium)	12%	1%	%
Delrus, Inc. (Russia)	6%	10%	5%

Long-lived assets are attributed to each region based on the physical location of the asset and are as follows (in thousands):

	2009	2008
Total Long-Lived Assets:		
United States	\$ 443	\$ 3,018
Europe	1,283	1,816
Totals	\$ 1,726	\$ 4,834

**Note 17. Discontinued Operation**

In November 2007, the Company sold its immunotherapy business to Anza Therapeutics, Inc. (Anza), which received initial funding from a syndicate of venture capital firms. The Company sold certain tangible and intangible assets in connection with this sale, consisting primarily of certain laboratory equipment and intellectual property. In exchange for the sale of the assets and intangible assets, the Company received 5,000,000 shares of Series AA Preferred Stock, constituting an equity interest of approximately 17.8% (15.5% fully diluted) of Anza's equity.

In connection with the sale, the Company accounted for its immunotherapy business as a discontinued operation, and restated its financial statements for 2007 and prior periods to reflect the discontinued operation. Anza ceased operations in early 2009.

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009**

In July 2009, the Company entered into a three-way license agreement with Anza and Aduro BioTech and separate agreements with each Anza Therapeutics and Aduro BioTech (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, the Company received preferred stock representing a 10% equity interest in Aduro BioTech, 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, the Company received cash of approximately \$0.3 million from Anza. As a result of entering into the Assignment Agreements, the Company no longer holds any equity in Anza. The Company believes that Aduro's technology platforms, which are largely based on Anza's in-process development programs, have a high risk of failure and that the Company has no basis to believe that it will receive economic benefit from its equity ownership in Aduro. As such, the Company has not assigned any value to its equity ownership in Aduro on its December 31, 2009 balance sheet. For the year ended December 31, 2009, the Company recorded the gain that resulted from the \$0.8 million in total cash received from the Assignment Agreements in the line item Loss on Long Term Investments in Related Parties, Net, on its consolidated statements of operations.

The following table summarizes the results of the Company's discontinued operation for the year ended December 31, 2007:

<b>(in thousands)</b>	<b>2007</b>
Revenue	\$ 4,356
Operating expenses	10,176
Loss from discontinued operations	(5,820)
Loss from sale of discontinued operations	(384)
Net loss from discontinued operations	\$ (6,204)

**Table of Contents****CERUS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2009****Note 18. Quarterly Financial Information** (Unaudited and in thousands except per share amounts)

	March 31, 2009	June 30, 2009	Three Months Ended September 30, 2009	December 31, 2009
Revenue:				
Product revenue	\$ 3,085	\$ 3,871	\$ 4,567	\$ 5,228
Government grants and cooperative agreements	403	335	247	246
Total revenue	3,488	4,206	4,814	5,474
Cost of product revenue	2,094	2,520	4,242	3,724
Gross profit	1,394	1,686	572	1,750
Operating expenses				
Research and development	2,012	1,625	1,230	1,505
Selling, general, and administrative	6,101	5,409	5,340	5,017
Restructuring	712	129	15	(15)
Loss on long-term investments in related parties, net				1,536
Gain on operating settlement				(1,381)
Total operating expenses	8,825	7,163	6,585	6,662
Operating loss	(7,431)	(5,477)	(6,013)	(4,912)
Other income (expense), net	34	(735)	376	23
Net loss	\$ (7,397)	\$ (6,212)	\$ (5,637)	\$ (4,889)
Net loss per share basic	\$ (0.23)	\$ (0.19)	\$ (0.16)	\$ (0.13)
Net loss per share diluted	\$ (0.23)	\$ (0.19)	\$ (0.16)	\$ (0.13)

	March 31, 2008	June 30, 2008	Three Months Ended September 30, 2008	December 31, 2008
Revenue:				
Product revenue	\$ 4,852	\$ 4,030	\$ 3,095	\$ 3,541
Government grants and cooperative agreements	117		787	85
Total revenue	4,969	4,030	3,882	3,626
Cost of product revenue	1,714	3,077	1,913	2,964
Gross profit	3,255	953	1,969	662
Operating expenses				
Research and development	2,784	2,670	2,483	2,268
Selling, general, and administrative	7,101	7,439	7,067	5,557

Edgar Filing: CERUS CORP - Form 10-K

Total operating expenses	9,885	10,109	9,550	7,825
Operating loss	(6,630)	(9,156)	(7,581)	(7,163)
Other income (expense), net <sup>1</sup>	690	209	(199)	649
Net loss	\$ (5,940)	\$ (8,947)	\$ (7,780)	\$ (6,514)
Net loss per share basic	\$ (0.18)	\$ (0.28)	\$ (0.24)	\$ (0.20)
Net loss per share diluted	\$ (0.18)	\$ (0.28)	\$ (0.24)	\$ (0.20)

**Table of Contents****SIGNATURES**

Pursuant to the requirement of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Concord, State of California, on the 10<sup>th</sup> day of March 2010.

## CERUS CORPORATION

By: */s/* CLAES GLASSELL  
**Claes Glassell**

*President and Chief Executive Officer*

Each person whose signature appears below constitutes and appoints Claes Glassell and Kevin D. Green, his true and lawful attorney-in-fact and agent, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to the Annual Report on Form 10-K and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> CLAES GLASSELL <b>Claes Glassell</b>	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 10, 2010
<i>/s/</i> KEVIN D. GREEN <b>Kevin D. Green</b>	Chief Accounting Officer and Vice President, Finance <i>(Principal Financial and Accounting Officer)</i>	March 10, 2010
<i>/s/</i> B. J. CASSIN <b>B. J. Cassin</b>	Chairman of the Board	March 10, 2010
<i>/s/</i> TIMOTHY B. ANDERSON <b>Timothy B. Anderson</b>	Director	March 10, 2010
<i>/s/</i> LAURENCE M. CORASH <b>Laurence M. Corash, M.D.</b>	Director	March 10, 2010
<i>/s/</i> BRUCE C. COZADD <b>Bruce C. Cozadd</b>	Director	March 10, 2010
<i>/s/</i> WILLIAM R. ROHN <b>William R. Rohn</b>	Director	March 10, 2010

Edgar Filing: CERUS CORP - Form 10-K

/s/ GAIL SCHULZE

Director

March 10, 2010

**Gail Schulze**

84

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

<b>Exhibit</b>	
<b>Number</b>	<b>Description of Exhibit</b>
3.1.1(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2 (17)	Bylaws of Cerus Corporation.
4.2 (1)	Specimen Stock Certificate.
4.3 (27)	Stockholder Rights Plan, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
4.4 (28)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
4.5 (26)	Form of Registered Direct Common Warrant.
10.1 (1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.2 (1)*	1996 Equity Incentive Plan.
10.3 (1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.4 (1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.5 (1)*	1996 Employee Stock Purchase Plan Offering.
10.6 (1)	Industrial Real Estate Lease, dated October 1, 1992, between Cerus Corporation and Shamrock Development Company, as amended on May 16, 1994 and December 21, 1995.
10.7 (1)	Real Property Lease, dated August 8, 1996, between Cerus Corporation and S.P. Cuff.
10.8 (1)	Lease, dated February 1, 1996, between Cerus Corporation and Holmgren Partners.
10.9 (2)	License Agreement, dated as of November 30, 1992, by and among Cerus Corporation, Miles Inc. and Diamond Scientific Corporation.
10.10(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus Corporation and Baxter Healthcare Corporation.
10.11(5)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.12(6)*	Amended and Restated Employment Agreement with Howard G. Ervin, dated December 22, 2008.
10.13(8)	Lease, dated December 17, 1999 between Cerus Corporation and Redwoods Office Center, L.P.
10.14(8)	Lease, dated October 12, 2001 between Cerus Corporation and California Development, Inc. (the Lease )
10.15(11)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008.
10.16(30)	Letter to California Development, Inc. exercising option to extend Lease
10.17(9)	Loan and Security Agreement, dated November 15, 2002, between Cerus Corporation and Baxter Capital Corporation.
10.18(10)*	1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.
10.19(6)*	Amended and Restated Employment Agreement with Claes Glassell, dated December 19, 2008.

**Table of Contents**

<b>Exhibit</b>	
<b>Number</b>	<b>Description of Exhibit</b>
10.20(13)*	Amended and Restated Employment Agreement with William J. Dawson, dated January 16, 2009.
10.21(30)	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.22(30)	License Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.23(14)	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.24(29)*	Bonus Plan for Senior Management of Cerus Corporation, as amended February 4, 2010.
10.25(15)	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.26(16)	Offer Letter to Gail Schulze, dated October 15, 2007.
10.27(18)	2008 Equity Incentive Plan
10.28(19)	Supply Agreement, dated December 19, 2007, by and between Cerus Corporation and Brotech Corporation d/b/a Purolite Company.
10.29(19)	Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus Corporation and Porex Corporation.
10.30(12)	Credit Agreement, dated as of June 18, 2008, by and between Cerus Corporation and Wells Fargo Bank, National Association
10.31(12)	Security Agreement, dated as of June 18, 2008, by and between Cerus Corporation and Wells Fargo Bank, National Association.
10.32(20)	Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus Corporation and Fenwal, Inc.
10.33(20)	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.34(20)*	Non-Employee Director Compensation Policy.
10.35(21)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.36(21)*	Form of Restricted Stock Unit Agreement under the 1999 Equity Incentive Plan, as amended.
10.37(22)*	Form of Indemnity Agreement, adopted April 24, 2009.
10.38(23)*	Employment Letter for Kevin D. Green dated May 1, 2009.
10.39(24)*	Form of Severance Benefits Agreement.
10.40(25)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.41(26)	Form of Subscription Agreement.
10.42(30)*	Base Salaries for Fiscal Year 2009 for Named Executive Officers.
21.1	List of Registrant's subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.



**Table of Contents****Exhibit**

<b>Number</b>	<b>Description of Exhibit</b>
24.1	Power of Attorney (see signature page).
31.1	Certification of the Chief Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Accounting Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

Registrant has requested confidential treatment for portions of this exhibit.

\* Compensatory Plan.

(a)	Previously filed.
(1)	Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(2)	Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 1997.
(3)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on July 22, 1998.
(4)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on November 12, 1999.
(5)	Incorporated by reference to Cerus Registration Statement on Form S-8, dated August 4, 1999.
(6)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on December 23, 2008.
(7)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2001.
(8)	Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2001.
(9)	Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2002.
(10)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2003.
(11)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended September 30, 2008.
(12)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended June 30, 2008.
(13)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on January 16, 2009.
(14)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2005.
(15)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2006.
(16)	Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2007.
(17)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on June 19, 2008.
(18)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on June 6, 2008.
(19)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2008.
(20)	Incorporated by reference to Cerus Annual Report on Form 10-K, for the year ended December 31, 2008.
(21)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.
(22)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on April 30, 2009.
(23)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.
(24)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on June 1, 2009.
(25)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on July 30, 2009.
(26)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on August 20, 2009.
(27)	Incorporated by reference to Cerus Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.
(28)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on October 30, 2009.
(29)	Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC February 10, 2010.
(30)	Filed herewith.