



CERUS

SAFETY, IT'S IN OUR BLOOD

# CERUS SAFE

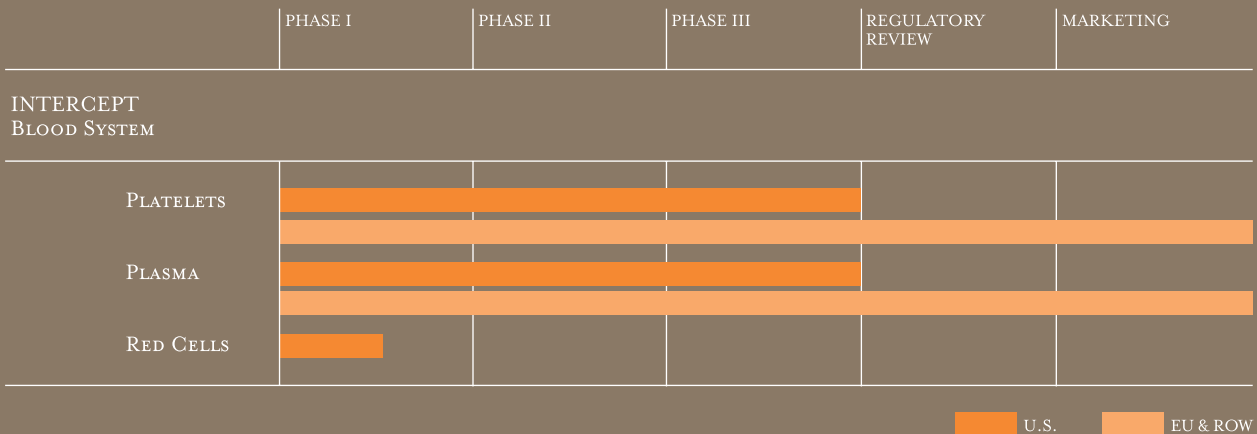
2008 Annual Report | Cerus Corporation

“ We believe that the INTERCEPT Blood System can provide significant value to patients and Cerus shareholders. Our focus today is on expanding our current commercial markets while reining in costs, improving our margins and extending our cash horizon. Investing in our near-term commercial opportunities is critical for building long-term shareholder value.”

CLAES GLASSELL, PRESIDENT & CEO



## 2008 PIPELINE



# dear SHAREHOLDER:

Cerus' progress in 2008 puts us on a path toward greater adoption of the INTERCEPT Blood System for platelets and plasma. Our sales nearly doubled compared to 2007, and we now have customers in 18 countries. In the United States we gained clarity regarding a potential pathway that could lead to FDA approval of the INTERCEPT Blood System for platelets. We also continued to make advances in our INTERCEPT red blood cell program. Importantly in today's climate, we have made reductions in operating expenses, which will significantly extend our cash runway.

## >Building Sales in Key Markets

In Germany, we signed a three-year supply agreement with the largest branch of the German Red Cross, covering Frankfurt and other regions. That organization received authorization to market INTERCEPT-treated platelets in February 2009, and we expect it to begin purchases after completing a hemovigilance study. We believe that adoption of INTERCEPT by this important group should lead to adoption by other customers in Germany and elsewhere in Europe. In Germany, we also expect that INTERCEPT adoption will be aided by a recent blood advisory group recommendation to shorten the shelf life of stored platelets that have not been treated with systems such as INTERCEPT. We continue to see substantial growth opportunity for INTERCEPT in Germany.

France continues to develop as a market for INTERCEPT, although more slowly than we had expected. INTERCEPT is currently being used successfully in four of France's 17 regional blood centers. In 2008 we were also awarded a contract with the French Army. Although modest in magnitude, the military contract is an important inroad into the French market. For plasma, pathogen inactivation has been employed in France for several years, using technologies other than INTERCEPT. The French authorities have been scrutinizing safety data for one of these technologies, which may open a door to broader adoption of INTERCEPT for plasma in France.

## >Expanding Our Opportunities

In 2008 we expanded our reach in Europe, Russia and the Middle East. Our distributor Grifols has helped to implement INTERCEPT in blood centers serving 30% of the Spanish population while also building our market in Portugal. In Belgium we have worked with blood centers to enable rapid adoption of INTERCEPT once the country's reimbursement policy is finalized, which is expected in 2009. We believe adoption in the U.K. could occur as early as 2010, opening a substantial market for INTERCEPT in a country for which we previously had modest expectations.

## >Continued Focus on Commercialization

Progress in our commercial operations continues to enhance INTERCEPT's positioning in key markets. Our existing customers can be a powerful voice in educating their peers on the clinical and commercial benefits of INTERCEPT. In 2009 we intend to leverage the satisfaction and success of existing INTERCEPT customers to expand our customer base. Our new two-bag system allows a single blood collection to be split into two therapeutic doses, enhancing the value we can offer our customers while also improving our margins on each kit.

## >Platelets

*As we expand the market for INTERCEPT platelets outside the United States, we are working closely with the FDA to establish data collection protocols that will support approval of the INTERCEPT platelet system and open the door to the U.S. market.*

## >Plasma

*Additional INTERCEPT plasma customers in Europe, Russia and the Middle East are expected to come on line in 2009, increasing the product's visibility and enabling us to demonstrate its clinical and commercial value.*

## >Red Cells

*In 2009 we expect to complete a Phase I study of our reformulated INTERCEPT Blood System for red cells, setting the stage for a future Phase III trial. Our initial indication comprises 80% of the estimated \$4 billion market for this product.*

### *>Progress in the United States*

In early 2008 the U.S. Food and Drug Administration indicated its willingness to consider data from a study of the INTERCEPT platelet system in standard medical practice in Europe, as an alternative to a more extensive and time-consuming blinded U.S. Phase III trial. We are working closely with the FDA to define a protocol for such a study. We expect to reach agreement on a protocol in 2009. We expect thereafter to initiate the study, depending on the availability of adequate funding to complete the study and regulatory submissions.

### *>Advances in the INTERCEPT Red Cell Program*

In 2008 we initiated a Phase I trial with a modified form of our INTERCEPT Blood System for red blood cells and expect to complete the trial in 2009. Success in this trial would position us to initiate a Phase III trial in acute anemia, which accounts for 80% of the estimated \$4 billion worldwide market for this system. Our continued investment in this program, however, will depend on securing funding for it, either through a partnership or additional financing activities. In the meantime, we expect to make some level of advancement of the program on a cash-neutral basis through government grants and participation of current and potential future partners.

### *>Disciplined Management of Our Financial Resources*

Reining in costs and conserving cash have never been more important than they are today. In 2008 and 2009 we have taken a number of measures to reduce our operational costs and preserve our cash resources. In addition, in December, we amended our supply agreement with Fenwal to reduce our cost of goods for INTERCEPT kits. We believe that capitalizing on our near-term commercial opportunities is the most effective way to build long-term value for our shareholders. We will move pragmatically to advance our U.S. and red blood cell opportunities in keeping with our financial resources.

### *>Because Safe Blood Matters*

Even in these challenging economic times, we believe that healthcare systems around the world must address significant unmet health and safety needs. Patients should not need to worry whether they will contract a serious disease through a blood transfusion. Increasingly, physicians, blood bankers and healthcare authorities are concluding that the INTERCEPT Blood System is the best way to provide patients the security they deserve. Cerus is committed to fulfilling its mission of providing safer blood products, and we look forward to seeing the greater fruits of our efforts in the months ahead.

Sincerely,



Claes Glassell  
President and Chief Executive Officer

March 10, 2009

“Recent data show that bacterial contamination of platelets is a greater risk than previously appreciated. A growing number of emerging — and unknown — pathogens pose a challenge to the current blood screening paradigm. Healthcare policy is adapting to these realities, and we believe that the INTERCEPT Blood System is very well positioned for success on both clinical and commercial grounds.”



**>Safe Blood.**

Blood banks and healthcare professionals strive for it. Patients need it. At Cerus, we are committed to raising the standards of blood safety. Current blood screening paradigms do not adequately address the threats posed by emerging pathogens and pathogens that have not yet been identified. Traditional blood processing methods fall short of eradicating bacterial contamination. Cerus' proprietary INTERCEPT Blood System inactivates viruses, parasites and bacteria that can slip through current screening, testing and processing methods. Because safety is in our blood.

## Executive Management & Board of Directors

### Executive Management

**Claes Glassell**  
President and Chief Executive Officer

**William M. Greenman**  
Senior Vice President,  
Business Development & Marketing

**Laurence M. Corash, M.D.**  
Senior Vice President and  
Chief Medical Officer

**William J. Dawson**  
Vice President, Finance and  
Chief Financial Officer

**Joseph J. Eiden, M.D.**  
Vice President, Clinical Research  
and Medical Affairs

**Howard G. Ervin**  
Vice President, Legal Affairs

**Suzanne C. Margerum**  
Vice President, Development  
and Manufacturing

**Carol M. Moore**  
Vice President, Regulatory Affairs  
and Quality

**Lori L. Roll**  
Vice President, Administration  
and Corporate Secretary

### Board of Directors

**B.J. Cassin**  
Chairman of the Board, Private  
Venture Capitalist

**Timothy B. Anderson**  
Former Senior Vice President,  
Baxter International Inc.

**Laurence M. Corash, M.D.**  
Senior Vice President and Chief Medical Officer

**Bruce C. Cozadd**  
Executive Chairman, Jazz Pharmaceuticals, Inc.

**Claes Glassell**  
President and Chief Executive Officer

**William R. Rohn**  
Former Chief Operating Officer, Biogen Idec Inc.

**Gail Schulze**  
Chairman & Chief Executive Officer  
Zosano Pharma, Inc.

## Corporate Information

### Corporate Headquarters

2411 Stanwell Drive  
Concord, California 94520  
Telephone: (925) 288-6000  
Fax: (925) 288-6001  
www.cerus.com

### European Headquarters

Stationsstraat 79-D  
3811 MH Amersfoort  
Netherlands  
Telephone: 31 33 496 0600  
Fax: 31 33 496 0606

### Corporate Counsel

Cooley Godward Kronish LLP  
Palo Alto, California

### Patent Counsel

Morrison & Foerster LLP  
Palo Alto, California

### Auditors

Ernst & Young LLP  
Palo Alto, California

### Registrar and Transfer Agent

Wells Fargo Bank, N.A.  
161 North Concord  
South St. Paul, Minnesota 55075  
Telephone: (800) 401-1957  
Fax: (651) 450-4033

## Annual Report on Form 10-K

A copy of the company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission is available without charge on request to:

### Investor Relations Department

Cerus Corporation  
2411 Stanwell Drive  
Concord, California 94520  
Telephone: (925) 288-6000

### Stock Information

Common stock, traded on the Nasdaq Stock Market under the symbol: CERS

### Annual Meeting of Stockholders

9:00 a.m., Monday, June 1, 2009  
Cerus Corporation  
2411 Stanwell Drive  
Concord, California 94520

## Forward-looking Statement

Statements in this annual report regarding rate and timing of customer adoption, future clinical trials, future regulatory activities, filings and approvals, potential efficacy of products, potential collaborations, future product development and commercial potential are forward-looking statements that involve risks and uncertainties. Actual results could differ materially from these forward-looking statements as a result of certain factors, including the risks and uncertainty of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development process, the adequacy of cash resources to fund future operations, additional financing activities, performance by partners, manufacturing, commercialization and market acceptance of any products, competitive conditions, and other factors discussed in the Company's most recent filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this annual report. The Company does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

Cerus, INTERCEPT and INTERCEPT Blood System are trademarks of Cerus.



Cerus Corporation  
2411 Stanwell Drive  
Concord, California 94520  
tel (925) 288-6000  
fax (925) 288-6001  
[www.cerus.com](http://www.cerus.com)

FORM 10-K



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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2008

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-21937

**CERUS CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2411 Stanwell Dr.**  
**Concord, California**  
(Address of principal executive offices)

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

**94520**  
(Zip Code)

**(925) 288-6000**

(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:  
NASDAQ Global Market**

**Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, par value \$.001 per share  
(Title of Class)**

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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 \$98.8 million.(1)

As of February 19, 2009, there were 32.6 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 2009 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, 2008, are incorporated by reference into Part III of this annual report on Form 10-K.

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(1) Based on a closing sale price of \$4.09 per share on June 30, 2008. Excludes 8.4 million shares of the registrant's common stock held by executive officers, directors and affiliates at June 30, 2008.

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## PART I

*This report contains forward-looking statements that involve risks and uncertainties. When used herein, the words “anticipate,” “believe,” “estimate,” “expect,” “plan” and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including our need for additional financing, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products, market acceptance of our products, reimbursement, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, a transition away from a reliance on Baxter International, Inc. and Fenwal, Inc. for sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fenwal and third parties to manufacture certain components of the INTERCEPT Blood System, our successful completion of our product components’ commercial design, our reliance on our relationship with BioOne Corporation for commercialization of the INTERCEPT Blood System for platelets and plasma in Asian markets, more effective product offerings by, or clinical setbacks of, our competitors, product liability, potential for financial return from the spin-off of our immunotherapy business, 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. The company currently markets 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 approvals 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, where commercialization rights to the platelet and plasma systems 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 Europe, Russia, the Middle East and in selected countries in other regions around the world. 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. We previously collaborated with subsidiaries of Baxter International Inc., or Baxter, in the development and commercialization of the INTERCEPT Blood System. In February 2005 and February 2006, we announced agreements with Baxter that resulted in our acquisition of all commercialization rights to the INTERCEPT Blood System that had not

been licensed to BioOne. 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.

## Product Development

We have incurred total research and development expenses from continuing operations of \$10.2 million, \$15.0 million and \$16.0 million for the years ended December 31, 2008, 2007 and 2006, respectively. The following table identifies our products and product development programs and their current status:

<u>Product or Product Under Development</u>	<u>Product or Development Status</u>	<u>Commercial Rights</u>
INTERCEPT Blood System—Platelets	Commercialized in Europe, Russia, the Middle East and other selected countries United States: Phase III clinical trial completed; supplemental data required	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 initiated in fourth quarter of 2008	Worldwide

### *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 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.

We have worldwide commercialization rights for the INTERCEPT Blood System, excluding certain countries in Asia. Baxter and we licensed to BioOne commercialization rights to the INTERCEPT Blood System for platelets and plasma in 2004 and 2005, respectively, in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore.

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

#### *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. Certain countries require additional approvals of INTERCEPT-treated blood products. Such additional approvals have been obtained for INTERCEPT-treated platelets and plasma in France and for INTERCEPT-treated platelets at several blood centers in Germany. Further clinical studies may be conducted to gain broader market acceptance, expand product labeling or provide data to support applications for regulatory and/or reimbursement approval in some countries.

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 and supplemental analysis, and understand that the FDA may consider non-randomized data derived from the use of the platelet system in the context of standard medical practice in conjunction with data from the previously completed Phase III trial. 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, 2008, 2007 and 2006 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. We have prioritized the commercial launch of the plasma system in Europe ahead of further regulatory efforts to obtain approval of the plasma system in the United States. We obtained French approval of INTERCEPT-treated plasma in early 2007. Pathogen inactivated plasma for transfusion is already reimbursed in many European countries, including France.

Information regarding our revenues from the plasma system for the years ended December 31, 2008, 2007, and 2006 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 blood cells in one patient in the chronic arm of the trial. However, there were no medical sequelae 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. We initiated a new Phase I clinical trial for the red blood cell system in the United States in the second half 2006 with our modified process, which was completed in mid-2007. While we determined that the modifications we tested in this Phase I clinical trial appeared to be safe, they resulted in

dehydration and an unacceptably short lifespan of the treated red blood cells. In 2008, we completed a series of *in vitro* and *in vivo* tests with further modifications to the red blood cell system designed to correct the shorted lifespan and initiated another Phase I clinical trial in the fourth quarter of 2008. Subject to the availability of adequate funding from partners, government grants, and/or capital markets, we expect to spend approximately two years developing and implementing commercial product and system design changes to the original red blood cell system prior to entering Phase III clinical trials. We may be unable to fund continued commercial product and system design efforts and required Phase III clinical trials, unless we obtain third-party funding for such efforts.

## **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. We were informed by Baxter that Fenwal had 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. BioOne received exclusive marketing and distribution rights in each of those countries. We understand 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. At December 31, 2008, we reported an investment in BioOne of \$2.3 million on our consolidated balance sheets. We received no significant milestone or royalty payments from BioOne in 2008.

### *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 \$28.5 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.

### **Investment in Anza Therapeutics, Inc.**

Effective October 16, 2007, we ceased funding operations of our former immunotherapy business. In November 2007, we announced that we had sold certain assets that made up our 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. There is no assurance that the equity will have monetary value at such time we are able to sell it or that we will receive any proceeds in the event of liquidation or sale of Anza. The terms of sale provided Anza a right to redeem up to 1,000,000 of such shares for a nominal amount upon the failure to occur of certain circumstances relating to possible research grant funding from the DoD. We were advised informally in February 2009 that based upon such provision, Anza may seek to redeem 1,000,000 shares held by us. If such shares were redeemed by Anza, we would own fewer shares of Anza's Preferred Stock, reducing our preferred equity interest to approximately 16.0% of Anza's outstanding preferred equity. We are evaluating whether such clause is applicable in the present circumstances. We were informed in February 2009 that Anza had ceased operations.

The immunotherapy business is accounted for as a discontinued operation on our financial statements as of December 31, 2007. Accordingly, we restated our statements of operations for periods prior to December 31, 2007 to reflect that accounting treatment.

### **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 that amends and restates our February 2005 manufacturing and supply agreement with Baxter, which was assumed by Fenwal in 2007. 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 agreement revises the pricing of purchased products for both clinical and commercial use. Fenwal is obligated to sell us a predetermined number of illuminators in Fenwal's existing inventory, but we will be otherwise free to purchase illuminators directly from third party manufacturers, including NOVA Biomedical Corporation, or NOVA. 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 on September 24, 2008. Under the terms of the NOVA agreement, we have the ability to purchase illuminators directly from NOVA. 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, an 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. We understand that a raw material supplier to Baxter, which in turn supplies Fenwal, for a proprietary plastic used in the platelet and plasma systems' disposable kits, has ceased production, and that Baxter may be unable to identify an alternate supplier on a timely basis. 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 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 units 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 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 will 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, 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 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, 2008, we owned approximately 23 issued or allowed United States patents and approximately 47 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2012 and 2018. 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 between 2010 to 2022. 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, forecasts, and inventory turnover.

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, 2008, the Company had three customers each accounting for more than 10% of the Company's outstanding trade receivables and aggregating approximately 60% of outstanding trade receivables. To date, the Company has not experienced collection difficulties from 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. 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 2008, 2007, and 2006.

## **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. Several countries require additional in-country studies to support an approval to market products beyond the CE marks.

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.

In addition, the FDA 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. The FDA will require a PMA for each of the INTERCEPT systems for platelets, plasma and red blood cells. In addition, the FDA will require site-specific licenses from our United States-based blood center customers before they can engage in interstate transport of blood components processed using our pathogen inactivation systems, and a delay in obtaining these licenses would adversely impact our ability to sell products in the United States.

The FDA regulates the INTERCEPT Blood System as a biological medical device. The FDA Center for Biologics Evaluation and Research, or CBER, is principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our blood safety products, CBER also regulates the blood collection centers and the blood products they prepare using the INTERCEPT Blood System.

Before the FDA determines whether to approve our blood safety products, we expect our approval applications 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. Before a medical device may be marketed in the United States, the FDA must approve a pre-market approval application for the product.

Baxter used a modular process for our PMA application for the platelet system in the United States, which we have followed since assuming responsibility for regulatory activities in the United States under terms of the February 2005 and 2006 agreements. 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.

In addition to the regulatory requirements applicable to the INTERCEPT Blood System, there are regulatory requirements applicable to our prospective customers, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA before using the INTERCEPT Blood System. There can be no assurance that any blood centers will be able to obtain the required licenses on a timely basis, or at all.

To support applications for regulatory approval to market the INTERCEPT Blood System, we conduct various types of studies, including toxicology studies to evaluate product safety, laboratory and animal studies to evaluate product effectiveness and human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components. We 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.

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. If we decide to seek FDA approval of the platelet system for use in treating pooled random donor platelets, additional clinical studies will be required. In addition, there currently are three principal manufacturers of automated apheresis platelet collection equipment, including Fenwal. The equipment of each manufacturer collects platelets into plastic disposables designed for that equipment; thus, a pathogen inactivation system designed for disposables used by one manufacturer will not necessarily be compatible with other manufacturers' collection equipment. If we pursue regulatory approval of the platelet system in the United States, we may initially seek limited approval of the platelet system configured for Fenwal's apheresis collection equipment. If we determine that compatibility with other equipment is desirable, additional processing procedures and system configurations will need to be developed. We believe that the FDA will also require supplemental clinical data before approving our system for use with platelets collected using other equipment.

### **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 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, 2008, we had 107 employees, 44 of whom were engaged in research and development and 63 in selling, general, and administrative activities. Of the 63 employees engaged in selling, general, and administrative activities, 29 were employed by our European subsidiary, Cerus Europe B.V. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

## Available Information

We maintain a website at [www.cerus.com](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.

## 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. There may be additional risks faced by our business.*

***If we fail to obtain the capital necessary to fund our future 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 trials 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 we will be able to make reductions in our operating expenses and inventory, which, together with our expected revenues, will result in sufficient capital to fund operations into 2010. 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 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 may be adversely impacted by current economic conditions, including the effects of the recent disruptions to the credit and financial markets in the United States and worldwide. In addition, our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern. This opinion may make it more difficult for us to raise funds when needed. 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 due to the recent 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 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 regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system.

Historically, we had received significant awards in funding under cooperative agreements with the DoD. We also received funding under grants from the National Institutes of Health, largely in support of the immunotherapy business that we spun-off in late 2007. Further funding awarded under Federal grants and cooperative agreements for the INTERCEPT Blood Systems may decline when compared to historic levels. It 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. Additionally, we no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the National Institutes of Health and regulated by Small Business Administration. Historically, a significant portion of our grant revenue came from awards surrounding our former immunotherapy business. 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. In addition, we are required separately to administer and account for our work under government contracts and grants on an on-going basis as a condition to accepting government funding, which places administrative, accounting and reporting burdens on us beyond those we have assumed as a public company. If we fail to comply with applicable governmental administrative, accounting and reporting regulations with respect to these grants and cooperative agreements, funds currently available to us may be reduced or lost. These conditions may also result in increased selling, general, and administrative spending beyond what we have experienced.

***Our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern.***

Our audited financial statements for the fiscal year ended December 31, 2008, were prepared on a going concern basis in accordance with United States generally accepted accounting principles. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. However, our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern. We may be forced to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings. However, we cannot guarantee that we will be able to obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

***Our declining creditworthiness may make us unable to obtain additional funds through debt financings, which will impair our ability to continue as a going concern***

Our lack of sufficient revenues to meet our working capital needs has caused our creditworthiness to decline. As a result, we may be unable to raise additional funds through debt financings or, if we are able to raise such funds, we may not be able to do so on terms satisfactory to us. If we fail to generate operating income or raise additional funds through sales of our securities or debt financings, we may not be able to continue as a going concern.

***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 year ended December 31, 2005. At December 31, 2008, we had an accumulated deficit of approximately \$385.9 million. Except for sales of the platelet and plasma systems, we have not received significant revenue from product revenue. 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 would reduce and may eliminate our gross profit on sales. Pricing levels may differ widely from country to country, depending on economic, social and industry practices specific to each country. At our present low unit 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. We may be unable to increase sales to a level sufficient to generate profit contribution. Because the contracts with large, public-sector customers, such as the EFS, for the INTERCEPT Blood System may not be confidential due to the public tender process, their terms may set contractual precedents that would not be acceptable to us if applied to contracts with our other customers. Historically, we received substantially all of our revenue from our agreements with our development partners and from federal research grants and cooperative agreements and were required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. Contribution from product sales is unlikely to exceed the costs we incur in research, development, and commercialization of the INTERCEPT Blood System for the foreseeable future. We expect our losses to continue at least until the INTERCEPT Blood System is commercialized more broadly and achieves more significant market acceptance. Costs of developing and testing the red blood cell system in later stage human clinical trials will 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, 2008, 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 current 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. 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. 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. 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.

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

We may encounter governmental and blood banking community resistance to commercial adoption for any or all of our products. Some potential customers may await further safety information or additional studies before choosing whether to adopt 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 who may ultimately benefit from INTERCEPT-treated blood components, 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, efficacious and cost effective.

For logistical and financial reasons, the transfusion 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 additional 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”) 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. Our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens, including prions, may limit their acceptance. In addition, 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. In addition, we have developed, but have not yet received an expanded label claim for a configuration of our platelet system that may make it compatible with the common practice of collecting two units of platelets from a single apheresis donor. 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.

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. It is difficult to predict the reimbursement status of newly approved, novel medical device products. In certain foreign markets, 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 can be expected to continue and may limit the prices we can obtain for our products.

Product revenue 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. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable.

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 in any final PEI marketing authorization of INTERCEPT-treated platelets 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 delayed. Blood center economics in certain European countries, including Germany and the United Kingdom, may require that we develop disposable kit configurations of the platelet system that treat larger volumes of platelets, which would serve to reduce the number of kits we might sell to address market demand in those countries, even though our selling price and margin might be higher on such disposable kit configurations. 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 decreased.

***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 product emerging from any successful trials would not reach the market for several years.

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 and in-country regulatory approvals for the INTERCEPT platelet and plasma systems, which allow us to sell our platelet and plasma systems only in certain countries, mainly in Europe, Russia, the Middle East, and Asia. 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. We will need to complete validation studies and obtain in-country regulatory approvals and gain national reimbursement in certain European countries before we can market and sell our products in those countries.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or 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, it is likely that the FDA would not approve those 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 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 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. 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.

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 with which we have little or no familiarity.

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 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. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in lost product revenue and profitability. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals. For example, we recently received notice from Health Canada that the license for the platelet system that was issued to Baxter had been suspended until such time as we can supply Health Canada with additional data to meet its requirements.

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 inconsistent event reporting. 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, which showed statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. We have had several interactions with the FDA subsequent to the final report submission. We understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the apparent differences observed in that trial between the treatment groups in the category of pulmonary adverse events. Based upon further discussions with the FDA following submission of that report, we understand that the FDA may consider non-randomized, unblinded, and noncontrolled data gathered from monitoring patients transfused with INTERCEPT-treated platelets in the context of standard medical practice in conjunction with data from the previously completed Phase III trials. We understand that the design of such a study would be novel and resulting data may not be sufficient to approximate the quality of similar data that could be expected from a randomized, blinded, and controlled Phase III clinical trial. Such data will need to be gathered prospectively and must be in a form and substance deemed acceptable to the FDA in its sole discretion. There is no assurance that we will be able to reach agreement with the FDA on the data to be collected and endpoints to be monitored, that transfusing physicians with patients in the study will adhere to post diagnostic medical procedures that may be mandated in the agreed upon study protocol, that we will be able to collect such data, or that the FDA will find such data from commercial use adequate to answer questions that the FDA has concerning the safety and efficacy of the platelet system. We may conclude that the cost of gathering such data or the time required to do so is too great or that gathering such data is not logistically achievable. The FDA may not find the data from standard medical practice in Europe to be acceptable for approval in the United States. As a result, the FDA may still require a larger, randomized, blinded clinical trial than we and Baxter completed in 2001 before a product license application can be finalized and the platelet system considered for approval in the United States.

Such an additional Phase III trial would have to be designed to demonstrate no greater frequency in the incidence of such adverse events relative to a control group on a statistically significant basis. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. The additional European study or Phase III clinical trial will need to be completed and data submitted to the FDA before we can complete our regulatory submission. In addition, the FDA will require that certain manufacturing and distribution facilities operated by the third parties with whom we contract to produce the platelet system be compliant with Good Manufacturing Practice, or GMP, regulations and Quality System Regulations, or QSR, before the FDA would consider the applications for approval.

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.

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 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. We expect the FDA to require us to demonstrate a very low level of potential side effects in non-randomized data from standard medical practice in Europe or in additional randomized Phase III trials of the platelet system we may conduct in the United States or elsewhere. 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 the 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. 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, including determining the appropriate design of additional Phase I, subsequent Phase II clinical trials, if deemed necessary, and Phase III clinical trials, we will need to develop a commercially feasible red blood cell system, including disposables, hardware and software for implementing the process in blood collection centers. In the aggregate, these activities will require significant funding beyond our current resources. We will not commence the next phase of activities until we have secured adequate funds. We expect that we can continue some level of program advancement on a cash neutral basis with grant funding from the Department of Defense and existing and potential partners. A delay in completing such

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 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 number of foreign 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. We no longer rely upon Baxter or Fenwal for these activities. 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. 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 EU 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 national distribution agreements in Spain, Portugal and Chile, Russia, Poland, Greece, and Kuwait, as well as regional distribution agreements in Italy. We rely on these distributors to market and sell the INTERCEPT

Blood System, obtain any necessary in-country regulatory approvals beyond the CE marks, provide customer 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 or may do so on terms which are not economic to us. 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.

***We must develop regulatory capabilities for clinical-stage and post-approval trials involving the INTERCEPT Blood System globally.***

Failure to develop regulatory capabilities in support of international commercialization of the INTERCEPT Blood System may slow the rate of adoption of the platelet and plasma systems. We may not have adequate internal resources and capabilities to manage clinical-stage and post-approval trials and to respond appropriately to possible customer complaints or required regulatory reporting of adverse events arising from the use of the platelet and plasma systems. We will need to increase our regulatory and trial management resources or contract with independent regulatory consultants, which we may be unable to do on a timely basis. Adding regulatory and trial management resources will result in increased costs and may potentially delay regulatory filings. Delays or inability to complete regulatory filings and obtain approvals will also delay or prevent us from being able to recognize sales of our products and attaining profitability.

***We rely on third parties for manufacturing and supplying components of our platelet and plasma systems. We are dependent on Fenwal to manufacture disposable kits for the platelet and plasma systems through the end of 2013. Over a longer period, we may need to identify, select and qualify alternate third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system if our agreement with Fenwal cannot be extended or broadened.***

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 and Intersol additive solution or to do so on a cost effective basis, which would subject us to loss of revenue and reduced contribution margin. In addition, because the components of the INTERCEPT Blood System are manufactured and assembled at multiple facilities owned by both Fenwal and Baxter leading up to final assembly, Fenwal and Baxter will remain interdependent with respect to the INTERCEPT Blood System supply chain. Fenwal and Baxter 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, 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. Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons, causing at least temporary interruptions in supply. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. 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. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. We will 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.

We will also be dependent on Baxter and Fenwal to transfer know-how relevant to the INTERCEPT Blood System; however, certain of Fenwal's materials, manufacturing processes and methods are proprietary to Fenwal or Baxter. We may be unable to establish alternate sources of supply to Fenwal 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. We have recently contracted directly with third-party suppliers of certain components of the platelet and plasma systems which Fenwal had used historically in an effort to make the supply of components more reliable, though doing so will increase our investment in raw material and work-in-process inventories and subject us to minimum purchase requirements. We understand that a raw material supplier to Baxter, which in turn supplies Fenwal, for a proprietary plastic used in the platelet and plasma systems' disposable kits has ceased production, and that Baxter may be unable to identify an alternate supplier on a timely basis, 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.

***Our potential remedies against Fenwal or other manufacturers may be inadequate in assuring that these manufacturing partners meet their contractual obligations.***

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.

***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 and to a more limited extent in Europe.

Our system for platelets is designed to work with platelets collected using a proprietary platelet storage solution, called Intersol, manufactured by Fenwal. 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, again because this method facilitates the use of Intersol as an additive solution to the platelet concentrate. As a result, we have conducted most of our clinical studies using either Fenwal's equipment or buffy

coat platelets. More recently, we have begun conducting studies in Europe supporting the use of the platelet system in combination with other collection and preparation platforms and with other additive solutions and with platelets suspended in plasma. We may not be successful in developing data supportive of commercialization using other collection and preparation platforms and with other additive solutions, which would limit customer adoption of the INTERCEPT Blood System. 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 permitted 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 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 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.

***Because the INTERCEPT Blood System products have not been manufactured on more than a limited commercial scale, we face manufacturing uncertainties that could limit their commercialization. If our third-party manufacturers fail to produce our products or compounds satisfactorily, at acceptable cost and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations.***

The INTERCEPT Blood System products, including many of the components, have been manufactured on a commercial scale on only a limited basis. Fenwal relies on third parties, including Baxter, to manufacture and assemble some of the platelet and plasma system components, many of which are customized and have not been manufactured on a commercial scale. Fenwal has produced some pathogen inactivation systems in modest commercial quantities, but may not be able to manufacture and assemble other systems or in larger quantities, or do so economically. Because of low sales volumes and other reasons, Fenwal's costs to manufacture commercial components for the platelet and plasma systems have been greater than we previously anticipated and may continue to rise. It is uncertain what effect Fenwal's independence from Baxter will have on its cost structure or on transfer prices from Baxter to Fenwal and costs ultimately passed on to us. These issues may result in reducing our potential gross profit margin from platelet and plasma system sales.

We are in the initial stages of commercializing the INTERCEPT Blood System and may not accurately forecast demand for the INTERCEPT Blood System. 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 be inadequate to meet customer demand. If Fenwal or third-party manufacturers fail to produce our products or Intersol products satisfactorily, at acceptable costs and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations.

Fenwal and we purchase certain key components of the INTERCEPT Blood System from a limited number of suppliers. It would be expensive and time-consuming to establish additional or replacement suppliers for these components. Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require Fenwal or 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. We understand that a raw material supplier to Baxter, which in turn supplies Fenwal, for a proprietary plastic used in the platelet and plasma systems' disposable kits has ceased production, and that Baxter may be unable to identify an alternate supplier on a timely basis, if at all. If Fenwal or we are unable to identify and supply replacement components, we may be unable to supply products to our customers. If we were required to redesign the products, our development costs would increase, and our programs and commercialization efforts could be delayed significantly.

We use third-party manufacturers to produce commercial quantities of the chemical compounds used in our products. We currently do not have any third-party manufacturing agreements in place for commercial production of compounds used in our red blood cell system, which is in early stages of 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.

Our platelet and plasma systems 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 at our expense.

***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.***

The system disposables and instruments of our red blood cell system that we used in our preclinical studies and clinical trials in the United States historically and those we are now using in the current 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 have tested additional modifications of the red blood cell system to improve the lifespan of treated red blood cells. *In vitro* and *in vivo* studies of such modifications to the red blood cell system may not be indicative of red blood cell lifespan in humans. Additional early-stage trials will be necessary to determine whether our modifications, including these new approaches, may lead to a product with acceptable commercial characteristics. We also are assessing whether such modifications would be acceptable clinically, economically and/or operationally to potential customers. 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.

Fenwal is not obligated to provide manufacturing services related to the red blood cell system. We will need to identify parties to provide those manufacturing services related to our red blood cell system. It may be difficult to enter into these types of agreements on reasonable terms. In particular, it will be time-consuming for other manufacturers to develop the capability to manufacture the INTERCEPT Blood System products and blood component storage solutions economically and to gain regulatory approval to do so for commercial use. 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.

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

Baxter and we have 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. We understand Fenwal has assumed the rights and obligations of Baxter with regard to Baxter's agreements with BioOne. BioOne is dependent on Fenwal 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 dependent 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 abilities to commercialize the platelet and plasma systems in its Asian territories will be compromised. 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. If competitors encounter difficulties or failures in human clinical trials or in commercial settings, we may face additional clinical, regulatory and commercial challenges.***

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 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. Competitors in platelet pathogen inactivation may be able to offer customers systems using additive solutions other than Intersol, which we use in the INTERCEPT platelet system. 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. Caridian is developing a pathogen inactivation system for blood products and has been issued CE marks for a pathogen reduction system for both platelets and plasma. Caridian also commenced trials on a pathogen inactivation system for whole blood, which may offer competitive advantages over our INTERCEPT Blood System, with its three distinct components for platelets, plasma and red blood cells.

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. Continued delays in commercialization of our platelet and plasma systems in France and Germany may impact our ability to compete with bacterial testing for platelets. Other competitors 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 coverages 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. 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.

***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.

***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. In exchange for contributed tangible and intangible assets, we received preferred stock representing an equity interest of approximately 20% of Anza's preferred equity. The terms of sale provided Anza a right to redeem up to 1,000,000 of such shares for a nominal amount upon the failure to occur of certain circumstances relating to possible research grant funding from the DoD. We were advised informally in February 2009 that, based upon such provision, Anza may seek to redeem 1,000,000 shares held by us. If such shares are redeemed by Anza, we would own fewer shares of Anza's preferred stock, reducing our preferred equity interest to approximately 16.0% of Anza's outstanding preferred equity. We are evaluating whether such clause is applicable in the present circumstances. There is no assurance that the equity will have monetary value at such time we are allowed to sell it or that we will receive any proceeds upon liquidation or sale of Anza. We were informed in February 2009 that Anza had ceased operations.

***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 2018. 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 2022. 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.

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, 2006, to December 31, 2008, 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 \$14.76. 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 in both the United States and foreign countries;
- status of development partnerships;
- dilution from future issuances of common stock, including through the exercise of vested stock options;
- debt or other financings, with terms that may not be viewed favorably by shareholders;
- 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 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.***

On October 17, 2008, Nasdaq temporarily suspended one of the listing requirements for continued listing on the Nasdaq Global Market that requires a company's minimum bid price to be above \$1.00 per share. This suspension was further extended by Nasdaq on December 19, 2008 until April 19, 2009. Our stock price is currently trading at below \$1.00 per share. If our stock price does not return to a minimum bid price above \$1.00 per share before April 19, 2009, we will be subject to delisting by Nasdaq for failure to meet the continued listing requirements. Delisting from Nasdaq 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 institutional 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.

**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. Certain of our Concord laboratory space has been sublet by Anza Therapeutics, a related party. The sublease with Anza Therapeutics will expire by March 31, 2009. 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. The following table depicts the functional nature of our leases, size, location, and term of our leased space.

<u>Function</u>	<u>Location</u>	<u>Square Footage</u>	<u>Lease Expiration Date</u>	<u>Expiration if Renewal Options Exercised</u>
Corporate Offices . . . . .	Concord, CA, USA	21,400	July 2010	July 2013
Corporate Offices . . . . .	Concord, CA, USA	4,500	August 2009	August 2012
Sales & Administrative . . . . .	Amersfoort, The Netherlands	7,300	January 2013	December 2013
Laboratories – Blood Safety . . . . .	Concord, CA, USA	17,400	June 2009	
Laboratories – Blood Safety <sup>1</sup> . . . . .	Concord, CA, USA	9,900	January 2010	January 2013
Laboratories – Blood Safety <sup>2</sup> . . . . .	Concord, CA, USA	31,800	November 2013	November 2018

<sup>1</sup> – Approximately 7,500 square feet is subleased to Anza Therapeutics, which expires by July 31, 2009;

<sup>2</sup> – Approximately 14,000 square feet is subleased to Anza Therapeutics, which expires by March 31, 2009;

**Item 3. Legal Proceedings**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

## 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:

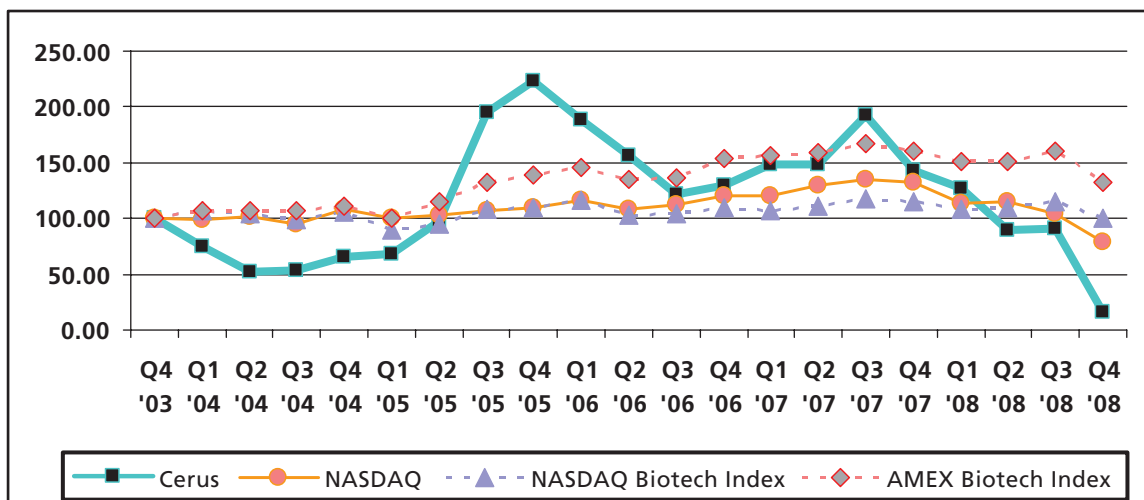
	<u>High</u>	<u>Low</u>
Year Ended December 31, 2007:		
First Quarter . . . . .	\$ 7.02	\$5.11
Second Quarter . . . . .	8.11	5.11
Third Quarter . . . . .	9.08	6.05
Fourth Quarter . . . . .	10.29	6.17
Year Ended December 31, 2008:		
First Quarter . . . . .	7.29	4.18
Second Quarter . . . . .	7.24	4.09
Third Quarter . . . . .	5.35	3.20
Fourth Quarter . . . . .	\$ 4.37	\$0.55

On February 19, 2009, the last reported sale price of our common stock on the Nasdaq Global Market was \$0.72 per share. On February 19, 2009, we had approximately 182 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.

**Performance Measurement Comparison (1)**

The following graph shows the total stockholder return of an investment of \$100 in cash on December 31, 2003 for (i) our common stock, (ii) the NASDAQ Stock Market (United States) Index, (iii) the NASDAQ Biotech Stocks Index, and (iv) the Amex Biotech Index.

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



	December 31,					
	2003	2004	2005	2006	2007	2008
Cerus Corporation	\$100.00	\$ 64.98	\$223.57	\$129.07	\$143.39	\$ 15.42
NASDAQ Biotech Index	100.00	106.13	109.14	110.25	115.30	100.68
Amex Biotech Index	100.00	111.05	138.93	153.90	160.48	132.05
NASDAQ	100.00	108.59	110.08	120.56	132.39	78.72

(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.

**Item 6. Selected Financial Data**

The following table summarizes certain selected financial data for the five years ended December 31, 2008. The information presented should be read in conjunction with the financial statements and notes 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.

	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
	(in thousands, except per share data)				
<b>Statement of Operations Data: (1)</b>					
Product revenue .....	\$ 15,518	\$ 8,015	\$ 2,975	\$ 485	\$ —
Other revenue .....	989	3,029	27,335	13,012	11,317
Total revenue .....	<u>16,507</u>	<u>11,044</u>	<u>30,310</u>	<u>13,497</u>	<u>11,317</u>
Cost of product revenue .....	9,668	5,228	1,541	—	—
Gross profit .....	<u>6,839</u>	<u>5,816</u>	<u>28,769</u>	<u>13,497</u>	<u>11,317</u>
Operating expenses:					
Research and development .....	10,205	14,957	16,036	10,660	17,990
Selling, general and administrative .....	27,164	24,575	15,082	10,785	11,517
Impairment of long-term investment in related party .....	—	9,450	—	—	—
Restructuring .....	—	—	—	—	2,861
Total operating expenses .....	<u>37,369</u>	<u>48,982</u>	<u>31,118</u>	<u>21,445</u>	<u>32,368</u>
Loss from operations .....	(30,530)	(43,166)	(2,349)	(7,948)	(21,051)
Net interest and other income (expense) .....	1,349	4,066	4,701	22,405	(4,327)
Net income (loss) from continuing operations .....	<u>\$ (29,181)</u>	<u>\$ (39,100)</u>	<u>\$ 2,352</u>	<u>\$ 14,457</u>	<u>\$ (25,378)</u>
Discontinued operations:					
Loss from discontinued operations .....	—	(5,820)	(7,131)	(1,393)	(5,775)
Loss from sale of discontinued operations .....	—	(384)	—	—	—
Net loss from discontinued operations .....	<u>—</u>	<u>(6,204)</u>	<u>(7,131)</u>	<u>(1,393)</u>	<u>(5,775)</u>
Net income (loss) .....	<u>\$ (29,181)</u>	<u>\$ (45,304)</u>	<u>\$ (4,779)</u>	<u>\$ 13,064</u>	<u>\$ (31,153)</u>
Net income (loss) from continuing operations per common share:					
Basic .....	\$ (0.90)	\$ (1.23)	\$ 0.09	\$ 0.65	\$ (1.15)
Diluted .....	\$ (0.90)	\$ (1.23)	\$ 0.08	\$ 0.60	\$ (1.15)
Net loss from discontinued operations per common share:					
Basic .....	\$ —	\$ (0.19)	\$ (0.27)	\$ (0.06)	\$ (0.26)
Diluted .....	\$ —	\$ (0.19)	\$ (0.25)	\$ (0.06)	\$ (0.26)
Net income (loss) per common share:					
Basic .....	\$ (0.90)	\$ (1.42)	\$ (0.18)	\$ 0.58	\$ (1.41)
Diluted .....	\$ (0.90)	\$ (1.42)	\$ (0.17)	\$ 0.55	\$ (1.41)
Weighted average common shares outstanding used for basic and diluted income (loss) per common share:					
Basic .....	32,430	31,870	26,870	22,350	22,143
Diluted .....	32,430	31,870	28,610	23,950	22,143
	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments ...	\$ 22,578	\$ 56,850	\$ 93,416	\$ 45,805	\$ 95,334
Working capital .....	29,145	55,582	87,929	27,690	23,782
Total assets .....	47,339	78,209	115,817	58,660	102,078
Loan and interest payable .....	—	—	—	4,826	39,000
Capital lease obligations, less current portion .....	—	2	32	68	—
Accumulated deficit .....	(385,907)	(356,726)	(311,422)	(306,643)	(319,707)
Total stockholders' equity .....	<u>\$ 34,278</u>	<u>\$ 59,887</u>	<u>\$ 100,971</u>	<u>\$ 35,275</u>	<u>\$ 21,489</u>

(1) Historical statement of operations data has been restated to reflect the treatment of our former immunotherapy business as a discontinued operation.

## **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 our Annual Report on Form 10-K for the year ended December 31, 2008. Operating results for the year ended December 31, 2008 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. With the exception of the financial reporting effects of a non-recurring gain recognized in 2005, we have been generally unprofitable since inception and, as of December 31, 2008, had an accumulated deficit of approximately \$385.9 million. 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 trials 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 can 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 we will be able to make reductions in our operating expenses and inventory, which, together with our expected revenues, will result in sufficient capital to fund operations into 2010. 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 regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system.

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 our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented 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. In addition, our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern. This opinion may make it more difficult for us to raise funds when needed. 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 recent 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.

Since February 2006, we have begun to recognize growing, but still 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. Prior to initiating such commercial operations, our primary sources of revenue were milestone payments, development contracts and collaborative agreements and grants from United States government agencies, including the United States Armed Forces and the National Institutes of Health, or National Institutes of Health, or NIH. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products that, together with anticipated 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.

Under the agreements with BioOne, we have received in the past milestone payments and may receive additional contingent milestone payments and royalties on future product sales.

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. This royalty structure replaced the profit sharing arrangement of previous agreements between us and Baxter under which we had received a defined share of gross profit from product sales. Baxter also agreed to manufacture systems for the platelet and plasma systems on a cost-plus basis through December 31, 2008, and components through December 31, 2009. The terms of our supply agreement with Baxter also provided that Baxter would supply only

very limited types of components for the prototype of the red blood cell system. In March 2007, we were informed that Fenwal had assumed Baxter's manufacturing obligations to us and that our royalty payments would be made directly to Fenwal. In December 2008, we amended and extended our supply agreement with Fenwal to include Fenwal's manufacture 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.

We are responsible for the commercialization and ongoing development of the platelet and plasma systems, except in parts of Asia, where BioOne is responsible for such commercialization. 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 if we can attract financing from partners, government grants, and/or the capital markets.

In November 2007, we spun-off our immunotherapy business to Anza. In exchange for contributed tangible and intangible assets, we received Preferred Stock representing an equity interest of approximately 20% of Anza's preferred equity. The terms of sale provided Anza a right to redeem up to 1,000,000 of such shares for a nominal amount upon the failure to occur of certain circumstances relating to possible research grant funding from the DoD. We were advised informally in February 2009 that, based upon such provision, Anza may seek to redeem 1,000,000 shares held by us. If such shares are redeemed by Anza, we would own fewer shares of Anza's Preferred Stock, reducing our preferred equity interest to approximately 16.0% of Anza's outstanding preferred equity. We are evaluating whether such clause is applicable in the present circumstances. There is no assurance that the equity will have monetary value at such time we are allowed to sell it or that we will receive any proceeds upon liquidation or sale of Anza. We were informed in February 2009 that Anza had ceased operations.

We accounted for the immunotherapy business as a discontinued operation and restated our consolidated financial statements for prior periods to reflect the discontinued operation. Because of the risks and uncertainties underlying Anza's business, we have not assigned a value to our ownership interest in Anza on our consolidated balance sheets. We have provided certain transition services to Anza under terms of a transition services agreement under which Anza reimburses us for our direct costs associated with providing such services. The transition services we are providing to Anza are generally ancillary in nature and do not involve Anza's core business or any scientific research or development. We also sublease 14,800 square feet to Anza under a month-to-month sublease that on its terms will expire no later than March 31, 2009.

Through December 31, 2008, 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. As a result of selling our immunotherapy business to Anza, previously reported revenue associated with grants and cooperative agreements with the NIH are reported as a component of loss from discontinued operations for all periods presented.

### **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) products and/or services have been delivered or rendered, respectively; (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 signed sales contract as evidence of a written agreement. We sell INTERCEPT Blood System for platelets and plasma directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective product. Deliverables and the units of accounting vary according to the provisions of each customer agreement. 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.

Revenue related to substantive at-risk milestones specified under development contracts is recognized as the milestones are achieved. To date, we have not received license fees or milestone payments that are refundable. To the extent that license fees or milestone payments that we have received are subject to future performance criteria, we recognize revenue ratably over the estimated term of the license or the development period. We have received up-front payments from collaboration agreements which are deferred and recognized over the period during which we estimate we are likely to have involvement. We have also received equity in two privately held companies in addition to cash as consideration for licensed rights or technologies. We evaluate several criteria to determine the fair value of the equity received and to conclude whether the facts and circumstances support a fair value for revenue recognition and the investment balance. These criteria include, but are not limited to, third-party investor interest and participation in recent equity offerings at current pricing, business outlook of the privately held company, and available financial information of the privately held company. The financial information we receive is generally only available on an infrequent basis. Although management uses the best available information at the time, there can be no absolute assurance that facts and circumstances will not change in the future. Should these facts and circumstances change, they may negatively impact our consolidated financial statements.

•**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 balance sheet, can take over one year to complete production 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. Our platelet and plasma system 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. 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 using a number of factors including product expiration dates, open and unfulfilled orders, forecasts, and inventory turnover.

•**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.

•**Stock-based compensation**—We issue stock-based awards to our employees, members of our Board of Directors, members of our Scientific Advisory Board and certain contractors as strategic, long-term incentives. We recorded stock-based compensation expense for employee awards under Statement of Financial Accounting Standards, or FAS, No. 123R, “Accounting for Stock-Based Compensation” (FAS 123R). We determine the grant-date fair value of a stock award using the Black-Scholes option pricing model. We continue to apply the provisions of Emerging Issues Task Force, or EITF, 96-18, “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 EITF 96-18, 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 discreet 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, as illustrated in the Securities and Exchange Commission Staff Accounting Bulletin No. 107 and 110, “Share-Based Payment,” or SAB 107 and SAB 110. 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 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. Financial Accounting Standards Board Interpretation No. 48, “Accounting for Uncertainty in Income Taxes,” or FIN 48, became effective for us on January 1, 2007. FIN 48 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 Financial Accounting Standard 109, “Accounting for Income Taxes,” or FAS 109, 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, 2008 or 2007. 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. The adoption of FIN 48 has not have a significant impact on us. 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, 2008, 2007, and 2006

#### Revenue

(in thousands, except percentage)	Years Ended December 31,			% Change 2008 to 2007	% Change 2007 to 2006
	2008	2007	2006		
Product revenue . . . . .	\$15,518	\$ 8,015	\$ 2,975	94%	169%
Government grant and cooperative agreements . . . . .	989	3,029	4,836	(67)%	(37)%
Milestone and development funding . .	—	—	2,017	— %	(100)%
Milestone and development revenue from related party . . . . .	—	—	20,482	—	(100)%
Total revenue . . . . .	<u>\$16,507</u>	<u>\$11,044</u>	<u>\$30,310</u>	49%	(64)%

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 the prior year. 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. For the year ended December 31, 2007, we recognized \$8.0 million of product revenue from sales of the INTERCEPT Blood System for platelets and plasma, compared to \$3.0 million during the same period in 2006. The increase was largely driven by an increase in sales of platelet disposable kits and UVA illuminators. 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. These annual results may not be indicative of INTERCEPT Blood System revenue in the future.

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 a decrease in the activities subject to reimbursement under current awards with the United States DoD, or DoD. Of the total awarded amount during the year ended December 31, 2008, the majority of the grant revenue came from reimbursement under a DoD award for development activities related to our red blood cell system. For the year ended December 31, 2007, the majority of the grant revenue was also from an award from the DoD for our red blood cell system. We recognized \$3.0 million in revenue from government grants and cooperative agreements for the year ended December 31, 2007, compared to \$4.8 million for the comparable period in 2006. The decrease was due primarily to the reduced awards from the Armed Forces for research activities for our INTERCEPT Blood System programs. We no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the NIH and regulated by the Small Business Administration. As a result, we are not eligible to apply for any new grants for which only small businesses are eligible.

We recognized no milestone and development funding during the years ended December 31, 2008, and 2007, down from \$2.0 million in the comparable period in 2006, when we last received cost reimbursement funding from Baxter under previous and now terminated agreements. In 2006, we also recognized \$20.5 million in milestone revenue from BioOne, a related party. This revenue was the result of our achieving certain milestones under our platelet and plasma agreements with BioOne. We do not anticipate receiving significant milestones or royalties from BioOne in the near future.

Total revenue increased \$5.5 million to \$16.5 million during the year ended December 31, 2008, compared to \$11.0 million during the comparable period in 2007. The increase of \$5.5 million was largely due to an increase in the number of disposable platelet and plasma system kits sold to customers in Europe, Russia, and the Middle East, offset partially by a decrease in revenue recognized from government grants and cooperative agreements. Total revenue decreased \$19.3 million to \$11.0 million during the year ended December 31, 2007, compared to \$30.3 million during the comparable period in 2006. The decrease from 2006 to 2007 was largely due to the \$20.5 million in milestone payments from BioOne and the \$2.0 million in development funding from Baxter recognized in 2006 compared to no milestone payment or development funding recognized in 2007, a decrease of \$1.8 million from government grant and cooperative agreement revenue, offset by \$5.0 million in higher product revenue.

### ***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, and certain order fulfillment costs. Inventory is accounted for on a first-in, first-out basis.

<u>(in thousands, except percentage)</u>	<u>Years Ended December 31,</u>			<u>% Change 2008 to 2007</u>	<u>% Change 2007 to 2006</u>
	<u>2008</u>	<u>2007</u>	<u>2006</u>		
Cost of product revenue . . . . .	\$9,668	\$5,228	\$1,541	85%	239%

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. The 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. In addition, royalties owed to Fenwal increased during the year ended December 31, 2008, compared to the same period in 2007, also due to 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 reserve of \$0.4 million for potentially unusable work-in-progress inventory. We are currently in the process of evaluating whether or not any of this potentially unusable work-in-progress inventory can be salvaged. If we are able to salvage some, or the entire inventory, we may record a reversal of the reserve as the inventory is sold to customers, which would have a positive effect on our gross margins in the period of reversal.

Similarly, cost of product revenue increased \$3.7 million to \$5.2 million during the year ended December 31, 2007, compared to \$1.5 million during the comparable period in 2006 due to the higher number of disposable platelet system kits and illuminators sold during the year ended December 31, 2007 and the corresponding royalties owed to Fenwal for those sales compared to the same period in 2006.

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 38% in 2008, up from 35% in 2007, and down from 48% in 2006. 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.

### ***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, and costs associated with our infrastructure, and laboratory chemicals and supplies.

<u>(in thousands, except percentage)</u>	<u>Years Ended December 31,</u>			<u>% Change 2008 to 2007</u>	<u>% Change 2007 to 2006</u>
	<u>2008</u>	<u>2007</u>	<u>2006</u>		
Research and development . . . . .	\$10,205	\$14,957	\$16,036	(32)%	(7)%

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. The decrease in our research and development expenses during the year ended December 31, 2008, compared to 2007 was the result of reduced development activities regarding our plasma system and lower clinical trial costs associated with our red blood cell system.

Research and development expenses decreased \$1.1 million to \$15.0 million for the year ended December 31, 2007, compared to \$16.0 million during the comparable period in 2006. The decrease in our research and development expenses during the year ended December 31, 2007, compared to 2006 was a result of a decline in development activities associated with our plasma system subsequent to receiving a CE mark in November 2006. In addition during the second half of 2006 we initiated a Phase I clinical trial related to our red blood cell system. Costs associated with this Phase I clinical trial were higher in 2006 than in 2007, the period in which the clinical trial concluded.

Of our total research and development costs incurred, non-cash stock based compensation represented \$0.5 million, \$1.2 million and \$1.1 million for the years ended December 31, 2008, 2007, and 2006, respectively.

We anticipate our research and development spending will continue and, subject to funding from government grants or potential partners, at times may increase as a result of ongoing product development and

later stage, more expensive clinical trials, and as potential new products move from development to preclinical and clinical trials. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, uncertainty of future pre-clinical and clinical study results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, 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.

<u>(in thousands, except percentage)</u>	<u>Years Ended December 31,</u>			<u>% Change 2008 to 2007</u>	<u>% Change 2007 to 2006</u>
	<u>2008</u>	<u>2007</u>	<u>2006</u>		
Selling, general and administrative . . .	\$27,164	\$24,575	\$15,082	11%	63%

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, the increase in selling, general and administrative expenses for the year ended December 31, 2008, was primarily due to continued expansion of our commercial operations based in Europe, including increases in personnel costs, and to a lesser extent, increased marketing activities.

Selling, general, and administrative expenses increased \$9.5 million to \$24.6 million for the year ended December 31, 2007, compared to \$15.1 million during the comparable period in 2006. The increase in selling, general and administrative expenses from 2006 to 2007 was primarily due to the costs of maintaining and expanding our commercial operations in Europe, representing \$8.8 million of the increase, as well as increased legal and outside professional fees, marketing, and travel expenses.

Of the total selling, general, and administrative expenses incurred, non-cash stock based compensation represented \$1.6 million, \$1.4 million, and \$1.4 million for the years ended December 31, 2008, 2007, and 2006 respectively.

We anticipate that we will be focused on maintaining our selling, general, and administrative spending at no more than current levels over the next year, as part of a larger effort to lower operating expenses and conserve cash.

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

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

<u>(in thousands, except percentage)</u>	<u>Years Ended December 31,</u>			<u>% Change 2008 to 2007</u>	<u>% Change 2007 to 2006</u>
	<u>2008</u>	<u>2007</u>	<u>2006</u>		
Interest income (expense) and other, net . . . .	\$1,349	\$4,066	\$4,701	(67)%	(14)%

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. The decrease in income was primarily due to lower interest income 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.

Interest income and other, net, was \$4.1 million and \$4.7 million for the years ended December 31, 2007, and 2006, respectively. The decrease in interest income and other, net, was primarily due to the recognition of a non-operating gain of \$1.8 million during the year ended December 31, 2006, resulting from cash consideration received from Baxter as a component of the February 2006 commercialization transition agreement. In addition, during 2007, we recognized losses on certain marketable securities that we felt were experiencing an other-than-temporary decline in fair value. The recognized losses adjusted our carrying value to the fair value of the securities at December 31, 2007, which became our basis for recording future gains or losses upon sale or maturity. Partially offsetting this decrease from 2006 was an increase in interest income of \$0.7 million for the year ended December 31, 2007. The increase in interest income was primarily due to consistently higher cash and investment balances maintained during the year ended December 31, 2007, compared to the comparable period in 2006, primarily as a result of our public offerings in March and December 2006.

We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. However, due to the recent turmoil of the credit markets and in the financial services industry, the interest paid on certain of our investments 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 March and December 2006, we completed public offerings of our common stock, which resulted in increased cash balances. 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.

### ***Loss from Discontinued Operations***

The results of our former immunotherapy segment for the years ended December 31, 2008, 2007, and 2006 are summarized in the following table:

<u>(in thousands, except percentage)</u>	<u>Years Ended December 31,</u>			<u>% Change 2008 to 2007</u>	<u>% Change 2007 to 2006</u>
	<u>2008</u>	<u>2007</u>	<u>2006</u>		
Revenue . . . . .	\$—	\$ 4,356	\$ 5,270	(100)%	(17)%
Operating expenses . . . . .	—	10,176	12,401	(100)%	(18)%
Loss from discontinued operations . . . . .	—	(5,820)	(7,131)	(100)%	(18)%
Loss from sale of discontinued operations . . . . .	—	(384)	—	(100)%	100%
Net loss from discontinued operations . . . . .	<u>\$—</u>	<u>\$ (6,204)</u>	<u>\$ (7,131)</u>	(100)%	(13)%

### **Liquidity and Capital Resources**

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, the loan from Baxter Capital, payments received under our agreements with Baxter, BioOne and others, United States government grants and cooperative agreements, and, to a lesser degree and more recently, contribution from product sales net of expenses and interest income.

At December 31, 2008, we had cash, cash equivalents and short-term investments of \$22.6 million. Net cash used in operating activities was \$34.5 million for the year ended December 31, 2008, compared to \$37.4 million during the comparable period in 2007. The decrease in net cash used in operating activities was primarily due to changes in 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. Cash used in operating activities during the year ended December 31, 2007, was \$37.4 million compared to \$14.7 million during the comparable period in 2006. The increase in cash used was primarily due to decreases in our revenues and related cash collections in 2007 compared to 2006, as well as changes in our operating assets and liabilities, notably increases in our inventory balances. Net cash provided by investing activities during the year ended December 31, 2008, was \$23.9 million compared to \$9.3 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. Net cash provided by financing activities during the year ended December 31, 2008, was \$1.3 million, compared to cash provided by financing activities of \$1.4 million and \$63.1 million for the same periods in 2007 and 2006, respectively. The cash provided from financing activities in 2008 and 2007 was primarily due to cash received from the exercise of stock options, while cash from financing activities in 2006 was primarily the result of two issuances of common stock yielding \$63.1 million in net proceeds, offset by the repayment of a loan from Baxter Capital of \$4.5 million plus accrued interest. Working capital decreased to \$29.1 million at December 31, 2008, from \$55.6 million and \$87.9 million at December 31, 2007, and 2006, 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. Although our independent registered public accountants have indicated a substantial doubt as to our ability to continue as a going concern, we believe that we will be able to make reductions in our operating expenses and inventory, which, together with our expected revenues, will result in sufficient capital to fund operations into 2010. 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 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 current and 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. 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. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented 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. If we are unable to raise additional capital due to the recent disruptions to the credit and financial markets in the United States and worldwide or other factors, we will need to curtail planned development activities and commercialization activities.

Historically, we had received significant awards in funding under cooperative agreements with the DoD for the INTERCEPT Blood system. We also received funding under grants from the National Institutes of Health, largely in support of the immunotherapy business that we spun off in late 2007. 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. Additionally, we no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the National Institutes of Health and regulated by Small Business Administration. Historically, a significant portion of our grant revenue came from awards surrounding our former immunotherapy business. If we are unable to obtain Federal grant and cooperative agreement funding for future blood safety 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. In addition, we are required separately to administer and account for our work under government contracts and grants on an on-going basis as a condition to accepting government funding which places administrative, accounting and reporting burdens on us beyond those we have assumed as a public company. If we fail to comply with applicable governmental administrative, accounting and reporting regulations with respect to these grants and cooperative agreements, funds currently available to us may be reduced or lost. These conditions may also result in increased selling, general, and administrative spending beyond what we have experienced.

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, however, our ability to sell shares under this shelf registration statement may be limited due to applicable rules of the Securities Act.

## Commitments and Off-Balance Sheet Arrangements

### *Commitments*

Our commitments are as follows (in thousands):

	<u>Payments Due by Period from December 31, 2008</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>After 5 years</u>
<b>Contractual obligations:</b>					
Minimum purchase requirements . . . . .	\$3,515	\$1,608	\$1,210	\$ 697	\$—
Operating leases . . . . .	4,240	1,462	1,684	1,094	—
Other commitment . . . . .	91	22	45	24	—
Total contractual cash obligations . . . . .	<u>\$7,846</u>	<u>\$3,092</u>	<u>\$2,939</u>	<u>\$1,815</u>	<u>\$—</u>

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

### *Operating Leases*

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



options are exercised. Our facility leases qualify as operating leases under FAS No. 13, "Accounting for Leases" and as such, are not included on our balance sheet.

#### *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.

#### *Credit Facility*

In June 2008, we entered into a senior secured revolving credit facility with Wells Fargo Bank, N.A., or the Facility, which allows us to borrow up to \$10.0 million to be used for working capital and general operating needs. The initial term of the Facility is one year, if not extended. In December 2008 we amended the terms of the Facility. Interest on borrowings under the Facility accrues on a fixed rate of LIBOR plus three and one half percent (3.5%) for borrowings in excess of \$0.5 million for one, two, three, or six months. The Facility is secured by all of our assets, excluding intellectual property. The Facility also contains certain customary financial and non-financial conditions, as well as certain specific financial covenants, including covenants that require us to maintain certain minimum cash balances and incur maximum net operating losses in any given quarter during which the Facility is in place. These covenants presently preclude us from borrowing under the Facility until such time as we have cured conditions that gave rise to a default under these financial covenants. At December 31, 2008, no amount was outstanding under the Facility.

#### **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, 2008, and 2007, totaled \$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 State government agency securities, asset-backed 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, 2007, and 2006, we recognized other than temporary impairments for certain investments in our portfolio totaling \$0.3 million, \$0.2 million, and \$0.0 million, respectively. 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 \$22.6 million at December 31, 2008, approximately 46% had original maturity dates of less than 90 days, and none had original maturities of 90 days to 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 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.

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, commercial paper, 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. 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 SFAS No. 115, *Accounting for Certain Investments in 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, 2008 (dollar amounts in thousands):

	<u>Fair Value</u>	<u>Weighted Average Interest Rate</u>
Cash and Cash equivalents (0 – 90 days <sup>(1)</sup> ) . . . . .	\$10,303	0.84%
Short-term investments (91 days – 1 year <sup>(1)</sup> ) . . . . .	—	— %
Short-term investments (1 – 3 years <sup>(1)</sup> ) . . . . .	<u>12,275</u>	<u>3.46%</u>
Total investments . . . . .	<u>\$22,578</u>	<u>2.27%</u>

(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, generally 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.

**Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* Our chief executive officer and chief financial officer are responsible for establishing and maintaining “disclosure controls and procedures” (as defined in Rule 13a-15(e) and Rule 15d-15(e), promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of December 31, 2008, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective.

*Changes in Internal Control over Financial Reporting.* During the last quarter of our fiscal year ended December 31, 2008, 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 financial 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, 2008, is discussed in the Management’s Report on Internal Control Over Financial Reporting included on page 52.

**Item 9B. Other Information**

None.

### **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,” “Information Regarding the Board of Directors and Corporate Governance,” “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 1, 2009, 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 2008 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” 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 “Transactions with Related Persons” 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 “Policy on Audit Committee Pre-Approval” in the proxy statement.

## 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.*

	<u>Page</u>
Management's Report on Internal Control Over Financial Reporting . . . . .	52
Reports of Ernst & Young LLP, Independent Registered Public Accounting Firm . . . . .	53
Consolidated Balance Sheets as of December 31, 2007, and 2008 . . . . .	55
Consolidated Statements of Operations for the three years ended December 31, 2008 . . . . .	56
Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2008 . . . . .	57
Consolidated Statements of Cash Flows for the three years ended December 31, 2008 . . . . .	58
Notes to Consolidated Financial Statements . . . . .	59

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

(b) *Exhibits.*

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
3.1.1(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2 (16)	Bylaws of Cerus.
4.2 (1)	Specimen Stock Certificate.
10.1 (1)	Form of Indemnity Agreement entered into between Cerus 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.
10.7 (1)	Industrial Real Estate Lease, dated October 1, 1992, between Cerus and Shamrock Development Company, as amended on May 16, 1994 and December 21, 1995.
10.8 (1)	Real Property Lease, dated August 8, 1996, between Cerus and S.P. Cuff.
10.9 (1)	Lease, dated February 1, 1996, between Cerus and Holmgren Partners.
10.11(2)†	License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation.
10.12(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.13(4)	Stockholder Rights Plan, dated November 3, 1999.
10.14(5)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.15(6)*	Amended and Restated Employment Agreement with Howard G. Ervin, dated December 22, 2008.
10.16(8)	Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P.

Exhibit Number	Description of Exhibit
10.17(8)	Lease, dated October 12, 2001 between Cerus and California Development, Inc.
10.18(9)	Loan and Security Agreement, dated November 15, 2002, between Cerus and Baxter Capital Corporation.
10.19(10)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.21(6)*	Amended and Restated Employment Agreement with Claes Glassell, dated December 19, 2008.
10.22(12)*	Amended and Restated Employment Agreement with William J. Dawson, dated January 16, 2009.
10.23(13)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.24(13)†	License Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.25(13)†	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.26(14)*	Bonus Plan for Senior Management of Cerus Corporation, dated January 1, 2006.
10.27(14)†	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.28(15)†	Asset Transfer and License Agreement, dated November 20, 2007, by and between Cerus Corporation and Anza Therapeutics, Inc.
10.29(15)	Offer Letter to Gail Schulze, dated October 15, 2007.
10.30 (17)	2008 Equity Incentive Plan.
10.31(18)	Supply Agreement, dated December 19, 2007, by and between Cerus and Brotech Corporation d/b/a Purolite Company.
10.32(18)	Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus and Porex Corporation.
10.33(11)	Credit Agreement, dated as of June 18, 2008, by and between Cerus and Wells Fargo Bank, National Association.
10.34(19)††	First Amendment and Waiver to Credit Agreement, dated as of December 29, 2008, by and between Cerus and Wells Fargo Bank, National Association.
10.35(11)	Security Agreement, dated as of June 18, 2008, by and between Cerus and Wells Fargo Bank, National Association.
10.36(19)††	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus and NOVA Biomedical Corporation.
10.37(19)††	Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus and Fenwal, Inc.
10.38(19)*	Non-Employee Director Compensation Policy.
10.39(19)*	Base Salaries for Fiscal Year 2008 for Named Executive Officers.
12.1(19)	Statement Regarding Computation of Ratio of Earnings to Fixed Charges and Ratio of Combined Fixed Charges and Preference Dividends to Earnings.
21.1	List of Registrant's subsidiaries.

Exhibit Number	Description of Exhibit
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 pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial 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, dated June 30, 1998.
- (4) Incorporated by reference to Cerus' Current Report on Form 8-K, dated November 3, 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, dated 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 June 30, 2008.
- (12) Incorporated by reference to Cerus' Current Report on Form 8-K, dated January 16, 2009.
- (13) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- (14) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.
- (15) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2007.
- (16) Incorporated by reference to Cerus' Current Report on Form 8-K, dated June 19, 2008.
- (17) Incorporated by reference to Cerus' Current Report on Form 8-K dated June 6, 2008.
- (18) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.
- (19) Filed herewith.

## 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, 2008. 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, 2008, 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, 2008. Ernst and Young's attestation report on internal control over financial reporting is included at page 53.

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 disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system 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 disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.



## **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, 2008, 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, 2008, 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, 2008, and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008, and our report dated March 10, 2009, expressed an unqualified opinion thereon that included an explanatory paragraph regarding Cerus Corporation's ability to continue as a going concern.

/s/ ERNST & YOUNG LLP  
Palo Alto, California  
March 10, 2009

## 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, 2008, and 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2008. 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, 2008, and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with United States generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that Cerus Corporation will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses. This condition raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The 2008 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organization of the Treadway Commission and our report dated March 10, 2009 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP  
Palo Alto, California  
March 10, 2009

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

	<b>2008</b>	<b>2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 10,303	\$ 19,625
Short-term investments .....	12,275	37,225
Accounts receivable, net of allowance of \$180 and \$0 at December 31, 2008 and 2007, respectively .....	7,152	7,772
Inventories .....	11,109	7,062
Prepaid and other current assets .....	1,204	2,218
Total current assets .....	42,043	73,902
Property and equipment, net .....	1,844	1,322
Long-term investment in related party .....	2,329	1,874
Restricted cash .....	315	239
Other assets .....	808	872
Total assets .....	\$ 47,339	\$ 78,209
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 7,963	\$ 10,107
Accrued liabilities .....	4,490	6,679
Deferred revenue .....	445	1,504
Current portion of capital lease obligations .....	—	30
Total current liabilities .....	12,898	18,320
Long term portion of capital lease obligations .....	—	2
Other long-term liabilities .....	163	—
Total liabilities .....	13,061	18,322
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, 2008, and 2007; aggregate liquidation preference of \$9,496 at December 31, 2008, and 2007 .....	9,496	9,496
Common stock, \$0.001 par value; 50,000 shares authorized: 32,544 and 32,112 shares issued and outstanding at December 31, 2008, and 2007, respectively .....	33	32
Additional paid-in capital .....	410,444	407,010
Accumulated other comprehensive income .....	212	75
Accumulated deficit .....	(385,907)	(356,726)
Total stockholders' equity .....	34,278	59,887
Total liabilities and stockholders' equity .....	\$ 47,339	\$ 78,209

See accompanying notes.

**CERUS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Years Ended December 31,		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Revenue:			
Product revenue .....	\$ 15,518	\$ 8,015	\$ 2,975
Government grants and cooperative agreements .....	989	3,029	4,836
Milestone and development funding .....	—	—	2,017
Milestone and development revenue from related party .....	—	—	20,482
Total revenue .....	<u>16,507</u>	<u>11,044</u>	<u>30,310</u>
Cost of product revenue .....	<u>9,668</u>	<u>5,228</u>	<u>1,541</u>
Gross profit .....	6,839	5,816	28,769
Operating expenses:			
Research and development .....	10,205	14,957	16,036
Selling, general, and administrative .....	27,164	24,575	15,082
Impairment of long-term investment in related party .....	—	9,450	—
Total operating expenses .....	<u>37,369</u>	<u>48,982</u>	<u>31,118</u>
Loss from operations .....	<u>(30,530)</u>	<u>(43,166)</u>	<u>(2,349)</u>
Interest income (expense) and other, net .....	<u>1,349</u>	<u>4,066</u>	<u>4,701</u>
Net income (loss) from continuing operations .....	<u>(29,181)</u>	<u>(39,100)</u>	<u>2,352</u>
Discontinued operations:			
Loss from discontinued operations .....	—	(5,820)	(7,131)
Loss from sale of discontinued operations .....	—	(384)	—
Net loss from discontinued operations .....	<u>—</u>	<u>(6,204)</u>	<u>(7,131)</u>
Net loss .....	<u>\$(29,181)</u>	<u>\$(45,304)</u>	<u>\$(4,779)</u>
Net income (loss) from continuing operations per common share:			
Basic .....	\$ (0.90)	\$ (1.23)	\$ 0.09
Diluted .....	\$ (0.90)	\$ (1.23)	\$ 0.08
Net loss from discontinued operations per common share:			
Basic .....	\$ —	\$ (0.19)	\$ (0.27)
Diluted .....	\$ —	\$ (0.19)	\$ (0.25)
Net loss per common share:			
Basic .....	\$ (0.90)	\$ (1.42)	\$ (0.18)
Diluted .....	\$ (0.90)	\$ (1.42)	\$ (0.17)
Weighted average common shares outstanding used for basic and diluted net income (loss) per share:			
Basic .....	32,430	31,870	26,870
Diluted .....	32,430	31,870	28,610

See accompanying notes.

**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, 2005 .....	3	\$9,496	22,457	\$ 23	\$332,694	\$(295)		\$(306,643)	\$ 35,275
Issuance of common stock, net of expenses of \$2,323 .....	—	—	9,079	9	66,538	—		—	66,547
Issuance of common stock under stock option restricted stock, and employee stock purchase plans .....			198		1,121			—	1,121
Stock-based compensation .....					2,535				2,535
Net change in unrealized gain on investments ...	—	—	—	—	—	272	\$ 272	—	272
Net loss .....	—	—	—	—	—	—	(4,779)	(4,779)	(4,779)
Total comprehensive loss .....							\$ (4,507)		
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 .....	<u>3</u>	<u>\$9,496</u>	<u>32,544</u>	<u>\$ 33</u>	<u>\$410,444</u>	<u>\$ 212</u>		<u>\$(385,907)</u>	<u>\$ 34,278</u>

See accompanying notes.

**CERUS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years Ended December 31,		
	2008	2007	2006
<b>Operating activities</b>			
Net loss	\$(29,181)	\$(45,304)	\$ (4,779)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	651	774	716
Stock-based compensation	2,145	2,600	2,535
Non-cash equity received in satisfaction of milestone and development funding	—	—	(10,000)
Loss (gain) on sale of equipment	(34)	231	—
Impairment of long-term investment in related party	—	9,450	—
Changes in operating assets and liabilities:			
Accounts receivable	660	(2,493)	(579)
Inventories	(4,047)	(5,229)	(1,833)
Other assets	572	(991)	(1,741)
Accounts payable	(2,145)	3,442	4,573
Accrued liabilities	(2,107)	(800)	1,972
Deferred gain	—	(586)	586
Deferred revenue	(1,059)	1,504	(6,135)
Net cash used in operating activities	(34,545)	(37,402)	(14,685)
<b>Investing activities</b>			
Purchases of furniture and equipment	(1,194)	(700)	(1,108)
Purchases of short-term investments	(2,285)	(44,481)	(42,310)
Sales of short-term investments	5,091	1,601	—
Maturities of short-term investments	22,281	52,882	35,478
Net cash provided by (used in) investing activities	23,893	9,302	(7,940)
<b>Financing activities</b>			
Net proceeds from issuance of common stock	1,290	1,522	67,668
Loan repayments	—	—	(4,500)
Issuance cost for credit facility	(25)	—	—
Proceed from note payable	97	—	—
Payments on capital lease obligations	(32)	(84)	(36)
Net cash provided by financing activities	1,330	1,438	63,132
Net increase (decrease) in cash and cash equivalents	(9,322)	(26,662)	40,507
Cash and cash equivalents, beginning of period	19,625	46,287	5,780
Cash and cash equivalents, end of period	<u>\$ 10,303</u>	<u>\$ 19,625</u>	<u>\$ 46,287</u>

See accompanying notes.

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2008**

**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 has modest revenue to date from product sales of the INTERCEPT platelet and plasma systems. A substantial majority of revenue recognized by the Company prior to recent commercialization efforts resulted from the Company's collaboration agreements with Baxter International, Inc., or Baxter, BioOne and others and Federal research grants and cooperative agreements with the government. 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.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has incurred recurring operating losses and negative cash flows from operating activities from inception through December 31, 2008. In addition, the Company had an accumulated deficit of \$385.9 million as of December 31, 2008. Through December 31, 2008, the Company has relied primarily on the proceeds from public and private equity offerings, partnering proceeds, US government grant and cooperative agreements, and, to a lesser degree, contributions from product sales. The Company's longer-term capital requirements will be dependent on generating positive cash flows from operations and access to public and private equity and debt capital markets, as well as to additional collaborative arrangements. Management believes the Company can fund its operations without additional financing into 2010. These plans are based on a number of assumptions including expected revenue levels and reductions in operating expenses and inventory. If management's plans and assumptions prove to be incorrect, the Company's available cash, cash equivalents and short-term investments may be consumed sooner and additional funding may be required. Additional funding may not be available on favorable terms, on a timely basis or at all. If the Company is unable to raise additional capital to fund its operations, it will need to curtail planned activities to reduce costs. Doing so may affect the Company's ability to effectively operate. The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties.

**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 years ended December 31, 2007, and 2006. As such, results previously reported have been restated to reflect the discontinued operation treatment of the immunotherapy business. The Company also reclassified certain legal costs from research and development to selling, general and administrative for the year December 31, 2006.

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

**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 SEC's published Staff Accounting Bulletin No. 104, "Revenue Recognition" or SAB 104, and Emerging Issues Task Force, or EITF 00-21, "Accounting for Revenue 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 through December 31, 2008 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 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, 2008 and December 31, 2007, the Company had \$0.4 million and \$1.5 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 EITF 00-10, "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 Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards, or FAS, No. 2, "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



**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

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 Statement of Financial Accounting Standards, or FASB, No. 115, "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.

Unrealized gains and losses at December 31, 2008, and 2007, 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, 2008, and 2007, the Company recognized losses totaling \$0.3 million and \$0.2 million, respectively, associated with investments experiencing an other-than-temporary decline in fair value. These investments primarily relate to fixed income securities. At December 31, 2008, 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, 2008, 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 within other long-term assets on its consolidated balance sheets at December 31, 2008, and 2007.

**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

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

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, 2008, 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 did not have any allowances at December 31, 2007, or 2006. However, the Company did record allowances for potentially uncollectible accounts receivable of approximately \$0.2 million during the year ended December 31, 2008. 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 three customers each accounting for more than 10% of the Company's outstanding trade receivables and aggregating approximately 60% and 54% of outstanding trade receivables at December 31, 2008 and December 31, 2007, respectively. To date, the Company has not experienced collection difficulties from these customers.

**Inventories**

At December 31, 2008 and December 31, 2007, inventory consists of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the 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. At December 31, 2008, and December 31, 2007, the Company had written down approximately \$0.1 million and \$0.2 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 SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", or FAS144. 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

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

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 2008, 2007 or 2006.

**Long-Term Investment in Related Party**

At December 31, 2008, and 2007, the Company held approximately 13% interest in the voting securities of BioOne and accounted for its investment in BioOne under the cost method. The Company regularly evaluates several criteria in determining whether or not it has the ability to exercise significant influence over the operating and financial policies of BioOne. These criteria include but are not limited to: limited availability of and infrequency of access to financial information of BioOne, majority shareholder mix in BioOne, and the Company's lack of representation on BioOne's board of directors. As a result of its evaluations, at December 31, 2008, and 2007, the Company has accounted for its investment under the cost method, as it has concluded that predominant evidence exists to support this conclusion.

In July, 2007, BioOne completed an equity financing on terms reflecting a valuation substantially below the valuations of previous rounds of financing. As a consequence, the Company recorded a non-cash charge of \$9.5 million on the carrying value of its equity interest in BioOne in 2007. The Company's investment in BioOne is included in long-term investments in related party on its balance sheets at the estimated fair value of \$2.3 million at December 31, 2008. To the extent that the criteria used to support the carrying value of the Company's investment in BioOne's equity at December 31, 2008, change further, the Company will need to reassess the recorded basis of its investment in BioOne.

**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 gains of \$0.5 million and \$0.7 million during the years ended December 31, 2008, and 2007, respectively, and foreign currency losses of \$0.1 million during the year ended December 31, 2006.

**Stock-Based Compensation**

The Company maintains an active stock compensation plans as 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 Statement of Financial Accounting Standards No. 123R, "Share Based Payment," or FAS123R. Under the fair value recognition provisions of FAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

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 have been met and the option vests.

The Company continues to apply the provisions of EITF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," or EITF 96-18 for its non-employee stock-based awards. Under EITF 96-18, 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.

Total stock-based compensation recognized on the Company's consolidated statement of operations for the years ended December 31, 2008, 2007, and 2006, impacted loss per share by \$0.07 per share, \$0.08 per share, and \$0.09 per share, respectively.

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

**Other Comprehensive Income (Loss)**

Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income establishes the standards of reporting and displaying comprehensive income (loss) and its components in the consolidated financial statements. 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 2008, 2007, and 2006 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 based upon Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes," or FAS 109. 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, Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," or FIN 48 became effective for the Company. FIN 48 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 FAS 109 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, 2008, or 2007. 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 it accrued for or made payments for interest and penalties. The adoption of FIN 48 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 2004 through 2008 remain subject to examination by the taxing jurisdictions to which the Company is subject.

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

**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):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Denominator:			
Basic weighted average number of common shares outstanding . . . . .	32,430	31,870	26,870
Effect of dilutive potential common shares resulting from stock options, unvested restricted common stock and ESPP shares . . . . .	<u>—</u>	<u>—</u>	<u>1,740</u>
Diluted weighted average number of common shares outstanding . . . . .	<u>32,430</u>	<u>31,870</u>	<u>28,610</u>

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):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Antidilutive securities—weighted average shares . . . . .	5,374	5,649	5,206

**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 Financial Accounting Standards Board Interpretation No. 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others,” or FIN 45. 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, 2008. Accordingly, at December 31, 2008, the Company has not accrued for any potential future warranty costs.

***Fair Value of Financial Instruments***

The Company adopted the provisions of Financial Accounting Standards No. 157, or FAS 157, “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

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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**

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations," or FAS 141(R). FAS 141(R) retains the fundamental requirements of Statement No. 141 to account for all business combinations using the acquisition method (formerly the purchase method) and for an acquiring entity to be identified in all business combinations. However, the new standard requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction; establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; and requires the acquirer to disclose to investors and other users all of the information they need to evaluate and understand the nature and financial effect of the business combination. FAS 141(R) is effective for annual periods beginning on or after December 15, 2008. FAS No. 141(R) may have an impact on the Company's consolidated financial statements if and when the Company enters into a business combination. This statement is effective for the Company beginning in the first quarter of 2009.

In April 2008, the FASB issued FASB Staff Position, or FSP, No. 142-3, "Determination of the Useful Life of Intangible Assets," or FSP 142-3. FSP 142-3 amends the factors an entity should consider in developing renewal or extension assumptions used in determining the useful life of recognized intangible assets under FAS No. 142, "Goodwill and Other Intangible Assets". This new guidance applies prospectively to intangible assets that are acquired individually or with a group of other assets in business combinations and asset acquisitions. FSP 142-3 is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. Early adoption is prohibited. The Company is currently evaluating the impact, if any, that FSP 142-3 will have on its consolidated financial statements.

In September 2006, the FASB issued Statement of FAS No. 157, "Fair Value Measurements," or FAS 157, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. FAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. FAS 157 is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB FSP 157-2 which delays the effective date of FAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. The Company adopted FAS 157 for financial assets beginning January 1, 2008. The adoption of FAS 157 did not have a material impact on the Company's consolidated financial position, results of operations, or cash flows.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities," or FAS 159. FAS 159 permits companies to choose to measure certain financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. FAS 159 became effective for the Company beginning January 1, 2008, although the Company has not chosen to measure eligible assets and liabilities at fair value under the provisions of FAS 159. As such, the adoption of FAS 159 did not have an impact on the Company's consolidated statements of position, results of operations, or cash flows.

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In November 2007, the EITF ratified a consensus on EITF Issue No. 07-1, “Accounting for Collaborative Arrangements,” or EITF 07-1, which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for the Company beginning in the first quarter of fiscal year 2009. The Company is currently evaluating the impact of the provisions of EITF 07-1 on its financial position, results of operations and cash flows, however, it does not anticipate the adoption of EITF 07-1 will have a material impact.

In June 2007, the EITF ratified a consensus on EITF Issue No. 07-3, “Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,” or EITF 07-3, which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 was adopted by the Company on January 1, 2008. The adoption of EITF 07-3 did not have a material impact on the Company’s consolidated financial position, results of operations, or cash flows.

**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 remaining maturities of three months or less at the date of purchase, as cash equivalents. Cash equivalents consist of corporate commercial paper and money market funds, for which the carrying amount is a reasonable estimate of fair value.

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

<u>Fixed income available-for-sale-securities</u>	<u>Total</u>	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		(Level 1)	(Level 2)	(Level 3)
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	—
	<u>\$19,458</u>	<u>\$7,183</u>	<u>\$12,275</u>	<u>\$—</u>

- (1) Included in cash and cash equivalents on our consolidated balance sheet.
- (2) Included in short-term investments on our consolidated balance sheet.

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

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standard inputs to models which vary by asset class. The Company did not hold financial assets and liabilities 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, 2008.

**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):

	<u>2008</u>		
	<u>Carrying Value</u>	<u>Unrealized Gain (Loss)</u>	<u>Fair Value</u>
Cash and cash equivalents:			
Cash .....	\$ 3,120	\$—	\$ 3,120
Money Market funds .....	7,183	—	7,183
Total cash and cash equivalents .....	<u>\$10,303</u>	<u>\$—</u>	<u>\$10,303</u>
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 .....	<u>\$12,063</u>	<u>\$212</u>	<u>\$12,275</u>
	<u>\$22,366</u>	<u>\$212</u>	<u>\$22,578</u>
	<u>2007</u>		
	<u>Carrying Value</u>	<u>Unrealized Gain (Loss)</u>	<u>Fair Value</u>
Cash and cash equivalents:			
Cash .....	\$ 2,404	\$—	\$ 2,404
Money Market funds .....	8,134	—	8,134
Commercial paper .....	9,087	—	9,087
Total cash and cash equivalents .....	<u>\$19,625</u>	<u>\$—</u>	<u>\$19,625</u>
Short-term investments			
Corporate debt securities .....	\$25,019	\$ (3)	\$25,016
Commercial paper .....	5,313	2	5,315
United States government agency securities .....	6,818	76	6,894
Total short-term investments .....	<u>\$37,150</u>	<u>\$ 75</u>	<u>\$37,225</u>
	<u>\$56,775</u>	<u>\$ 75</u>	<u>\$56,850</u>

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

	<u>2008</u>	<u>2007</u>
Due in one year or less .....	\$ 7,183	\$24,972
Due greater than one year and less than three years .....	12,275	29,474
Total .....	<u>\$19,458</u>	<u>\$54,446</u>



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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, and were not material during the year ended December 31, 2006. 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, 2006. 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,	
	2008	2007
Work in progress .....	\$ 3,750	\$ 715
Finished goods .....	7,359	6,347
	\$11,109	\$7,062

The Company's inventory at December 31, 2008, and 2007, consisted of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the 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,	
	2008	2007
Leasehold Improvements .....	\$ 7,999	\$ 7,772
Machinery and Equipment .....	2,530	2,922
Demonstration Equipment .....	94	—
Office Furniture .....	1,124	702
Computer Equipment .....	642	587
Computer Software .....	710	706
Consigned demonstration equipment .....	420	—
Construction-in-Progress .....	325	129
	13,844	12,818
Less accumulated depreciation and amortization .....	(12,000)	(11,496)
	\$ 1,844	\$ 1,322

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
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**Note 7. Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2008	2007
Accrued compensation and related . . . . .	\$ 636	\$2,157
Accrued inventory . . . . .	2,121	1,760
Accrued contract and other accrued expenses . . . . .	1,733	2,762
	\$4,490	\$6,679

**Note 8. Loan Payable to Baxter Capital Corporation**

In January 2003, the Company received proceeds from a \$50.0 million loan from Baxter Capital, a financial subsidiary of Baxter International Inc. separate from Baxter. The interest rate on the loan was 12% per annum. Under the terms of the loan, no payment of principal or interest was due until 2008. The loan was secured by the Company's current and future accounts receivable from sales of the platelet system under the agreement with Baxter.

In October 2003, Baxter Capital commenced legal proceedings against the Company seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleged that changes in the Company's business constituted a default under the loan agreement. The Company did not agree that any default occurred and therefore believed that, under the terms of the loan, no principal or interest payments should be due until January 2008.

Concurrent with the 2005 restructured agreements between Baxter and the Company, Baxter Capital and the Company entered into an agreement under which the Company immediately paid \$34.5 million to Baxter Capital and entered into a promissory note for \$4.5 million, payable with 8% interest. Baxter Capital agreed to accept these payments in full satisfaction of the loan obligation, and the parties dismissed all related legal actions. As a result of the 2005 restructured agreements, the Company recorded net gains of approximately \$22.1 million in its consolidated statement of operations for the year ended December 31, 2005.

During the year ended December 31, 2006, the Company repaid the \$4.5 million note payable and the related interest of \$0.3 million, reflecting the terms of the February 2006 Commercialization Transition Agreement with Baxter.

**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.

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

<u>Year ending December 31,</u>	
2009 .....	\$1,462
2010 .....	957
2011 .....	727
2012 .....	722
2013 .....	372
Thereafter .....	<u>—</u>
Total minimum lease payments .....	<u>\$4,240</u>

Rent expense for office facilities was \$1.4 million, \$1.5 million and \$1.2 million for the years ended December 31, 2008, 2007, and 2006, respectively.

The Company's total non-cancelable commitments at December 31, 2008 are as follows (in thousands):

	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>After 5 years</u>
Minimum purchase requirements .....	\$3,515	\$1,608	\$1,210	\$ 697	\$—
Operating leases .....	4,240	1,462	1,684	1,094	—
Other commitment .....	<u>91</u>	<u>22</u>	<u>45</u>	<u>24</u>	<u>—</u>
Total contractual obligations .....	<u>\$7,846</u>	<u>\$3,092</u>	<u>\$2,939</u>	<u>\$1,815</u>	<u>\$—</u>

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 \$1.1 million, \$0.9 million, and \$0.1 million, for goods under contracts which are subject to minimum purchase commitments during the years ended December, 31, 2008, 2007, and 2006, respectively.

**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 allows the Company to borrow up to \$10.0 million to be used for working capital and general operating needs. In December 2008 the Company amended the terms of the Facility. The initial term of the Facility is one year, if not extended. Interest on borrowings under the Facility accrues at a fixed rate LIBOR plus three and one half percent (3.5%). The Facility is secured by all of the Company's assets, excluding intellectual property. The Facility also contains certain customary financial and non-financial conditions, as well as certain specific financial covenants, including covenants which require the Company to maintain certain minimum cash balances and incur maximum net losses and net operating losses in any given quarter for which the Facility is effective, which presently preclude the Company from borrowing under the Facility until such time as the Company has cured conditions that gave rise to a default under these financial covenants. At December 31, 2008, no amount was outstanding under the Facility.

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**Note 11. Stockholders' Equity**

**Common Stock Offerings**

In March 2006, the Company completed a public offering of 5,175,000 shares of common stock, which included the underwriters' exercise of their over-allotment option, resulting in net cash proceeds of approximately \$42.4 million. In December 2006, the Company completed a registered direct offering of 3,903,952 shares of common stock, resulting in net cash proceeds of approximately \$24.3 million.

**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.

**Stockholder Rights Plan**

In November 1999, the Company's Board of Directors adopted a 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. Baxter will be exempt from the rights plan, unless it and its pension plan acquire beneficial ownership in aggregate of 20.1% or more of the Company's common stock, excluding shares of the Company's common stock issuable upon conversion of Series B preferred stock currently held by Baxter. 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 a stock compensation plan as long-term incentives for employees, contractors, and members of its Board of Directors and Scientific Advisory Boards. 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 3.6 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 calendar year. During the year ended December 31, 2008, the Company granted performance based stock options totaling 50,000 shares.

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*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.

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

<u>Year Ended December 31,</u>	<u>Units granted</u>	<u>Grant date fair value per unit</u>	<u>Units vested at December 31, 2008</u>
2008 .....	43,086	\$ 6.99	—
2007 .....	60,620	5.54	20,207
2006 .....	<u>37,098</u>	10.32	<u>24,732</u>
Total .....	<u>140,804</u>		<u>44,939</u>

*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, 2008, 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.

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*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:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Expected term (in years) . . . . .	5.25-6.50	4.16-6.73	4.10-5.13
Volatility . . . . .	59.1%-84.1%	59.1%-64.3%	64.6%
Risk free interest rate . . . . .	2.80%-4.03%	4.03%-4.62%	4.62%

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

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Expected term (in years) . . . . .	0.50	0.50	0.50
Volatility . . . . .	54.6%-78.8%	54.6%-57.1%	57.1%
Risk free interest rate . . . . .	2.0%-4.4%	4.4%-4.8%	4.8%

Total stock-based compensation recognized on the Company's consolidated statements of operations for the years ended December 31, 2008, 2007, and 2006, was as follows (in thousands):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Research and development . . . . .	\$ 531	\$1,160	\$1,107
Selling, general and administrative . . . . .	1,614	1,440	1,428
	<u>\$2,145</u>	<u>\$2,600</u>	<u>\$2,535</u>

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

	<b>Number of Options Outstanding</b>	<b>Weighted Average Exercise Price per Share (\$)</b>
Balances at December 31, 2005 .....	4,598	\$13.03
Granted .....	984	6.96
Cancelled .....	(190)	15.41
Exercised .....	<u>(137)</u>	3.26
Balances at December 31, 2006 .....	5,255	\$12.06
Granted .....	895	7.90
Cancelled .....	(654)	9.79
Exercised .....	<u>(323)</u>	3.92
Balances at December 31, 2007 .....	5,173	\$12.13
Granted .....	941	4.45
Cancelled .....	(652)	21.17
Exercised .....	<u>(399)</u>	2.86
Balances at December 31, 2008 .....	<u>5,063</u>	\$10.27

The weighted average fair value of options granted during the years ended December 31, 2008, 2007, and 2006, was \$2.88, \$4.34 and \$4.00 per share, respectively. The intrinsic value of options exercised during the years ended December 31, 2008, 2007, and 2006 was \$1.1 million, \$1.3 million, and \$0.5 million, respectively.

Information regarding the stock options outstanding at December 31, 2008, 2007, and 2006 is set forth below (in thousands except per share amounts and years):

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (years)</b>	<b>Aggregate Intrinsic Value</b>
2008				
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	\$ —
2007				
Shares Outstanding .....	5,173	\$12.13	5.61	\$7,516
Shares vested and expected to vest .....	5,016	\$12.28	5.54	\$7,439
Shares exercisable .....	3,527	\$14.68	4.70	\$5,943
2006				
Shares Outstanding .....	5,255	\$12.06	5.46	\$6,931
Shares vested and expected to vest .....	4,982	\$12.40	5.42	\$6,646
Shares exercisable .....	2,959	\$17.25	4.94	\$3,735

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, 2008. As of December 31, 2008, the Company had stock-based compensation expense of \$4.2 million related to non-vested stock options not yet recognized, which is expected to be recognized over an estimated weighted average period of 2.7 years.

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

**Note 13. Development and License Agreements**

**Restructured Agreements with Baxter and Fenwal**

Prior to February 2005, Baxter and the Company shared development expenses for the INTERCEPT Blood Systems for platelets (the “platelet system”) and red blood cells (the “red blood cell system”) under the parties’ existing development and commercialization agreements. The agreements provided for the Company to be solely responsible for funding development expenses for the INTERCEPT Blood System for plasma (the “plasma system”). During the year ended December 31, 2006, the Company recognized development funding revenue of \$2.0 million under these agreements. Under the agreements, Baxter had been responsible for manufacturing and marketing the platelet system, which is approved for sale in some countries in Europe. The agreements provided for the Company to receive approximately 33.5% of revenue from sales of system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts. The Company recognized product sales of \$3.0 million in the year ended December 31, 2006.

In February 2005, Baxter and the Company entered into agreements that reaffirmed the previous agreements in certain respects and modified them in other respects (the “2005 agreements”). Under the 2005 agreements, Baxter remained solely responsible for sales and marketing expenses for the products/countries as to which it maintained commercialization rights. For 2005 and 2006, Baxter agreed to fund \$13.1 million of expenses for platelet and plasma system sales and marketing and for activities directed toward CE mark approval of the plasma system. Baxter also agreed to furnish specified levels of personnel to conduct sales and marketing of the platelet system and, upon approval, plasma system in Europe. The Company’s agreements with Baxter provided for sales and marketing strategy surrounding Baxter’s commercialization rights to be set by a joint Cerus/Baxter governance committee.

Under the 2005 agreements, the Company remained responsible for funding 100% of development expenses for the plasma system, except that \$2.2 million of Baxter’s \$13.1 million commitment (described above) may be applied to activities directed toward obtaining CE mark approval of and launch preparation for the plasma system. For the year ended December 31, 2006, the Company applied \$2.0 million of Baxter’s commitment to expenses incurred during the periods directed toward obtaining CE mark approval of the plasma system, which was recognized as development funding revenue.

Effective February 1, 2006, the Company entered into an additional restructuring of its agreements with Baxter related to the INTERCEPT Blood System. Under the terms of the February 2006 agreement, the Company gained worldwide rights to the INTERCEPT Blood System for platelets (the “platelet system”) and the INTERCEPT Blood System for plasma (the “plasma system”) previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. As a result of the agreement, the Company records all of the platelet and plasma system revenues.

Prior to entering into the February 2006 agreement, the Company received 33.5 % of the adjusted gross margins from sales of the platelet system, which are shown as product revenue on its consolidated statements of operations. 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. The Company agreed to purchase UVA illumination devices from Baxter in inventory in February 2006 and, INTERCEPT Blood System disposable kit finished from Baxter’s inventory for the platelet and plasma systems. Baxter agreed to manufacture systems and components for the platelet and plasma systems on a cost-plus basis through December 31, 2008, and components through December 31, 2009, subject to extension under certain specified conditions. Baxter also agreed to supply only



**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

very limited types of components for the prototype of the red blood cell system. The Company 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 and 5% for the red blood cell system, and 6.5% for sales of UVA illuminate. As a result of the 2006 restructuring agreement, the Company recognized gains and deferred gains in excess of \$6.5 million in 2006 and \$0.6 million in remaining deferred gains in 2007 as the services were completed by the vendors.

Also as a result of this agreement, the Company repaid a \$4.5 million promissory note and the related accrued interest in 2006. Interest expense was recorded as a component of interest income (expense) and other, net on the Company's consolidated statements of operations. This promissory note had been payable to Baxter since February 2005 and had an original maturity date of December 2006 with interest of 8%.

In March 2007, Baxter sold its Transfusion Therapies business, the unit of Baxter that had performed many of the manufacturing and supply chain activities related to the Company's relationship with Baxter, to a new company, Fenwal Inc. Fenwal has assumed Baxter's obligations to the Company under the manufacturing agreement and the Company is obligated to pay royalties on INTERCEPT Blood System product sales to Fenwal, rather than to Baxter. 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, 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.

**Agreements with BioOne**

In April 2004, the Company made an investment in the common stock of BioOne, a privately held Japanese corporation. 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.

*Platelet Agreement*

In June 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. In July 2004 and October 2004, Baxter and the Company each received up-front payments of \$10.0 million from BioOne. The Company's portion of the up-front payments was being deferred and recognized ratably as development funding over the development period. The agreement also provides for contingent milestone payments and royalties on future product sales, which would be shared equally by Baxter and the Company. The Company recognized \$2.8 million of revenue under this agreement during the year ended December 31, 2006. The Company did not recognize any revenue under this agreement during the years ended December 31, 2008, or 2007.

*Plasma Agreement*

In December 2004, Baxter and the Company signed a letter of intent with BioOne to enter into a definitive agreement for commercialization of the INTERCEPT Blood System for plasma in parts of Asia. Under the letter of intent, the Company received a payment of \$3.0 million from BioOne, which was recorded as deferred revenue as of December 31, 2004. A definitive agreement with BioOne for the plasma system was signed by

## CERUS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2008

Baxter and the Company in June 2005, and in December 2005 the Company received additional up-front payments of \$2.0 million in cash and \$5.0 million in BioOne's equity, both of which were recorded upon receipt as deferred revenue and recognized over the remaining development period. In December 2006, the Company received a milestone payment from BioOne of \$4.5 million in cash and \$5.0 million in BioOne's equity, both of which were in recognition of the Company receipt of a CE mark for the plasma system. The Company evaluates several criteria to determine the fair value of the equity received and to conclude whether or not the facts and circumstances support a fair value for revenue recognition and investment balance. 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. Based on this evaluation, the Company recognized the entire \$5.0 million of equity received as revenue in December 2006. Since BioOne is a privately-held Japanese company, it is only obligated to provide the Company with annual financial information at the end of its fiscal year which ends in May. Therefore, although the Company used the best available information at the time, there was and can be no absolute assurance that facts and circumstances will not change in the future. The Company recognized \$17.7 million of revenue under this agreement during the year ended December 31, 2006. The Company did not recognize any revenue under this agreement during the years ended December 31, 2008, or 2007.

Overall, revenues recognized from BioOne represented 67% of total revenues for the year ended December 31, 2006. The Company did not recognize any revenue for the years ended December 31, 2008, or 2007. At December 31, 2008, and 2007, the Company held approximately 13% of the voting securities of BioOne. The Company has evaluated several criteria in determining that it does not have the ability to exercise significant influence over BioOne. As a result of this evaluation, at December 31, 2008, the Company continues to account for its investment under the cost method, as it has concluded that predominant evidence exists to support this conclusion.

In 2007, BioOne received equity financing from institutional and corporate investors at a price per share below the Company's carrying value. The Company did not participate in this equity offering. However, as a consequence, the Company recorded a \$9.5 million non-cash impairment charge on the carrying value of its interest in BioOne equity in 2007. As result of the impairment charge, the Company's investment in BioOne, which had been recorded at \$11.2 million as of December 31, 2006, was written down to \$1.9 million as of December 31, 2007, and \$2.3 million as of December 31, 2008, which represents the Company's best current estimate of the fair value of its investment in BioOne. To the extent that the criteria used to support the carrying value of the Company's investment in BioOne at December 31, 2008, deteriorate further, it will need to reassess the recorded basis of its investment in BioOne.

#### **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 also supports advanced development of the Company's blood safety technologies. The Company recognized \$1.0 million, \$3.0 million, and \$4.8 million of revenue under these agreements during the years ended December 31, 2008, 2007, and 2006, respectively. As of December 31, 2008, the Company has received \$30.9 million of cash payments from these awards.

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

**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):

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Net operating loss carryforward . . . . .	\$ 110,000	\$ 101,300
Research and development credit carryforward . . . . .	33,200	31,800
Realized loss from cost basis investment . . . . .	3,800	3,800
Capitalized inventory cost . . . . .	400	—
Realized loss on other-than-temporary impairments of marketable securities . . . . .	100	—
Capitalized research and development . . . . .	22,500	26,400
Certain expenses not currently deductible for tax purposes . . . . .	1,600	1,900
Accrued liabilities . . . . .	2,600	200
Stock-based compensation . . . . .	2,600	1,800
Other . . . . .	2,800	2,900
	<u>179,600</u>	<u>170,100</u>
Gross deferred tax assets . . . . .	179,600	170,100
Valuation allowance . . . . .	<u>(179,600)</u>	<u>(170,100)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance increased by \$9.5 million, \$18.4 million, and \$8.0 million for the years ended December 31, 2008, 2007, and 2006, 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 \$0.2 million at December 31, 2008. 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.

Although management's operating plans assume, beyond the near-term, taxable and operating income in future periods, management's evaluation of all available information in assessing the realizability of the deferred tax assets in accordance with FAS 109, indicates that such plans were subject to considerable uncertainty. Therefore, the valuation allowance was adjusted to fully reserve the Company's deferred tax assets. The Company will continue to assess the realizability of the deferred tax assets based on actual and forecasted operating results. For the year ended December 31, 2008, the Company reported net losses of \$29.2 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, 2008, the Company had net operating loss carryforwards of approximately \$276.9 million for federal and \$265.2 million for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately \$21.6 million for federal income tax purposes and approximately \$17.7 million for state income tax purposes at December 31, 2008. The federal net operating loss and tax credit carryforwards expire between the years 2009 and 2028. The state net operating loss carryforwards expire between the years 2012 and 2028. 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, 2008, 2007, and 2006.

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

At December 31, 2008, and 2007, 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 years ended December 31, 2007, and 2006, have been restated to show the Company's former immunotherapy segment as a discontinued operation. Results for the Company's 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.

Revenues by region are as follows (in thousands):

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Revenues:			
United States .....	\$ 989	\$ 3,029	\$ 6,853
Europe, Russia, Middle East and ROW .....	15,518	8,015	2,975
Japan .....	—	—	20,482
Totals .....	<u>\$16,507</u>	<u>\$11,044</u>	<u>\$30,310</u>

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

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

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Customer			
A .....	33%	12%	— %
B .....	10%	5%	— %
C .....	14%	25%	— %

Each of the above customers with at least 10% of product revenue operates in a separate country outside of the United States. During the years ended December 31, 2008, 2007, and 2006, we also recognized non-product revenue from one customer which represents 6%, 27% and 16% of total revenue, respectively.

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

	<u>2008</u>	<u>2007</u>
Total Assets:		
United States .....	\$27,308	\$62,560
Europe .....	<u>20,031</u>	<u>15,649</u>
Totals .....	<u>\$47,339</u>	<u>\$78,209</u>

**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. There is no assurance that the equity will have monetary value at such time the Company is able to sell it or that it will receive any proceeds in the event of liquidation or sale of Anza. The terms of sale provided Anza a right to redeem up to 1,000,000 of such shares for a nominal amount upon the failure to occur of certain circumstances relating to possible research grant funding from the DoD. The Company was advised informally in February 2009 that based upon such provision, Anza may seek to redeem 1,000,000 shares held by us. If such shares are redeemed by Anza, the Company would own fewer shares of Anza’s Preferred Stock, reducing its preferred equity interest to approximately 16.0% of Anza’s outstanding preferred equity. The Company is evaluating whether such clause is applicable in the present circumstances. The Series AA Preferred Stock is non-voting and has no rights of representation on Anza’s board of directors, but otherwise generally carries the same rights and privileges as the Series A Preferred Stock of Anza purchased by the venture capital investors.

As a result of the sale of its immunotherapy business, the Company recorded losses of \$0.4 million representing the carrying value of the tangible assets sold. Prior to the sale of the immunotherapy business, the Company had expensed all costs associated with its immunotherapy business in the periods incurred. The Company has not assigned any value to the equity interest it has received in Anza due to the lack of marketability of the equity received.

The Company has accounted for its immunotherapy business as a discontinued operation, and has restated its financial statements for prior periods to reflect the discontinued operation. The Company is providing certain

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

transition services to Anza, generally for less than one year, under terms of a transition services agreement in which Anza will reimburse the Company for its direct costs associated with providing such services. The transition services the Company is providing to Anza are generally ancillary in nature and do not involve Anza's core business or any scientific research or development. The Company also subleases 14,800 square feet to Anza under a sublease which expires on March 31, 2009, unless terminated sooner. At December 31, 2008, Anza owed an insignificant amount to the Company for these services. In addition, in 2008, the Company sold certain equipment to Anza for an insignificant amount, which remained unpaid at December 31, 2008.

The Company was informed in February 2009 that Anza had ceased operations.

The following table summarizes the results of the Company's former immunotherapy segment for the two years ended December 31:

	<b>2007</b>	<b>2006</b>
<b>(in thousands, except percentage)</b>		
Revenue .....	\$ 4,356	\$ 5,270
Operating expenses .....	10,176	12,401
Loss from discontinued operations .....	(5,820)	(7,131)
Loss from sale of discontinued operations .....	(384)	—
Net loss from discontinued operations .....	\$ (6,204)	\$ (7,131)

**Note 18. Quarterly Financial Information** (Unaudited and in thousands except per share amounts)

	<b>Three Months Ended</b>			
	<b>March 31, 2008</b>	<b>June 30, 2008</b>	<b>September 30, 2008</b>	<b>December 31, 2008</b>
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
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 <sup>1</sup> .....	\$ (0.18)	\$ (0.28)	\$ (0.24)	\$ (0.20)
Net loss per share—diluted <sup>1</sup> .....	\$ (0.18)	\$ (0.28)	\$ (0.24)	\$ (0.20)

<sup>1</sup> The Company has adjusted amounts previously reported for Other income (expense), and net loss per share – basic and diluted for the three months ended March 31, 2008, June 30, 2008, and September 30, 2008. The adjustment resulted from the translation of inventory into US Dollars and affected other income (expense), net by \$(0.6) million, \$0.1 million, and \$1.0 million for the three months ended March 31, 2008, June 30, 2008, and September 30, 2008, respectively. Loss per share was impacted by \$(0.02), \$0.00, and \$0.03 per share for the three months ended March 31, 2008, June 30, 2008, and September 30, 2008, respectively.

**CERUS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008**

	Three Months Ended			
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007
Revenue:				
Product revenue . . . . .	\$ 1,187	\$ 1,671	\$ 2,762	\$ 2,395
Government grants and cooperative agreements . . . . .	1,064	1,551	414	—
Total revenue . . . . .	2,251	3,222	3,176	2,395
Cost of product revenue . . . . .	824	1,067	1,673	1,664
Gross profit . . . . .	1,427	2,155	1,503	731
Operating expenses				
Research and development . . . . .	3,266	3,559	4,006	4,126
Selling, general, and administrative . . . . .	5,322	6,151	5,631	7,471
Impairment of long-term investment in related party . . . . .	—	9,450	—	—
Total operating expenses . . . . .	8,588	19,160	9,637	11,597
Operating loss . . . . .	(7,161)	(17,005)	(8,134)	(10,866)
Other income, net . . . . .	1,088	996	1,334	648
Net loss from continuing operations . . . . .	\$(6,073)	\$(16,009)	\$(6,800)	\$(10,218)
Discontinued operations:				
Loss from discontinued operations . . . . .	(735)	(1,906)	(2,351)	(828)
Loss from sale of discontinued operations . . . . .	—	—	—	(384)
Net loss from discontinued operations . . . . .	(735)	(1,906)	(2,351)	(1,212)
Net loss . . . . .	\$(6,808)	\$(17,915)	\$(9,151)	\$(11,430)
Net loss from continuing operations per share—basic . . . . .	\$ (0.19)	\$ (0.50)	\$ (0.21)	\$ (0.32)
Net loss from continuing operations per share—diluted . . . . .	\$ (0.19)	\$ (0.50)	\$ (0.21)	\$ (0.32)
Net loss from discontinued operations per share—basic . . . . .	\$ (0.02)	\$ (0.06)	\$ (0.08)	\$ (0.04)
Net loss from discontinued operations per share—diluted . . . . .	\$ (0.02)	\$ (0.06)	\$ (0.08)	\$ (0.04)
Net loss per share—basic . . . . .	\$ (0.21)	\$ (0.56)	\$ (0.29)	\$ (0.36)
Net loss per share—diluted . . . . .	\$ (0.21)	\$ (0.56)	\$ (0.29)	\$ (0.36)

## 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 13th day of March 2009.

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 William J. Dawson, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>          /s/  CLAES GLASSELL          </u> <b>Claes Glassell</b>	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 13, 2009
<u>          /s/  WILLIAM J. DAWSON          </u> <b>William J. Dawson</b>	Chief Financial Officer and Vice President, Finance <i>(Principal Financial and            Accounting Officer)</i>	March 13, 2009
<u>          /s/  B. J. CASSIN          </u> <b>B. J. Cassin</b>	Chairman of the Board	March 13, 2009
<u>          /s/  TIMOTHY B. ANDERSON          </u> <b>Timothy B. Anderson</b>	Director	March 13, 2009
<u>          /s/  LAURENCE M. CORASH          </u> <b>Laurence M. Corash, M.D.</b>	Director	March 13, 2009
<u>          /s/  BRUCE C. COZADD          </u> <b>Bruce C. Cozadd</b>	Director	March 13, 2009
<u>          /s/  WILLIAM R. ROHN          </u> <b>William R. Rohn</b>	Director	March 13, 2009
<u>          /s/  GAIL SCHULZE          </u> <b>Gail Schulze</b>	Director	March 13, 2009



## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1.1(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2 (16)	Bylaws of Cerus.
4.2 (1)	Specimen Stock Certificate.
10.1 (1)	Form of Indemnity Agreement entered into between Cerus 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.
10.7 (1)	Industrial Real Estate Lease, dated October 1, 1992, between Cerus and Shamrock Development Company, as amended on May 16, 1994 and December 21, 1995.
10.8 (1)	Real Property Lease, dated August 8, 1996, between Cerus and S.P. Cuff.
10.9 (1)	Lease, dated February 1, 1996, between Cerus and Holmgren Partners.
10.11(2)†	License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation.
10.12(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.13(4)	Stockholder Rights Plan, dated November 3, 1999.
10.14(5)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.15(6)*	Amended and Restated Employment Agreement with Howard G. Ervin, dated December 22, 2008.
10.16(8)	Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P.
10.17(8)	Lease, dated October 12, 2001 between Cerus and California Development, Inc.
10.18(9)	Loan and Security Agreement, dated November 15, 2002, between Cerus and Baxter Capital Corporation.
10.19(10)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.21(6)*	Amended and Restated Employment Agreement with Claes Glassell, dated December 19, 2008.
10.22(12)*	Amended and Restated Employment Agreement with William J. Dawson, dated January 16, 2009.
10.23(13)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.24(13)†	License Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.25(13)†	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.26(14)*	Bonus Plan for Senior Management of Cerus Corporation, dated January 1, 2006.
10.27(14)†	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.

Exhibit Number	Description of Exhibit
10.28(15)†	Asset Transfer and License Agreement, dated November 20, 2007, by and between Cerus Corporation and Anza Therapeutics, Inc.
10.29(15)	Offer Letter to Gail Schulze, dated October 15, 2007.
10.30(17)	2008 Equity Incentive Plan.
10.31(18)	Supply Agreement, dated December 19, 2007, by and between Cerus and Brotech Corporation d/b/a Purolite Company.
10.32(18)	Supply and Manufacturing Agreement, dated March 1, 2008, by and between Cerus and Porex Corporation.
10.33(11)†	Credit Agreement, dated as of June 18, 2008, by and between Cerus and Wells Fargo Bank, National Association.
10.34(19)††	First Amendment and Waiver to Credit Agreement, dated as of December 29, 2008, by and between Cerus and Wells Fargo Bank, National Association.
10.35(11)†	Security Agreement, dated as of June 18, 2008, by and between Cerus and Wells Fargo Bank, National Association.
10.36(19)††	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus and NOVA Biomedical Corporation.
10.37(19)††	Amended and Restated Manufacturing and Supply Agreement, dated December 12, 2008, by and between Cerus and Fenwal, Inc.
10.38(19)*	Non-Employee Director Compensation Policy.
10.39(19)*	Base Salaries for Fiscal Year 2008 for Named Executive Officers.
12.1(19)	Statement Regarding Computation of Ratio of Earnings to Fixed Charges and Ratio of Combined Fixed Charges and Preference Dividends to Earnings.
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 pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial 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, dated June 30, 1998.

(4) Incorporated by reference to Cerus' Current Report on Form 8-K, dated November 3, 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, dated 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 June 30, 2008.
- (12) Incorporated by reference to Cerus' Current Report on Form 8-K, dated January 16, 2009.
- (13) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- (14) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.
- (15) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2007.
- (16) Incorporated by reference to Cerus' Current Report on Form 8-K, dated June 19, 2008.
- (17) Incorporated by reference to Cerus' Current Report on Form 8-K dated June 6, 2008.
- (18) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.
- (19) Filed herewith.

**STATEMENT REGARDING COMPUTATION OF RATIO OF EARNINGS TO FIXED CHARGES  
AND RATIO OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED STOCK  
DIVIDENDS**  
(in thousands, except ratios)

The following table sets forth our ratio of earnings to fixed charges and our ratio of earnings to combined fixed charges and preferred stock dividends for the years ended December 31, 2004, 2005, 2006, 2007, and 2008. As the ratios of earnings to fixed charges and earnings to combined fixed charges and preferred stock dividends indicate less than one-to-one coverage for the years ended December 31, 2004, 2007, and 2008, we have provided the coverage deficiency amounts. Earnings are the sum of (i) loss from continuing operations before losses from equity affiliates, and (ii) amortization of capitalized interest, less (i) interest capitalized. Fixed charges are the sum of (i) interest expensed and capitalized, and (ii) amortization of capitalized expenses related to indebtedness.

	Year Ended December 31,				
	2004	2005	2006	2007	2008
Income (loss) from continuing operations before income tax *	\$(25,316)	\$14,457	\$2,352	\$(39,100)	\$(29,181)
Plus: Amortization of capitalized interest	6,411	696	372	287	255
Less: Interest capitalized	—	1	1	—	—
Earnings, as adjusted	<u>\$(18,905)</u>	<u>\$15,152</u>	<u>\$2,723</u>	<u>\$(38,813)</u>	<u>\$(28,926)</u>
Fixed charges	6,411	696	372	286	255
Total fixed charges	<u>\$ 6,411</u>	<u>\$ 696</u>	<u>\$ 372</u>	<u>\$ 286</u>	<u>\$ 255</u>
Preferred stock dividends	—	—	—	—	—
Ratio of earnings to fixed charges	—	21.77	7.32	—	—
Ratio of earnings to combined fixed charges and preferred stock dividends	—	21.77	7.32	—	—
Deficiency of earnings available to cover fixed charges	<u>\$(12,494)</u>	<u>—</u>	<u>—</u>	<u>\$(38,527)</u>	<u>\$(28,671)</u>
Deficiency of earnings available to cover combined fixed charges and preferred stock dividends	<u>\$(12,494)</u>	<u>—</u>	<u>—</u>	<u>\$(38,527)</u>	<u>\$(28,671)</u>

\* Excluding losses from minority interest and income/loss from equity investees.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (Nos. 333-152680, 333-145007, 333-136452, 333-127541, 333-125043, 333-109170, 333-92254, 333-63132, 333-42588, 333-84497, 333-74991, 333-27097, ) of Cerus Corporation pertaining to the 1996 Equity Incentive Plan, Employee Stock Purchase Plan, 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan, and in the Registration Statements on Form S-3 (Nos. 333-93481, 333-47224, 333-61460, 333-61910, 333-67286, 333-75413, 333-72185, and 333-154842) and the related Prospectuses of Cerus Corporation of our reports dated March 10, 2009, with respect to the financial statements of Cerus Corporation and the effectiveness of internal control over financial reporting of Cerus Corporation, included in this Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 10, 2009

**CEO CERTIFICATION**

I, Claes Glassell, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2009

/s/ CLAES GLASSELL

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Claes Glassell  
Chief Executive Officer

**CFO CERTIFICATION**

I, William J. Dawson, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2009

/s/ WILLIAM J. DAWSON

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William J. Dawson  
Chief Financial Officer

**CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 United StatesC. § 1350), Claes Glassell, Chief Executive Officer of Cerus Corporation (the “Company”) and William J. Dawson, the Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2008, to which this Certification is attached as Exhibit 32.1 (the “Annual Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 13th day of March, 2009.

/s/ CLAES GLASSELL

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Claes Glassell  
Chief Executive Officer

/s/ WILLIAM J. DAWSON

\_\_\_\_\_  
William J. Dawson  
Chief Financial Officer

This certification “accompanies” the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cerus Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K, irrespective of any general incorporation language contained in such filing).