CERUS CORP
Form 10-K
February 26, 2007
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006

OR

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

For the transition period from to

Commission file number 0-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2411 Stanwell Dr.	
Concord, California	**94520**
(Address of principal executive offices)	**(Zip Code)**

(925) 288-6000

(Registrant s telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $.001 per share	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ¨ No x

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

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 x	Non-accelerated filer ¨

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

The approximate aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant s most recently completed second fiscal quarter, based upon the closing sale price of the registrant s common stock listed on the Nasdaq Global Market, was $158.5 million.(1)

As of February 8, 2007, there were 31.7 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 2006 annual meeting of stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2007, are incorporated by reference into Part III of this annual report on Form 10-K.

(1) Based on a closing sale price of $7.13 per share on June 30, 2006. Excludes 5.6 million shares of the registrant s common stock held by executive officers, directors and affiliates at June 30, 2006.

Table of Contents

TABLE OF CONTENTS

		Page
PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	15
Item 1B.	Unresolved Staff Comments	33
Item 2.	Properties	33
Item 3.	Legal Proceedings	34
Item 4.	Submission of Matters to a Vote of Security Holders	34
PART II		
Item 5.	Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	35
Item 6.	Selected Financial Data	37
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	38
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	48
Item 8.	Financial Statements and Supplementary Data	48
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	48
Item 9A.	Controls and Procedures	48
Item 9B.	Other Information	49
PART III		
Item 10.	Directors and Executive Officers of the Registrant	50
Item 11.	Executive Compensation	50
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	50
Item 13.	Certain Relationships and Related Transactions	50
Item 14.	Principal Accountant Fees and Services	50
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	51
SIGNATURES		84

Table of Contents

PART I

This report contains forward-looking statements that involve risks and uncertainties. When used herein, the words anticipate, believe, estimate, expect, plan and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including whether our preclinical and clinical data will be considered sufficient by regulatory authorities to grant marketing approval, market acceptance of our products, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, a transition away from a reliance on Baxter for sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Baxter 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, the early stage of development of our vaccine programs, our ability to attract and retain partners and collaborators for our immunotherapy programs, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our limited operating history and expectation of continuing losses, the need for additional financing, 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 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, *Helinx, INTERCEPT* and *INTERCEPT Blood System* are United States registered trademarks of Cerus Corporation.

Item 1. *Business*
Overview

We are developing and commercializing novel, proprietary products and technologies within the fields of blood safety and immunotherapy that are intended to provide safer, more effective medical options to patients in areas of substantial unmet medical need. In the field of blood safety, we are developing and commercializing the INTERCEPT Blood System for platelets, plasma and red blood cells, or INTERCEPT Blood System. The INTERCEPT Blood System, which is based on our proprietary Helinx technology for controlling biological replication, is designed to enhance the safety of donated blood components by inactivating viruses, bacteria, parasites and other pathogens, as well as potentially harmful white blood cells. In the field of immunotherapy, we are employing our proprietary attenuated *Listeria* vaccine platform to develop a series of novel therapies to treat cancer. We currently have three immunotherapeutic cancer vaccine product candidates, one of which entered Phase I human clinical trials in 2006 and two of which are in preclinical development. These product candidates are designed to stimulate both innate and adaptive immune pathways, generating highly specific and highly potent anti-tumor responses. We are collaborating in the development of these product candidates with investigators at The Johns Hopkins University, or Johns Hopkins, and with MedImmune, Inc., or MedImmune. Also in immunotherapy, we are applying our proprietary Killed But Metabolically Active, or KBMA, technology platform in the research and development of prophylactic and therapeutic vaccines for infectious diseases, including hepatitis C and HIV. We have two prophylactic KBMA vaccine product candidates in early stages of development, one against anthrax and the other against tularemia. Both of these programs have received funding from the National Institutes of Health, or NIH, under national bioterrorism initiatives.

We have worldwide commercialization rights for the INTERCEPT Blood System for platelets, plasma and red blood cells, excluding certain countries in Asia where we have licensed commercialization rights to the platelets and plasma systems to BioOne Corporation, or BioOne. We previously collaborated with subsidiaries of Baxter International Inc., or Baxter, in the development and commercialization of the INTERCEPT Blood

Table of Contents

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 have not been licensed to BioOne. The INTERCEPT platelet and plasma systems have both received CE mark approval in Europe and are being marketed for commercial sale. Certain European countries require additional approvals of INTERCEPT-treated blood products. Such additional approvals have been obtained for the platelet and plasma systems in France and for INTERCEPT-treated platelets at one blood center in Germany. The French plasma system approval is subject to publication in the official journal. We have prioritized the commercialization of the INTERCEPT Blood System for platelets and plasma in Europe and the continued development of the INTERCEPT red blood cell system ahead of our regulatory approval activities in the United States relating to these systems.

Cerus is a corporation that was incorporated in California in 1991 and reincorporated in Delaware in 1996. Information regarding our revenue, net income or losses, and total assets for the last three fiscal years can be found in the financial statements and related notes found elsewhere in this report. Our wholly-owned subsidiary, Cerus Europe B.V. was formed in the Netherlands in 2006.

Table of Contents

Product Development

We have incurred total research and development expenses of $29.5 million, $24.1 million and $27.7 million for the years ended December 31, 2006, 2005 and 2004, respectively. The following table identifies our products and product development programs and their current status:

Product or Product Under Development	Potential Therapeutic Indication/Use	Development Status	Commercial Rights
Blood Safety			
INTERCEPT Blood System Platelets	Inactivation of viruses, bacteria and other pathogens in platelets for transfusion	Europe: Commercialized in certain countries U.S.: Phase III clinical trial completed; supplemental clinical trial required	Cerus worldwide, except rights granted to BioOne in certain Asian countries
INTERCEPT Blood System Plasma	Inactivation of viruses, bacteria and other pathogens in plasma for transfusion	Europe: Commercialized in certain countries U.S.: Phase III clinical trials completed	Cerus worldwide, except rights granted to BioOne in certain Asian countries
INTERCEPT Blood System Red Blood Cells	Inactivation of viruses, bacteria and other pathogens in red blood cells for transfusion	Research and Phase I trial fully enrolled in late 2006, completion expected in mid-2007	Cerus
Immunotherapy Attenuated Listeria Platform			
CRS-100 (attenuated Listeria)	Cancers that have metastasized to the liver, including colorectal cancer	Phase I clinical trial initiated in 2006	Cerus
CRS-207 (attenuated *Listeria* expressing Mesothelin antigen)	Pancreatic and ovarian cancer	Preclinical development; IND filing expected in mid-2007	Cerus
MEDI-543 (EphA2) (attenuated *Listeria* expressing EphA2 antigen)	Breast, prostate and colon cancers and metastatic melanoma	Preclinical development	MedImmune
Immunotherapy KBMA Platform			
Hepatitis C Vaccine	Therapeutic vaccine against hepatitis C virus	Preclinical research and development	Cerus
HIV Vaccine	Therapeutic vaccine against HIV	Preclinical research and development	Cerus
Anthrax Vaccine	Prophylactic vaccine against anthrax	Preclinical research and development	Cerus
Tularemia Vaccine	Prophylactic vaccine against tularemia	Preclinical research and development	Cerus

Table of Contents

Blood Safety

Background

The INTERCEPT Blood System is designed to broadly target and inactivate blood-borne pathogens, such as viruses (HIV, West Nile, SARS, and hepatitis B and C, for example), 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 to detect their presence in donated blood. The INTERCEPT Blood System is based on our proprietary Helinx technology for controlling biological replication.

We have worldwide commercialization rights for the INTERCEPT Blood System, excluding certain countries in Asia. We previously collaborated with Baxter and have licensed to BioOne commercialization rights to the INTERCEPT Blood System for platelets and plasma 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. Certain European countries require additional approvals of INTERCEPT-treated blood products. Such additional approvals have been obtained for the platelet system in France and for INTERCEPT-treated platelets at one blood center in Germany. We must file an application for marketing approval and obtain such approval in Switzerland before being able to sell the platelet system there. The extent of the validation studies varies by country. Further clinical studies, ranging from small-scale experience studies to larger randomized trials, will be conducted in some regions and countries, such as the Netherlands. These 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 France, the platelet system has been approved for use by blood centers in treating platelets, but we do not expect widespread commercial adoption of the platelet system to occur until national reimbursement levels have been determined.

We completed a Phase III clinical trial of the platelet system in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the United States Food and Drug Administration, or FDA. Based on discussions with the FDA, an independent expert physician panel performed an additional analysis of some of the clinical trial data, which was collected by an independent contract research organization, 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 assessments of primary patient records on a blinded basis by the independent expert physician panel found no statistically significant differences in clinically significant pulmonary adverse events between test and control groups. These assessments differed from adverse events drawn from the case report forms from the Phase III clinical trial, which showed statistically significant differences in specific pulmonary events. Furthermore, this assessment supported our interpretation that the imbalance observed based on the case report forms was due to reporting differences among the clinical sites. Together with Baxter, we submitted in 2005 a final report of the analysis to the FDA for review. The final report included conclusions from the expert physician panel. We have had several interactions with the FDA subsequent to the final report submission and understand that the FDA will require a significantly 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.

Table of Contents

Information regarding our revenues from the platelet system for the years ended December 31, 2006, 2005, and 2004 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.*

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. We completed the last of three planned Phase III clinical trials of the plasma system in 2004, and the primary and secondary efficacy endpoints of the trial for therapeutic plasma exchange were met. The study showed no clinically and statistically significant differences in overall adverse events between the treatment group and the control group. A final Phase III report was submitted to the FDA in 2005. Based on the results of the Phase III clinical trials, we received CE mark approval for the plasma system in November 2006 and have prioritized the commercial launch of the plasma system in Europe ahead of further regulatory efforts relating to the plasma system in the United States. We obtained French in-country approval of the plasma system in January 2007, subject to publication in the official journal. Pathogen inactivated plasma is already reimbursed in many European countries.

Information regarding our revenues from the plasma system for the years ended December 31, 2006, 2005, and 2004 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.*

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 Phase III clinical trials of the red blood cell system due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients. We evaluated the antibodies detected in the trial and developed process changes that may greatly diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. We announced several findings related to these evaluations and developments in late 2004 and 2005 at several scientific and trade association meetings. Based on these findings and other preclinical work we have conducted, we re-entered Phase I clinical trials for the red blood cell system in the United States in the second half 2006 with our modified process, and expect to complete Phase I trial by mid-2007. 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 no earlier than late 2008.

Collaborations

Baxter

We collaborated with Baxter on the development and commercialization of the INTERCEPT Blood System commencing in 1993. Effective February 1, 2006, we entered into a restructuring of our agreements with Baxter pursuant to which we obtained exclusive worldwide commercialization rights to market, distribute and sell the platelet and plasma systems, excluding certain Asian countries where we have licensed rights to BioOne. We regained worldwide commercialization rights to market the red blood cell system from Baxter in February 2005. In connection with the transfer of commercialization rights to us, Baxter agreed to supply, at our expense, certain transition services, including regulatory, technical and related administrative support through December 31, 2006. We agreed to purchase UVA illumination devices from Baxter in inventory in February 2006 and, INTERCEPT platelet and plasma system disposable kits from Baxter s inventory. Baxter has 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. Baxter also has agreed to supply only very limited types of components for the prototype of the red blood cell system. We will be obligated to pay Baxter royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of

Table of Contents

product sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. As a result of the 2006 agreement, we recognized gains and deferred gains in excess of $6.5 million in 2006. At December 31, 2006, we had approximately $0.6 million in remaining deferred gains, all of which are associated with payments made to vendors by December 31, 2006 in support of INTERCEPT commercialization efforts. We anticipate recognizing the remainder of the deferred gain balance in 2007 as the services are completed by the vendors.

BioOne

In June 2004, we entered into an agreement with Baxter and BioOne for commercialization of our platelet system in specified parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for the platelet system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore in exchange for exclusive marketing and distribution rights in each of those countries. We have received a total of $10 million in up-front payments under the terms of the agreement and will be eligible to receive contingent milestone payments for our sole account and royalties on future product sales, which will be shared equally by Baxter and us.

In June 2005, we announced our entry into a definitive agreement with Baxter and BioOne for commercialization of our plasma system in specified parts of Asia. Under the terms of the definitive agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for the plasma system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore in exchange for exclusive marketing and distribution rights in each of those countries. We have received a total of $9.5 million in cash and $10.0 million in BioOne equity securities in connection with the definitive agreement as of December 31, 2006 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 Baxter and us.

U.S. 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. In September 2002, May 2003, January 2004, August 2004, July 2006, and September 2006 we were awarded additional funding of $5.0 million, $6.0 million, $5.5 million, $3.7 million, $1.0 million, and $3.5 million, respectively, 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 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 U.S. armed forces.

MedImmune

In April 2004, we entered into an agreement with MedImmune to co-develop a novel therapeutic vaccine designed to target antigens expressed in breast, prostate and colon cancer, as well as metastatic melanoma. MedImmune is developing MEDI-543 (EphA2) using our *Listeria* vaccine platform and MedImmune s EphA2 cancer antigen. Under the terms of the agreement, we have conducted preclinical development activities in support of MedImmune, which is responsible for preclinical development, clinical testing, manufacturing and commercialization of any product resulting from the collaboration, and development of a therapeutic vaccine candidate. We received development funding and may receive contingent milestone payments and royalties on future product sales. As of December 31, 2006, we had received up front and milestone payments of $1.5 million from MedImmune under the terms of the agreement, as well as development funding. The $1.5 million in milestone and upfront payments consist of a $1.0 million up front payment and a $0.5 million milestone payment. We recognized revenue of $0.3 million, $2.4 million and $1.6 million from MedImmune during the years ended December 31, 2006, 2005 and 2004, respectively.

Table of Contents

Immunotherapy

Background

We are using our proprietary, versatile vaccine platforms to develop therapies to stimulate the immune system to selectively target and attack cancer cells and infectious diseases. Our vaccine platforms are based on specially designed and proprietary strains of the bacterium *Listeria monocytogenes*. We believe that our proprietary strains of *Listeria,* alone or expressing cancer antigens, have the potential to harness the power of the immune system to selectively attack cancer cells. In September 2004, preclinical efficacy and safety data for our attenuated *Listeria*-based cancer immunotherapy technology were published in the *Proceedings of the National Academy of Sciences*, or PNAS. The PNAS paper described studies in which experimental vaccines based on our proprietary *Listeria* platform were engineered to express specific tumor antigens. These vaccines were shown to elicit therapeutic anti-tumor responses in tumor-bearing mice, resulting in prolonged survival. In addition, the *Listeria* strain used in these studies demonstrated a one thousand-fold reduction in toxicity when compared to wild-type *Listeria*.

In comparison to other strains, the optimized platform *Listeria* strain used in the studies was cleared more rapidly *in vivo* and showed significantly higher safety margins while preserving immunogenic potency. When used at comparable doses to unmodified *Listeria*, the optimized strain generated equivalent immune responses, yet could be administered at higher doses, resulting in more potent T cell responses than possible with wild-type *Listeria*. Finally, therapeutic administration of an experimental vaccine using the optimized strain resulted in a significant reduction in metastases and a significant increase in survival in mice with established tumors.

In addition to our attenuated *Listeria* vaccine platform, we have developed a second immunotherapy platform based on our KBMA technology. We currently are utilizing this platform to develop therapeutic and prophylactic vaccines for serious infectious diseases. Our KBMA platform is based on the application of our proprietary Helinx technology, which is designed to bind with the DNA of infectious pathogens resulting in their inability to replicate. Using this method, we are able to inhibit the infectivity, but maintain the metabolic activity of specially engineered, proprietary pathogens. Accordingly, we are seeking to develop KBMA vaccine candidates that retain the potency typically found in live viral and bacterial vaccines, but with the safety advantages of killed vaccines. A scientific paper detailing preclinical data on KBMA *Listeria* as a vaccine platform appeared in the August 2005 edition of *Nature Medicine*. Early research and development efforts relating to our KBMA technology platform have been funded in part by grants from the NIH and the National Institute of Allergy and Infectious Diseases, or NIAID. Under other grants, we are conducting early preclinical development of therapeutic vaccines for hepatitis C virus and HIV using our KBMA technology platform applied to our attenuated *Listeria* strain.

Product Candidates and Development Activities

Our Attenuated Listeria Vaccine Platform

CRS-100

We have conducted preclinical development of a strain of proprietary attenuated *Listeria* for use in treating liver metastases of certain cancers, including colorectal cancer. Preclinical experiments of our product candidate, CRS-100, suggest that our *Listeria* strain selectively stimulates an anti-cancer immune response in the liver. When administered intravenously to mice, CRS-100 is taken up by macrophages in the liver and induces a cascade of immune stimulating cytokines and chemokines. This inflammatory response leads to the recruitment and activation of immune cells to the liver, such as Natural Killer cells that mediate anti-tumor effects, and dendritic cells that prime long-lasting immunity against the tumor. We have conducted toxicology studies of CRS-100 in non-human primates and filed an investigational new drug application, or IND, with the FDA in late 2005, which was approved in early 2006. We initiated a Phase I clinical trial of CRS-100 in the United States in the second half of 2006. The Phase I trial is an open label, dose escalation study designed to assess safety and maximum tolerated dose of our attenuated *Listeria* strain, as well as to monitor biological activity associated with immune system activation. The trial is being conducted at multiple investigational sites in the United States.

Table of Contents

CRS-207

In collaboration with investigators at Johns Hopkins, we are conducting late-stage preclinical studies of a therapeutic pancreatic cancer vaccine candidate, CRS-207, using the same proprietary strain of attenuated *Listeria* used in CRS-100, but in this product application the strain is engineered to express Mesothelin. Mesothelin is an antigen that is prevalently expressed in pancreatic and ovarian tumors, but not in normal pancreatic or ovarian tissue. In clinical studies at Johns Hopkins, three pancreatic cancer patients vaccinated with an experimental, non-*Listeria* vaccine developed T cell responses against Mesothelin, and those patients are alive and disease-free more than seven years after their initial cancer diagnosis. Cytotoxic T cells isolated from these patients recognized and destroyed tumor cells *in vitro*, further validating Mesothelin as a target in pancreatic cancers. In December 2003, we licensed certain rights to Mesothelin from Johns Hopkins. In December 2004, we entered into an exclusive license with Chugai Pharmaceutical Co., Ltd., relating to the DNA sequence of Mesothelin in the field of cancer vaccines. We expect to file an IND for CRS-207 with the FDA in mid-2007.

MEDI-543 (EphA2)

In April 2004, we entered into an agreement with MedImmune to co-develop a novel immunotherapeutic vaccine for cancer. This product candidate, MEDI-543 (EphA2), combines our attenuated *Listeria* platform with MedImmune s proprietary EphA2 antigen, which is expressed in a number of solid tumor cancers. According to a paper published on August 1, 2004 in *Clinical Cancer Research* by researchers from the University of Texas M.D. Anderson Cancer Center, elevated levels of EphA2 have been linked to cancer progression and decreased patient survival in ovarian cancer patients. EphA2 is also overexpressed by other types of cancers, including breast, prostate and metastatic melanoma.

Under the terms of the agreement, we conducted preclinical development activities in support of MedImmune, who is now responsible for remaining preclinical development, clinical testing, manufacturing and commercialization of any product resulting from the collaboration. Ending in early 2006, we received development funding from MedImmune and may receive contingent milestone payments and royalties on future product sales. In September 2005, MedImmune selected a lead candidate strain as a predicate to advanced preclinical testing.

KBMA Platform

Hepatitis C and HIV Vaccines

We believe that our KBMA technology has the potential to be used to develop novel therapeutic vaccines for serious infectious diseases, such as hepatitis C and HIV. Hepatitis C establishes chronic infections in the liver, and can be treated with a combination of small molecule drugs and interferon, an immune-activating protein. However, current treatments are suboptimal because systemic interferon treatment is difficult for patients to tolerate and induces a flu-like syndrome. Our approach is to utilize our KBMA platform to produce killed but metabolically active strains of *Listeria*. We believe that these strains would take advantage of *Listeria s* natural tropism, or biological affinity, to the liver and induce localized production of cytokines, notably including interferon, that, in combination with small molecule drugs, may lead to elimination of the hepatitis C virus. We believe that our KBMA platform will also allow us to engineer KBMA *Listeria* strains that express hepatitis C antigens in order to elicit a specific and long-lasting T cell response against virally infected tissues. We believe that this approach may be better tolerated and have a higher rate of efficacy than current immunotherapies. We are also engaged in early preclinical research and development of therapeutic vaccine candidates to treat HIV using KBMA *Listeria* strains expressing HIV antigens, which may elicit specific and long-lasting T cell responses against virally infected tissues.

Table of Contents

Anthrax Vaccine

In July 2004, we were awarded a $3.8 million grant from the NIH to begin development of a prophylactic anthrax vaccine based on our KBMA vaccine platform. This award is shared with a consortium of researchers at the University of California at Berkeley and the University of New Mexico Health Sciences Center, with Cerus serving as the principal investigator. Exposure to the bacterium *Bacillus anthracis* leads to a serious and life-threatening infectious disease and has become a major concern due to its potential to be used as an agent for bioterrorism. The only currently licensed human anthrax vaccine was developed in the late 1950 s and has limited efficacy. We believe that an anthrax vaccine based on our KBMA platform technology has the potential to offer greater potency than the current vaccine. To date, we have demonstrated that a KBMA anthrax vaccine has the ability to induce broad-based immune responses and protect mice from developing anthrax after exposure to a usually lethal dose of anthrax spores.

Tularemia Vaccine

In October 2005, we announced that a consortium of which we are a member was awarded $24.8 million from the NIAID for the study of the basic biology of and development of a prophylactic vaccine against *Francisella tularensis*, the bacterium that causes the infectious disease tularemia. Of the total award amount, we expect to receive $2.7 million over a three-year period. Tularemia, also known as Rabbit Fever, is a serious and life-threatening infectious disease for which there is currently no effective human vaccine. Similar to anthrax, tularemia has emerged as a growing bioterrorism concern because of its high level of infectivity, ease of dissemination and substantial mortality rate. Our work with the consortium will center on the development of a prophylactic tularemia vaccine using our KBMA technology platform, and we and our collaborators are currently constructing vaccine candidates.

We intend to leverage the experience and know-how from our research and development efforts in prophylactic vaccines against anthrax and tularemia to develop therapeutic vaccines for other infectious diseases.

Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the inactivation compounds for the INTERCEPT Blood System and immunotherapy product candidates for use in clinical trials and for commercialization. We have no experience in manufacturing products for commercial purposes and have only limited manufacturing facilities capable of producing small lots of preclinical materials for our immunotherapy programs. Consequently, we are dependent on Baxter for INTERCEPT Blood System components and on contract manufacturers for the production of Helinx compounds and immunotherapy materials for development and commercial purposes.

Under our agreements with Baxter, we are responsible for developing and delivering our proprietary compounds to Baxter for incorporation into the final system configuration. Baxter is responsible for manufacturing or supplying the disposable units for the platelet and plasma systems, such as blood storage containers and related tubing, as well as any device associated with the inactivation process on a cost-plus basis through 2008 and components through 2009.

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 compound sufficient to support the anticipated commercial demand for the platelet and plasma systems in Europe.

We and our contract manufacturers purchase certain raw materials from a limited number of suppliers. While we believe that there are alternative sources of supply for such materials, establishing additional or replacement suppliers for any of the raw materials, if required, may not be accomplished quickly and could

Table of Contents

involve significant additional costs. Any failure to obtain from alternative suppliers any of the materials used to manufacture our compounds, if required, would limit our ability to manufacture our compounds.

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 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 expected to be on a blood center-by-blood center basis. While obtaining CE marks allow us to sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute before being allowed to sell platelets and plasma units treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, one blood center in Germany has received such requisite approvals and authorizations for the platelet system. In France, decisions on product adoption are expected to be on a region-by-region basis with national direction.

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, or HMOs), 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 platelet pathogen inactivation must be set before we would expect broad commercial adoption of the platelet system in France. National reimbursement rates for pathogen inactivated plasma units have been set in France, but need to be extended to include the INTERCEPT Blood System before we would expect broad commercial adoption of the plasma system in France.

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those technologies with the potential to improve the safety of the blood supply, such as the INTERCEPT Blood System. In addition, healthcare professionals may require further safety information or additional studies before adopting our products. Our products may require changes to our potential customers space and staffing requirements and require upfront investment in UVA illuminators, disposable kit inventory and staff training. Even if our product candidates receive regulatory approval for commercial sale, blood centers, physicians, patients and healthcare payors may not believe that the benefits of using our products justify their additional cost. Furthermore, our products may be inappropriate for certain patients, which could reduce the potential market size.

There is some volume loss in the yield of blood products as a result of our pathogen inactivation process. In addition, our process today is not fully compatible with the common practice of collecting two units of platelets from a single apheresis donor. If the volumetric reduction of blood product leads to increased costs, or our process requires changes in blood center or clinical regimens, customers may not adopt our product. In addition, our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may inhibit their acceptance.

Prior to February 2006, Baxter had been responsible for the marketing, sales and distribution of the platelet system in the United States, Europe and other regions not covered by the agreements with BioOne. Baxter also had been responsible for the marketing, sales and distribution of the plasma system following marketing approval in Europe and other countries, excluding North America, and the regions covered by the agreements with BioOne. As a consequence of the February 2006 agreement with Baxter, we have established a wholly-owned subsidiary, Cerus Europe B.V., located in the Netherlands and are building our own independent marketing and sales organization based in Europe to market and sell the INTERCEPT Blood System in Europe and Middle East. We also have a small scientific affairs group that supports the commercialization efforts.

Table of Contents

Under our April 2004 agreement with MedImmune, MedImmune is responsible for development, sales and marketing of any products resulting from our collaboration. We are solely responsible for the continued development, clinical trials, regulatory approval and subsequent marketing and sales of our immunotherapy product candidates that are not partnered. It will take a long time for us to complete preclinical development, clinical trials and regulatory approval for one or more of our immunotherapy product candidates. Before we submit any applications for regulatory approval of these products, we expect to have a sales and marketing plan in place, which could include formation of internal sales and marketing functions, collaborating with one or more third-parties with sales and marketing capabilities, or both.

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 on a distributed basis with single units of blood products, which allows for integration with current blood collection, processing and storage procedures. Competing products in development or currently on the market, such as solvent detergent-treated plasma, use centralized processing that takes blood products away from the blood center. In addition, some potential competitors utilize a pooling process prior to pathogen inactivation, which significantly increases the risk of cross-contamination by pathogens that are not inactivated. One potential competitor has initiated a Phase III clinical trial in France using a pathogen inactivation process for platelets. Other competitors are marketing pathogen inactivation products for plasma in Europe. There are no known competitors in the clinical development stage for pathogen inactivation of red blood cells. 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.

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, 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 biopharmaceutical field is characterized by rapid and significant technological changes. 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.

We believe our approaches to cancer and infectious disease immunotherapy have certain competitive advantages over currently available treatments or those now in development. However, the markets for treatments of cancer and infectious disease are intensely competitive and subject to rapid change. Many companies with significantly greater resources than ours have established products on the market, as well as promising product candidates in more advanced development stages than our programs. Our ability to bring to market products that achieve a significant degree of commercial success will be dependent on a number of factors, including their efficacy and safety as shown in human clinical trials relative to the standards of care then in place, our ability to receive regulatory approval to sell products in the United States and in foreign jurisdictions, our ability to scale up and manufacture at acceptable cost, the availability of reimbursement from managed care organizations, and our ability to establish distribution channels for our 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.

Table of Contents

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, 2006, we owned approximately 40 issued or allowed United States patents and approximately 50 issued or allowed foreign patents. Our patents expire at various dates between 2009 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 Baxter to United States and foreign patents relating to the INTERCEPT Blood System and have licenses to United States and foreign patents relating to our immunotherapy programs. 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.

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 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. Several European countries require additional in-country studies to support an approval to market the products in such countries.

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 or biologic may be approved for marketing in the United States pursuant to a pre-market approval application, or PMA, or a biologics license application, or BLA, respectively, generally include (i) preclinical laboratory and animal tests, (ii) submission to the FDA of an investigational device exemption (for medical devices) or an IND application (for drugs or biologics) for human clinical testing, which must become effective before human clinical trials may begin, (iii) appropriate tests to show the product s safety, (iv) adequate and well-controlled human clinical trials to establish the product s safety and efficacy for its intended indications, (v) submission to the FDA of a PMA or BLA, as appropriate, and (vi) FDA review of the PMA or BLA 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 systems for platelets, plasma and red blood cells, and a BLA for vaccines for cancer and infectious diseases. 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 product, CBER also regulates the blood collection centers and the blood products they prepare using our medical device.

Table of Contents

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 U.S. 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 consists of studies that differ from typical Phase I, Phase II and Phase III clinical studies.

Many of the INTERCEPT Blood System preclinical and clinical studies have been conducted using prototype system disposables and devices. We 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 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 collection equipment, including Baxter. 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 elect to prioritize regulatory efforts in the United States, we may initially seek FDA approval of the platelet system configured for Baxter 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.

Cancer immunotherapies and vaccines for infectious diseases are regulated by CBER. Cerus has filed one IND for which approval was granted in early 2006, and is planning to file one or more applications for

Table of Contents

immunotherapies in the future. Toxicology studies will be required. Completion of such studies could result in findings that limit the feasibility of one or more particular immunotherapy development programs. There is no assurance at this time that the FDA will accept the design of the planned clinical protocols until pre-IND meetings are held. For some immunotherapies, including CRS-207, submission to the Recombinant DNA Advisory Committee, or RAC, of the NIH will be necessary. The RAC may make recommendations that delay initiation of clinical trials. A series of clinical studies will be necessary to gain sufficient information to submit a BLA to the FDA. Failure of pivotal clinical trials to demonstrate safety and efficacy will preclude moving forward in clinical development or filing of the associated BLA for a product candidate. During the review process for the BLA, it is expected that the FDA will request review by an advisory committee, which will make recommendations for or against approval. There are a number of companies pursuing development of cancer immunotherapies. Failure of these types of approaches to demonstrate sufficient efficacy or safety to gain regulatory approval could influence the regulatory process for our product candidates.

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.

Employees

As of December 31, 2006, we had 124 employees, 71 of whom were engaged in research and development and 53 in selling, general, and administrative activities. Of the 53 employees engaged in selling, general, and administrative activities, 17 employees were employed by our European subsidiary, Cerus Europe B.V. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

Available Information

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

Table of Contents

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

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occur, 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. All references to Baxter in these Risk Factors should be read, as to future contingencies, to include any assignee of Baxter s obligations under our agreements.

The INTERCEPT Blood System may not achieve broad market acceptance.

Under our previous agreements, Baxter s sales and marketing organization had made only modest progress in commercializing the platelet system in European countries where it has been fully approved for sale. Despite obtaining CE mark approval of the platelet system in late 2002, Baxter and we have encountered governmental and blood banking community resistance to commercial adoption, including concerns from some national transfusion services, governmental agencies and healthcare policy groups regarding efficacy, cost and risk-benefit profile. Some potential customers have indicated that further safety information or additional studies would be required before adopting our products. There is some volume loss in the yield of blood products as a result of our pathogen inactivation process. In addition, our platelet system process today is not fully compatible with the common practice of collecting two units of platelets from a single apheresis donor. If the volumetric reduction of blood product leads to increased costs, or our process requires changes in blood center or clinical regimens, customers may not adopt our platelet system product. Our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens 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.

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into their 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 require upfront investment in UVA illuminators, disposable kit inventory and staff training. Even if our product candidates receive regulatory approval for commercial sale, blood centers, physicians, patients and healthcare payors may not believe that the benefits of using the INTERCEPT Blood System justify their additional cost. 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 Blood System-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 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 reimbursement discussions, which generally occur between blood centers and national or regional ministries of health and private payors. For example, while the platelet system has been approved in France for use by blood centers in treating platelets, commercial adoption has been delayed pending determination of national reimbursement rates for pathogen inactivated platelets. We may be required to seek explicit reimbursement in European countries for our plasma system, even though other competing pathogen inactivation products for plasma have been approved and are being reimbursed in Europe presently. It is difficult to predict the reimbursement status of newly approved, novel medical device or biopharmaceutical 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 such controls.

Table of Contents

The widespread adoption of managed care in the United States has also placed 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.

We may be required to reduce the sales price for our products in order to make them 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 and sell the systems are in excess of revenue. We may be unable to increase sales to a level sufficient to generate profit contribution. We believe that future product sales in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products, nor are we prioritizing seeking such approval. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable. In addition, failure to advance the red blood cell system toward regulatory approval and commercialization may have a negative impact on customers willingness to adopt the platelet and plasma systems, which could prevent us from achieving profitability. Deferring pursuit of regulatory approval of the INTERCEPT Blood System in the United States due to strategic priorities favoring Europe may have adverse consequences on market acceptance of the INTERCEPT Blood System globally.

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, 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 nation s 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, where general cost containment pressures have delayed consideration of the INTERCEPT Blood System to date. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a blood center-by-blood center basis, but depend on both local and centralized regulatory approvals. While the platelet system has received in-country regulatory approval in France, adoption has been delayed in the absence of national reimbursement rates for pathogen inactivated platelets. In-country regulatory approval in France for the plasma system was obtained in early 2007. However, adoption may be delayed until the existing national reimbursement rates for pathogen inactivated plasma are extended to the INTERCEPT plasma system. The Japanese Red Cross controls a significant majority of blood transfusions in Japan. 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.

Our products under development, and anticipated future products, 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;

Table of Contents

sales and distribution;

use standards and documentation;

post-launch surveillance;

quality;

advertising and promotion; and

reimbursement.

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. 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.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by the 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. Before entering human clinical trials, product candidates in our immunotherapy programs beyond CRS-100 likely will be subject to review by the RAC of the NIH, which could delay initiation of clinical trials.

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. We were found to be in compliance with ISO 13485 quality management system requirements in an audit conducted by European Union regulators in late 2006. 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. Gaining FDA approval for our platelet and plasma products would require additional investment and time, because the current manufacturing sites we rely upon for producing the platelet and plasma system products for European distribution 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 that could further delay or preclude regulatory approval 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 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, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation with which we have no familiarity.

We will be required to obtain a CE mark extension from European Union regulators for our platelet system, originally obtained by Baxter in 2002, by May 2007 and every five years thereafter. In addition to European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries, including France, Germany and England, to market our products. In addition, our customers in many

Table of Contents

countries must obtain regulatory approval to sell blood components treated with the INTERCEPT Blood System. The level of additional product testing varies by country, but could 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 sales and profitability.

To support our requests for regulatory approval to market our product candidates, we have conducted and intend to conduct various types of studies including:

- toxicology studies to evaluate product safety;
- laboratory and animal studies to evaluate product effectiveness;
- human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components or immunotherapies; and
- manufacturing and stability studies.

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 and our vaccine candidates 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 candidates 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. With respect to an additional Phase III trial of the platelet system in the United States, we expect the FDA to require us to demonstrate a very low level of potential side effects. Trials of this type may be too large and expensive to be practical.

Preclinical testing and clinical trials involving our immunotherapy product candidates are long, expensive and uncertain processes. We have only recently begun Phase I human clinical testing of our *Listeria* platform technology and we have not yet begun testing of our KBMA platform technology in humans. Preclinical results in animals and *in vitro* testing we have conducted to date with our two immunotherapy platform technologies may not translate to demonstration of safety and efficacy in human clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advancing stages of clinical trials, even after promising results in earlier preclinical and clinical trials. In addition, regulators and investigators may impose more stringent, time consuming and expensive clinical trial requirements than we might otherwise choose to pursue as a precondition to proceeding with clinical testing. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process.

We do not know whether we or our collaborators 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 cancer and infectious disease 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

Table of Contents

clinical trials and product candidates emerging from any successful trials would not reach the market for several years.

Regulatory delays can also materially impact our product development costs. If we experience delays in testing 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 make additional payments to third-party investigators and organizations to retain their services. If the delays are significant, our financial results and the commercial prospects for our product candidates 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 or animal data to support such claims. After regulatory approval for the initial indications, further clinical trials 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 applicable to our prospective customers of INTERCEPT Blood System products, 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 or European regulatory authorities before making available blood products processed with our pathogen inactivation systems to hospitals and transfusing physicians. This requirement or regulators delays in approving these supplements may deter some blood centers from using our products. Blood centers that do submit supplements 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.

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.

Except for the INTERCEPT platelet and plasma systems, which have received CE mark approval and regulatory approval in certain countries in Europe, we have no products that have received regulatory approval for commercial sale and are being marketed. Our product candidates are in various stages of development, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our product candidates 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 that demonstrate our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale.

In 2002, the platelet system received CE mark approval in Europe. We will need to complete validation studies and obtain regulatory and reimbursement approvals in certain European countries before we can market our products in those countries. We expect that further randomized clinical trials funded by third parties will be conducted in some European countries, such as the Netherlands. We also expect to conduct many smaller scale experience trials with prospective customers in a number of European countries. We expect that decisions to adopt the platelet system may be deferred until completion of the additional trials and experience studies in Europe. In certain countries, including Germany and Switzerland, the system must be approved for purchase or use by a specific governmental or non-governmental entity or entities, such as the Paul Ehrlich Institute in Germany. In France, the platelet system has been approved for use by blood centers in treating platelets; however, we do not expect to sell the platelet system broadly to commercial customers until national reimbursement rates for pathogen inactivated platelets treated with the INTERCEPT platelet system are set.

Table of Contents

We completed our Phase III clinical trial of the platelet system in the United States in March 2001 and have 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. The report included conclusions from the expert physician panel. Based upon further discussions with the FDA following submission of that report, we continue to expect that the FDA will require an additional, significantly larger Phase III clinical trial to evaluate the hemostatic efficacy and safety of the platelet system, using the Company s final commercial product design, as compared to conventional platelets. We also 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, and that data on such events would need to be gathered in the additional Phase III trial. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. The additional Phase III clinical trial would need to be completed and data from the trial submitted to the FDA before we could complete our regulatory submission. The FDA may not find the data from any additional clinical trials to be acceptable for approval. Before we begin an additional clinical trial, we will need to gain concurrence with the FDA on our trial design. We may not be able to reach concurrence on the size, scope or design of the study.

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. 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 may be required to perform additional clinical studies using the commercial configuration of the system in order to obtain regulatory approval.

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 two patients, 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 to date 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 are utilizing a manual processing system in the Phase I trial, which system is not in a commercially feasible form. 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 and while those clinical trials are being conducted, including determining the appropriate design of additional Phase I or subsequent Phase II clinical trials, if deemed necessary, and Phase III clinical trials, and developing a commercially feasible red blood cell system, including disposables, hardware and software for implementing the process in blood collection centers. These development initiatives may be costly and time consuming. Even if the project proceeds on course, we would not expect to initiate a Phase III trial for our red blood cell system prior to late 2008. 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.

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.

Table of Contents

It may take us several years to complete our clinical testing, and failure can occur at any stage of testing. Enrollment criteria for certain of our clinical trials may be quite narrow. Consequently, we may be unable to recruit suitable patients into the trial on a timely basis, if at all. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

We have very limited experience in marketing and sales, or in managing a commercial operation in Europe. We can no longer rely upon Baxter for sales, marketing, distribution and regulatory support of the INTERCEPT Blood System products and have formed a new subsidiary in Europe to assume such responsibilities. We have limited experience in managing regulatory affairs, particularly with foreign authorities.

Upon reaching agreements with Baxter in February 2006, we became fully responsible for sales, marketing and distribution support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. As a consequence, we will no longer be able to rely upon Baxter for sales, marketing and distribution support of the INTERCEPT Blood System. Further, the February 2006 agreements required that Baxter provide regulatory support for the INTERCEPT Blood System only through the end of 2006, and as a result, we can no longer rely on such support from Baxter. We have been particularly dependent on Baxter in Europe, where the platelet system and, more recently, the plasma system, have been approved for sale in certain countries. If we fail in our efforts to develop 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 must develop, build and manage marketing, sales, distribution, customer service and back office functions necessary to support commercialization of the INTERCEPT Blood System in Europe. Historically, we have had a small scientific affairs group that has helped support Baxter s European sales and marketing organization; however, we did not maintain our own independent sales and marketing organization. We may be unable to maintain existing customer relationships established by Baxter as we take on responsibility for sales, marketing and customer service. Beginning in early 2006, we began to recruit a small European organization dedicated primarily to selling and marketing the platelet system and more recently, the plasma system, in Europe. We may be unable to recruit suitable sales, marketing, regulatory, and quality assurance personnel on a timely basis, if at all. We also need to continue developing distribution, customer service, and back office capabilities either internally or by contracting with third parties, which we may be unable to accomplish on a timely or maintain on an affordable basis. In addition to adding sales and marketing capabilities, we have needed to develop appropriate inventory and logistics management, receivables and collections, foreign exchange, risk management, human resources, information and quality systems capabilities. Generally, such capabilities must be built in compliance with European standards and practices, with which we have little experience. We also have had to develop customer service capabilities to insure uninterrupted supply, timely calibration and servicing of UVA illuminators, and appropriate and timely resolution of customer complaints. We may be unable to operate a European organization effectively and efficiently, even after Cerus Europe B.V. is fully staffed. Developing sales, marketing and operational capabilities ourselves will increase our costs and may delay commercialization of our pathogen inactivation systems.

We must develop regulatory capabilities for clinical-stage and Phase IV trials involving the INTERCEPT Blood System globally. Following our February 2006 agreements with Baxter, we have taken on worldwide responsibility for regulatory activities regarding the INTERCEPT Blood System,

Table of Contents

except in territories covered by our agreement with BioOne for the platelet and plasma systems, provided that Baxter remained as the registrant or applicant under European registrations and applications for a transition period in 2006. We will need to complete the transition from Baxter, where we must gain regulatory approval to switch product labels to our brand. Failure to do so may slow the rate of sales of the platelet system or delay the launch of our plasma system. We need additional resources to support regulatory activities and post-approval trials relating to these products. We may not have adequate internal resources and capabilities to manage Phase IV 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 system. 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 inabilities 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 will continue to rely on Baxter for manufacturing and supplying components of our platelet and plasma systems for a limited period of time. Over a longer period, we will need to identify, select and qualify third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system.

We rely on third parties for manufacturing and supplying components of our platelet and plasma systems. Under the terms of our agreements, Baxter is currently responsible for manufacturing and supplying illuminators and disposable kits associated with the platelet and plasma systems for commercial use through 2008 and certain components of the platelet and plasma systems through 2009. We will also be dependent on Baxter to transfer know-how relevant to the INTERCEPT Blood System; however, certain of Baxter s materials, manufacturing processes and methods are proprietary to Baxter. We may be unable to establish alternate sources of supply to Baxter 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. If Baxter fails to manufacture an adequate supply of components or devices within quality specifications, we may be unable to supply products to our customers. Baxter 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. Any delay in the availability of devices or components from Baxter could delay further regulatory approvals, market introduction and subsequent sales of the systems. Moreover, the inclusion of components manufactured by others could require us to seek new approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. Baxter manufactures our platelet and plasma systems in facilities that are not FDA-approved. Our agreements do not require Baxter to validate these manufacturing facilities with the FDA. In order to be sold in the United States, our systems would be required to be manufactured in an FDA-approved facility. FDA validation of a manufacturing facility, whether owned by Baxter or by another party, will be costly and time-consuming.

Baxter has entered into a definitive agreement to sell its Transfusion Therapies business unit and, under that agreement, the buyer will assume Baxter s manufacturing obligations to Cerus. On October 3, 2006, Baxter announced that it had entered into a definitive agreement to sell 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 formed by an investment group led by Texas Pacific Group. Subject to regulatory approvals and other customary closing conditions, Baxter has informed us that it expects the transaction to close within the first quarter of 2007. We have been informed by Baxter that the new company will assume Baxter s obligations to us under the manufacturing agreement. However, the new company may fail to manufacture an adequate supply of

Table of Contents

components or devices of the INTERCEPT Blood System, which would subject us to the risks described above. Certain components of the INTERCEPT Blood System are currently manufactured or assembled at facilities not within the Transfusion Therapies business unit. Baxter and/or the new company will continue to be obligated to supply illuminators and disposable kits associated with the platelet and plasma systems to us generally through 2008 and for certain components through 2009. Failure to supply an adequate supply of components or devices of the INTERCEPT Blood System, would subject us to the risks described above. In addition, because the components of the INTERCEPT Blood System are manufactured and assembled at multiple facilities owned by both Baxter and the new company leading up to final assembly, Baxter and the new company will remain interdependent with respect to the INTERCEPT Blood System supply chain. Baxter and the new company 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 above.

We will be required to identify and enter into agreements with third parties to manufacture the INTERCEPT Blood System products and related blood component storage solutions. Baxter s manufacturing responsibilities for illuminators and disposable kits associated with the platelet and plasma systems in general extend through 2008 and for certain components of the platelet and plasma systems through 2009, after which we will assume manufacturing responsibilities. Except for very limited manufacturing of disposable components, Baxter is no longer 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 our products.

Our potential remedies against Baxter may be inadequate in assuring that Baxter meets its contractual obligations. In the event of a failure by Baxter to perform its 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 agreement with Baxter contains limitations on incidental and consequential damages that we may recover. Baxter s potential liability in the event of non-performance may not be sufficient to compel Baxter 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 manufactured by others.

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, by 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 Canada, 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 Baxter. For platelets collected by apheresis, the INTERCEPT platelet system is most compatible with Baxter 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

Table of Contents

concentrate. As a result, we have conducted most of our clinical studies using either Baxter 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.

In order to address the entire market in the United States, we would need to develop and test additional configurations of the INTERCEPT platelet system. Our efforts to develop the platelet system to date have focused almost entirely on apheresis platelets collected on Baxter s automated collection platform. 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. We may be required to make our systems compatible with random donor platelets. In order to develop a platelet pathogen inactivation system compatible with random donor platelets, we would need to perform additional product development and testing, including additional clinical trials. These development activities would increase our costs significantly, and may not be successful.

Baxter has committed to us to make Intersol collection and pooling products and conversion kits available to customers. However, Baxter 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. Making our platelet system readily compatible with the Haemonetics apheresis collection system will require certain changes in the Haemonetics device, and there can be no assurance that Haemonetics will undertake this effort on a timely basis or be commercially successful. Gambro, Inc., or Gambro, another major supplier of automated platelet collection systems, is conducting clinical trials of its own system for pathogen inactivation of platelets. For competitive reasons, Gambro may have little or no incentive to make its apheresis collection system compatible with our platelet system. Attaining compatibility with collection platforms manufactured by others would require adaptations to either our platelet 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 platelet system may be delayed until the system receives regulatory approval for use on such other equipment.

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 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. Baxter relies on third parties 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. Baxter 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, Baxter s costs to manufacture commercial components for the platelet system have been greater than we previously anticipated and may continue to rise. This may reduce our potential gross profit margin from platelet and plasma system sales.

We may be unable to contract with third parties to supply the INTERCEPT Blood System in adequate quantities or to manufacture the system or its components at acceptable cost. We are in the initial stages of commercializing the INTERCEPT Blood System in Europe and may not accurately forecast demand for the INTERCEPT Blood System. We may be unable to contract with third parties to supply adequate numbers of platelet and plasma systems and components to meet demand and, as a result, supply to our customers may be

Table of Contents

interrupted. If Baxter 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. In the United States, studies related to the platelet system disposable and compound manufacturing need to be completed and included in FDA submissions before the FDA would consider the applications for approval.

Baxter and we purchase certain key components of the INTERCEPT Blood System from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. 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 Baxter 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. If Baxter 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 intend to use third-party manufacturers to produce commercial quantities of the chemical compounds to be used in our products. These compounds have not yet been produced in quantities sufficient to support commercialization for all regions in which we may market our products. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, a proprietary compound used in our platelet and plasma systems. We currently do not have any third-party manufacturing agreements in place for commercial production of compounds used in our red blood cell system. 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.

We have relied on Baxter for transition services. We will need to perform these services ourselves or identify one or more alternative third-party providers.

Under the terms of our February 2006 agreement, Baxter was required to provide certain transition services relating to European activities, at our expense. These services included specified regulatory and clinical support activities, installation, maintenance and calibration services, and order entry, billing and collections from customers, device and systems development, monitoring and responding to customer complaints, and clinical education and training provided through December 31, 2006, and manufacturing technical information and advice, which Baxter is obligated to provide through December 31, 2008. We have also been reliant on Baxter to manage operational aspects of our presence in Europe, including compliance with local, national and EU regulations relating to labor law, taxes, logistics, credit and collections and administration. We need to continue to develop internal competencies in sales, marketing, distribution, regulatory support, operations and administration or arrange for third parties to provide certain of these necessary services. We may be unable to assume these functions ourselves or identify alternative third-party providers on a timely basis or on reasonable terms, if at all. Any delay in these activities could delay further regulatory approvals, market introduction and subsequent sales of the systems.

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.

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 our new 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

Table of Contents

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

We rely on BioOne for commercialization of our platelet and plasma systems in many Asian countries.

Baxter and we have licensed to BioOne, rights to commercialization of the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in those countries. We understand that Baxter does not intend to maintain its CE mark registration for the platelet system after it expires in mid-2007. In addition, we received CE mark approval for the plasma system independently from Baxter, and Baxter is not intending to apply for a CE mark for the plasma system. However, BioOne is dependent on Baxter for the manufacture and supply of the platelet and plasma systems well beyond the time when Baxter intends to let its CE mark registration for the platelet system lapse. BioOne is also dependent on Baxter for providing certain regulatory support and the timely transition of regulatory files and dossiers. BioOne may be unable to qualify the platelet and plasma systems for sale in certain countries in its territory in the absence of CE marks being held by Baxter, even if CE marks are held by us. BioOne has made only limited 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 sales. We understand that BioOne will need to raise additional capital in the first half of 2007 in order to fund its operations. There is no assurance that BioOne will be able to attract additional required capital to successfully commercialize those products licensed from Baxter and us. BioOne may not be successful in commercializing the platelet and plasma systems in its Asian territories, in which case the value of BioOne s equity likely would decline and may give rise to an impairment in the carrying value of our equity interest in BioOne.

Our vaccine programs are in an early stage of development.

Our vaccine programs are in an early stage of development and there is a high risk of failure. We will be required to perform extensive preclinical and clinical testing before any product candidate can be submitted for regulatory approval prior to commercialization. Clinical testing is very expensive, takes many years, and the outcome is uncertain. Failure to demonstrate the safety or efficacy of a product candidate in preclinical studies or clinical trials would delay or prevent regulatory approval of that product candidate. Our potential vaccine products must meet rigorous testing standards in order to advance to clinical testing. Other than CRS-100 being tested in our current Phase I clinical trial, no product candidates employing either our *Listeria* or our KBMA platform technologies have been tested in humans, and preclinical data in animal studies and from *in vitro* experiments may not be predictive of clinical safety and efficacy once product candidates are tested in humans. Our immunotherapy product candidates are unlikely to be used as single agents for the treatment of cancer or infectious diseases, but rather in combination with other drugs and treatment regimens. Testing our vaccines in

Table of Contents

combination with other drugs and treatment regimens in clinical trials will introduce additional clinical, timeline and regulatory risks and complexities, including added expense, delay in conducting clinical trials and uncertain regulatory requirements.

Naturally-occurring *Listeria* is a bacterium that is a human pathogen that can cause serious illness. Our immunotherapy product candidates for cancer indications use proprietary, modified strains of *Listeria* that are designed to have a substantially reduced ability to cause illness in humans. However, before our vaccine candidates can be accepted for clinical testing, we must successfully complete a number of preclinical safety studies. We may not be able to identify a dose range in which our product candidates are therapeutically effective and yet maintain adequate safety margins. Investigators have encountered and may continue to encounter difficulties in enrolling suitable patients in our trials, which have contributed to delays and increased costs in completing the CRS-100 Phase I trial. Clearance of a Phase I clinical trial using CRS-100 does not imply concurrence by FDA to our conducting later stage studies with CRS-100 and does not imply clearance for clinical trials of our other *Listeria* vaccine candidates expressing antigens, such as CRS-207. Because CRS-207 and our other preclinical product candidates using *Listeria* rely on the same base strain of *Listeria* used in CRS-100, any adverse findings in clinical trials of CRS-100 would likely adversely affect our ability to develop and test these other product candidates in human clinical trials. Our Phase I clinical trial for CRS-100 involves testing in a patient population with advanced disease. We may be unable to test CRS-100 and our other product candidates in subsequent trials in patient populations that we believe may be better suited clinically or commercially to our vaccines.

Because our vaccine candidates use novel platforms, the FDA or foreign regulators may require studies that we have not anticipated. In addition, we have contracted with third-party manufacturers to produce our vaccines for research, preclinical and clinical testing. We have manufactured CRS-100 for toxicology studies and Phase I clinical trials, but have not engaged in scale-up of the manufacturing process or the development of a commercial formulation. We also rely on third parties to conduct aspects of preclinical and clinical development on our behalf, including contract manufacturing and research services. These third parties may encounter delays, over which we have significantly less control than research and development activities performed in-house, or experience unexpected results. We may experience numerous unforeseen events during, or as a result of, the preclinical research and development process that could delay or prevent clinical testing, regulatory approval and commercialization of our potential products.

Our ability to successfully develop cancer and infectious disease products is dependent in part on being able to attract and retain partners and collaborators, as well as governmental funding sources.

The development and commercialization of product candidates employing our *Listeria* and KBMA platform technologies will be expensive, lengthy and uncertain. To date, we have relied not only upon internal scientific, development and financial resources, but also upon third parties. We have licensed our *Listeria* platform to MedImmune for use in developing a product candidate potentially applicable to cancers expressing EphA2, a proprietary antigen owned by MedImmune. We are collaborating with investigators at Johns Hopkins University on other cancer and infectious disease programs. We also rely on advice and insights from our scientific advisory board, a group of independent clinicians, professors and investigators, regarding our research and development activities. These relationships provide us with external perspectives and independent validation that may be critical to our future success. Loss of these relationships or failure to attract others may result in additional expense, delays in development and regulatory approval and failure to commercialize products. We have received significant funding from United States government agencies for research and development in both cancer and infectious disease, as well as funding from MedImmune under our license agreement relating to development of MEDI-543 (EphA2); however, development funding from MedImmune to Cerus ceased at the completion of contracted work we had performed through early 2006 and MedImmune is pursuing advanced preclinical work on MEDI-543 on its own. Due to budgetary constraints, funding from the Federal government, particularly funding from the Department of Defense and National Institutes of Health, is expected to be reduced from prior years and is subject to political and economic forces beyond our control. Additionally, we no longer

Table of Contents

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.

Academic and third-party funding we have been awarded to date for early-stage preclinical development of our therapeutic vaccine candidates for hepatitis C and HIV may be inadequate to allow us to demonstrate proof-of-concept of our KBMA *Listeria* approach as potential standalone or combination therapies for these indications. Federal funding in support of our programs to develop prophylactic vaccines against anthrax and tularemia is not expected to lead to substantial commercial opportunities beyond potential biodefense applications, and we cannot be certain that the research conducted into those two infectious diseases will readily translate into applications with greater commercial potential. We may be unable to attract additional external funding to allow us to continue development of these product candidates. Loss of funding from government sources and third parties would require us to reduce the scope of our research and development efforts in immunotherapeutics, narrowing the number of programs to those we could support through internal resources.

If our competitors develop and market products that are more effective than our product candidates, our commercial opportunity will be reduced or eliminated. Conversely, if competitors encounter difficulties or failures in human clinical trials, we may face additional clinical and regulatory challenges.

We expect our products to encounter significant competition. The INTERCEPT Blood System products may compete with other approaches to blood safety currently in use, as well as 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. In Europe, several companies, including Grifols, Octapharma AG and Maco Pharma International GmbH, are developing or have developed and are selling commercial pathogen inactivation systems to treat fresh frozen plasma. Navigant Biotechnologies, a wholly owned subsidiary of Gambro Group, is developing a pathogen inactivation system for blood products.

New methods of testing 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 the platelet system in France and Germany may impact our ability to compete with bacterial testing for platelets. Tests have recently been approved to detect West Nile Virus in blood products. Other groups 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 impair the potential market for our products.

There are many companies pursuing programs for the treatment of cancer and treatment and prevention of infectious disease. Some are large pharmaceutical companies, such as Pfizer, GlaxoSmithKline, Sanofi-Aventis, Bristol-Myers Squibb, Genentech and Gilead, which have greater experience and resources in product development, preclinical testing, human clinical trials, obtaining FDA and other regulatory approvals and in manufacturing and marketing new therapies. We are also competing with other biotechnology companies, such as Cell Genesys, Inc., Coley Pharmaceutical Group, and Dendreon Corporation, that have cancer vaccine programs that are in more advanced stages of development than ours. In addition, other companies are pursuing early-stage research and development of *Listeria*-based immunotherapies. If any of these companies products

Table of Contents

are shown to be more efficacious than ours, our *Listeria*-based products may fail to gain regulatory approval or commercial acceptance. If these companies products fail in human clinical trials, we may be required to overcome more significant regulatory barriers prior to gaining approval, face more challenging impediments to market acceptance and may be unable to raise capital to fund development of our *Listeria* or KBMA programs.

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.

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 in clinical trials or 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 at a single site that may be subject to lengthy business interruption in the event of a severe earthquake.

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

We may never achieve a profitable level of operations. To date, we have engaged primarily in research and development. 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. In 2005, we realized a $22.1 million nonrecurring gain associated with the restructuring of a loan payable in 2005 and, as a result of this gain, we recorded net income of $13.1 million in 2005. At December 31, 2006, we had an

Table of Contents

accumulated deficit of approximately $311.4 million. Except for the platelet and plasma systems, which have received European Union CE mark approval, all of our products are in the research and development stage, and we have not received significant revenue from product sales. We have received substantially all of our revenue from our agreements with our development partners and from federal research grants and cooperative agreements. We will be required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. We expect our losses to continue at least until more of our product candidates are commercialized and achieve significant market acceptance.

If we fail to obtain the capital necessary to fund our future operations, we will not be able to develop product candidates in our pipeline.

Our product development programs are capital-intensive. We may need to reduce or stop further investment in specific research and development or sales and marketing activities if we are unable to obtain additional capital or if any of our development programs are determined by us to be economically unfeasible. A product or program may be determined to be uneconomic if the commercial opportunity is insufficient to justify the investment required to develop and market the product or for other reasons. We expect that our spending in support of research, development and commercialization of the platelet and plasma systems will be in excess of contribution from product sales, milestone payments and development funding for such programs from third parties over the next year. We re-entered clinical trials for the red blood cell system in mid-2006 with only partial funding from governmental sources. In addition, as a consequence of the February 2006 restructuring agreement with Baxter, we have taken on increasing operational and financial responsibility for the commercialization of the platelet and plasma systems, particularly in Europe. As a result of these factors, further product development and commercialization of the INTERCEPT Blood System may take longer and be more expensive than we previously anticipated. We expect to continue to spend substantial funds for our operations for the foreseeable future. Our cash, liquidity and capital requirements will depend on many factors, including the development progress and costs of our programs, payments from collaborators, funding from agencies of the United States government, costs related to creating, maintaining and defending our intellectual property position, regulatory approval and successful commercialization of our product candidates, competitive developments and regulatory factors.

Through December 31, 2006, we had been awarded $38.7 million in funding under cooperative agreements with the Department of Defense, and have received $35.1 million in proceeds from these awards. We also have received funding under grants from the National Institutes of Health. Further funding awarded under federal grants and cooperative agreements is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. 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. If we are unable to obtain Federal grant and cooperative agreement funding for future 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.

Table of Contents

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 our work predates the invention disclosed in that patent. We are continuing to review that patent and will make a determination as to whether any action is necessary. In addition, others hold patents, and have pending patent applications, concerning *Listeria*-based immunotherapies. Those patents and new patents that may be issued upon the pending applications, if valid, would restrict us from bringing to market particular embodiments of *Listeria*-based immunotherapy products. While we believe that such restrictions do not preclude us from developing and commercializing our *Listeria*-based immunotherapy products, they may preclude us from pursuing certain product approaches that might otherwise be promising. Our patents expire at various dates between 2009 and 2018. Recent patent applications, principally related to our immunotherapy programs, will, if granted, result in patents with later expiration dates. 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.

Table of Contents

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 incur operating expenses in 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 (Expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. 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, 2004 to December 31, 2006, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of $1.60 to a high of $14.76. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

biological or medical discoveries;

technological innovations or new commercial services 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;

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.

The stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and medical device companies, and which have often been unrelated to the operating performance of such companies. These broad market fluctuations may adversely affect the market price of our common stock.

If there is an adverse outcome in the securities class action litigation that has been filed against us, our business may be harmed.

We and certain of our current and former officers and directors are named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Northern District of California. The lawsuit is brought on behalf of a purported class of purchasers of our securities, and seeks unspecified damages. In addition, our directors and certain of our current and former officers have been named as defendants in a derivative lawsuit in the Superior Court for the County of Contra Costa, California, which names Cerus as a nominal defendant. The plaintiff in this action is a Cerus stockholder who seeks to bring derivative claims on

Table of Contents

behalf of Cerus against the defendants. The lawsuit alleges breaches of fiduciary duty and related claims. On August 31, 2006, we announced that we had reached agreements to settle the outstanding class action and derivative lawsuits. Pursuant to the terms of the settlement agreements, the plaintiffs agreed to provide the defendants with a release of all claims related to such class action and derivative lawsuits without any admission of wrongdoing or liability by any party. Under these settlement agreements, the total cash settlements will be funded entirely by insurance carriers under our directors' and officers' liability insurance policy and will have no financial impact on Cerus.

On February 16, 2007, the federal district court granted final approval to the class action settlement. On February 21, 2007, the state court granted final approval to the derivative settlement. Both settlements will become effective upon the expiration of the time in which to appeal the judgments of dismissal that the federal and state courts have entered or soon will enter. Under terms of the settlements, the Company believes that these matters will not have a material effect on its results of operations or financial position; however, it cannot predict when, if ever, the settlements will become effective. If the settlements do not become effective, we may have to incur substantial expenses in connection with these lawsuits and in the event of an adverse outcome, our business could be harmed.

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 and reporting on these assessments. 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 our assessment of, 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 approximately 21,400 square feet for our main office facility in Concord, California. The lease for this facility extends through July 2007, with an option to renew for an additional three-year period. We also have leases for approximately 17,400 square feet, approximately 9,900 square feet, approximately 31,800 square feet, and approximately 4,500 at four other facilities, all of which contain laboratory and office space and are located near our main office facility in Concord. These leases extend through June 2009, January 2010, October 2007, and August 2009, respectively. Our 9,900 square foot facility contains three one-year renewal options, our 31,800 square foot facility contains four remaining one-year renewal options, and our 4,500 square foot facility contains three one-year renewal options. These facilities are utilized by both our blood safety and immunotherapy segments.

We also lease approximately 4,500 square feet of administrative office space in Leusden, The Netherlands. This lease extends through March 2008. Our European facility is utilized by our blood safety segment. We believe that our current facilities and available additional space will be adequate for the foreseeable future.

Table of Contents

Item 3. ***Legal Proceedings***

On August 31, 2006, we announced that we had reached agreement to settle the class action lawsuit, pending since 2003 in the United States District Court for the Northern District of California, against certain of our current and former directors, officers and us. The amended and consolidated complaint alleged that the defendants had violated the federal securities laws by making allegedly false and misleading predictions regarding the initiation and completion of clinical trials, submission of regulatory filings, receipt of regulatory approval and other milestones in the development of the platelet, plasma and red blood cell systems. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our securities during the period from December 9, 2000, through January 30, 2003.

On August 31, 2006, we also announced that we had reached agreement to settle the derivative lawsuit, pending since 2003 in the Superior Court for Contra Costa County, in which certain of our current and former directors and officers were named as defendants and the Company was named as a nominal defendant. The plaintiffs were Cerus stockholders who sought to bring derivative claims on behalf of the Company against the defendants. The consolidated complaint alleged breach of fiduciary duty and related claims and sought an unspecified amount of damages.

Pursuant to the settlement agreements, the plaintiffs in the class action and in the shareholders derivative lawsuit will release defendants from all known and unknown claims related to such litigation, without any admission of wrongdoing or liability by any party. Under these settlement agreements, the total cash settlements will be funded entirely by insurance carriers under our directors' and officers' liability insurance policy and will have no financial impact on us. Additionally, under the derivative suit settlement, we agree to take or continue certain corporate governance measures. These measures involve, among others, our making a good faith diligent effort to add one or two independent directors to our Board of Directors by September 1, 2007, (and if not added by such time, retaining a professional search firm to assist in the identification of such independent directors, and using our best efforts to add one or two independent directors to the Board of Directors by December 31, 2008); and our committing through January 1, 2009, unless otherwise required by law, that two thirds of our Board of Directors will in good faith and with diligent effort consist of independent directors.

On February 16, 2007, the federal district court granted final approval to the class action settlement. On February 21, 2007, the state court granted final approval to the derivative settlement. Both settlements will become effective upon the expiration of the time in which to appeal the judgments of dismissal that the federal and state courts have entered or soon will enter. Under the terms of the settlements, we believe that these matters will not have a material effect on our results of operations or financial position; however, we cannot predict when, if ever, the settlements will become effective.

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

None.

Table of Contents

PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

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

	High	Low
Year Ended December 31, 2005:		
First Quarter	$ 5.08	$ 2.93
Second Quarter	4.75	3.04
Third Quarter	9.23	4.27
Fourth Quarter	11.63	$ 6.46
Year Ended December 31, 2006:		
First Quarter	14.76	8.10
Second Quarter	8.73	6.29
Third Quarter	7.88	5.27
Fourth Quarter	$ 8.89	$ 5.42

On February 8, 2007, the last reported sale price of our common stock on the Nasdaq Global Market was $5.83 per share. On February 8, 2006, we had approximately 199 holders of record of common stock. We have not paid dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future.

Table of Contents

Performance Measurement Comparison

The following graph shows the total stockholder return of an investment of $100 in cash on December 31, 2001 for (i) our common stock, (ii) the NASDAQ Stock Market (U.S.) Index, (iii) the NASDAQ Pharmaceutical Stocks Index, and (iv) the Amex Pharmaceutical Index. All values assume reinvestment of the full amount of all dividends:

Comparison of 5-year Cumulative Total Return on Investment

	December 31,					
	2001	**2002**	**2003**	**2004**	**2005**	**2006**
Cerus Corporation	$ 100.00	$ 46.99	$ 9.92	$ 6.45	$ 22.19	$ 12.81
NASDAQ Biotech Index	100.00	69.14	103.37	112.49	118.81	122.45
Amex Pharm Index (DRG)	100.00	71.25	74.63	71.62	73.55	82.99
NASDAQ	100.00	44.34	63.91	67.80	71.99	71.77

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

Table of Contents

Item 6. ***Selected Financial Data***

The following table summarizes certain selected financial data for the five years ended December 31, 2006. The information presented should be read in conjunction with the financial statements and notes included elsewhere herein. The selected financial data for the periods prior to the financial statements included herein are derived from audited financial statements.

	2006	2005	2004	2003	2002
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 35,580	$ 24,371	$ 13,911	$ 9,665	$ 8,490
Operating expenses: (2)					
Cost of product revenue	1,541				
Research and development	29,507	24,134	27,651	52,484	56,421
General and administrative	14,012	9,578	10,225	11,016	11,346
Restructuring			2,861		
Total operating expenses	45,060	33,712	40,737	63,500	67,767
Loss from operations	(9,480)	(9,341)	(26,826)	(53,835)	(59,277)
Net interest and other income (expense)	4,701	22,405	(4,327)	(4,432)	2,085
Income (loss) before income taxes	(4,779)	13,064	(31,153)	(58,267)	(57,192)
Provision for income taxes					
Net income (loss)	$ (4,779)	$ 13,064	$ (31,153)	$ (58,267)	$ (57,192)
Net income (loss) per common share-(1):					
Basic	$ (0.18)	$ 0.58	$ (1.41)	$ (3.01)	$ (3.61)
Diluted	$ (0.18)	$ 0.55	$ (1.41)	$ (3.01)	$ (3.61)
Weighted average common shares outstanding used for basic and diluted income (loss) per common share: (1)					
Basic	26,870	22,350	22,143	19,367	15,833
Diluted	26,870	23,950	22,143	19,367	15,833

	2006	2005	2004	2003	2002
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 93,416	$ 45,805	$ 95,334	$ 110,010	$ 64,318
Working capital	87,929	27,690	23,782	49,819	50,486
Total assets	115,817	58,660	102,078	118,463	72,947
Loan and interest payable		4,826	39,000	55,834	
Capital lease obligations, less current portion	32	68			16
Accumulated deficit	(311,422)	(306,643)	(319,707)	(288,554)	(230,287)
Total stockholders equity	$ 100,971	$ 35,275	$ 21,489	$ 52,528	$ 56,169

(1) See Note 1 of Notes to Financial Statements for a description of the method used in computing the net loss per share.

(2) See Note 1 of Notes to Financial Statements for a description of the timing and impact of the adoption of FAS123R.

Table of Contents

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this report. This report contains forward-looking statements that involve risks and uncertainties. Results for the periods presented are not necessarily indicative of future results.

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, more recently, immunotherapies for cancer and infectious disease. With the exception of a non-recurring gain recognized during the three months ended March 31, 2005, we have been generally unprofitable since inception and, as of December 31, 2006, had an accumulated deficit of approximately $311.4 million. Except for the platelet and plasma systems, for which the European Union approved issuance of CE marks, all of our product candidates are in the research and development stage.

We initiated a Phase I clinical trial for CRS-100, a product candidate employing our attenuated *Listeria* technology platform, in 2006 after the FDA approved our earlier IND filing, and we re-entered Phase I human clinical trials in the United States for the red blood cell system in the late summer of 2006. To date, our primary source of revenue has been from milestone and development contracts and collaborative agreements and grants from U.S. government agencies, including the U.S. Armed Forces and the National Institutes of Health, or NIH. We have recognized modest European product revenues from the sale of our platelet system and had just launched the commercialization of our plasma system on a limited basis by the end of 2006. We anticipate continued growth of our product sales as we penetrate European markets and more fully launch our plasma system. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities on our product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after commercialization of additional products. 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 and immunotherapy product candidates. We may never achieve a profitable level of operations.

Through December 31, 2006, in addition to the product revenues from sales of our platelet systems, we have recognized revenue from an ongoing development agreement with MedImmune and commercialization agreements with BioOne, as well as from grants and cooperative agreements from the Armed Forces and the NIH. Under the agreements with MedImmune and BioOne, we have received milestone payments and development funding and may receive additional contingent milestone payments and royalties on future product sales.

As of December 31, 2006, we had cumulatively received $1.5 million of upfront and milestone payments from MedImmune under the terms of our agreement with them, consisting of a $1.0 million up- front payment and a $0.5 million milestone payment, and had received a total of $29.5 million in cash payments and equity securities from BioOne. Under the MedImmune agreement, we had also received development funding.

Table of Contents

We also entered into cooperative agreements with the Armed Forces and received grants and contracts from the NIH to conduct certain research and development activities. These cooperative agreements and grants are related to both our blood safety and immunotherapy and infectious disease platforms. The following table summarizes the revenues recognized from government grants and cooperative agreements and the programs which the revenues related for the years ended December 31, 2006, and 2005:

	Years Ended December 31,	
(in thousands, except percentage)	**2006**	**2005**
Blood Safety	$ 4,836	$ 4,110
Immunotherapy	5,009	8,079
Total revenue	$ 9,845	$ 12,189

In late 2005, we mutually agreed to discontinue development efforts whereby, along with the Pharmaceutical Division of Kirin Brewery Co. Ltd., or Kirin, we were developing and marketing products for stem cell transplantation.

Effective February 1, 2006, we entered into a new agreement with Baxter related to the INTERCEPT Blood System. Under terms of the February 2006 agreement, we gained worldwide rights to the INTERCEPT platelet and plasma systems previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. We previously acquired worldwide commercialization rights for the red blood cell system from Baxter. Beginning in 2007, we will pay Baxter royalties on product sales, at a rate of 10% of net sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. This royalty structure replaces the terms of previous agreements with Baxter under which we had received a defined share of the gross profits from product sales. Under the terms of the February 2006 agreement, Baxter agreed to supply certain transition services to us through 2006 at our expense, including regulatory, technical and back-office support, and to conduct certain continued development efforts relating to the plasma system at its expense. 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, and agreed to supply only very limited types of components for the prototype of the red blood cell system. On October 3, 2006, Baxter announced that it had entered into a definitive agreement to sell 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 formed by an investment group led by Texas Pacific Group. Subject to regulatory approvals and other customary closing conditions, Baxter has informed us that it expects the transaction to close within the first quarter of 2007. Our agreement with Baxter will remain in effect, although Baxter has informed us that it expects the new company to assume Baxter s manufacturing obligations to us.

As a result of the February 2006 agreement with Baxter, we recorded net gains and deferred gains in excess of $6.5 million and also repaid the $4.5 million promissory note plus accrued interest owed to Baxter Capital that had originally been due in December 2006. At December 31, 2006, we had $0.6 million in remaining deferred gains, all of which are associated with payments made to vendors by December 31, 2006, in support of INTERCEPT commercialization efforts. We anticipate recognizing the remainder of the deferred gain balance in 2007 as the vendors complete the services.

Under the terms of the February 2006 agreement, we are responsible for the commercialization and development of the platelet and plasma systems, except in parts of Asia. We expect that our spending over the next year in support of research, development and commercialization of the platelet and plasma systems will be in excess of the contribution from product sales to customers and from milestone payments and development funding for such programs from Baxter, BioOne, the Armed Forces and others. We also anticipate increasing our expenditures in support of clinical trials and device development of our red blood cell system, as well as the preclinical and early stage clinical development of our immunotherapy programs in both cancer and infectious disease.

Table of Contents

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 collaborative arrangements, contract research and other contingencies, and non-cash stock compensation assumptions. 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 and research and development expenses Revenue is recognized when (i) a written agreement with the funding party exists; (ii) services have been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable. Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects 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 they are subject to future performance criteria, we recognize revenue ratably over the estimated license or development period. We have received up-front payments from collaboration agreements. These up-front payments are deferred and recognized over the period we estimate we are likely to have involvement. We have also received equity in a privately held company in addition to cash as consideration in milestone payments. 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. We receive certain United States government grants and contracts that support our research effort 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.

Accrued expenses We record accrued liabilities for 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, Board of Directors, Scientific Advisory Boards and certain contractors as strategic, long-term incentives. Beginning in the first quarter of 2006, we recorded stock-based compensation expense for these awards under Statement of Financial Accounting Standards No. 123R, or FAS 123R. We have elected to use the modified-prospective method of adoption. We record compensation expense to our income statement based on the grant-date fair value of a stock award and expense the fair value on a straight-line basis over the requisite service period, which is the vesting period. We determine the grant-date fair value of a stock award using the Black-Scholes option pricing model.

Table of Contents

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, or SAB 107. The expected term of employee stock purchase plan shares is the average of the remaining purchase periods under 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.

Estimated Volatility. We estimate the volatility of our common stock by using both historical volatility of our common stock and implied volatility in market traded options in accordance with SAB 107. Our decision to use both historical volatility and implied volatility was based upon the limited availability of actively traded options on our common stock and our assessment that due to the limited availability of actively traded options, historical volatility should be given greater prominence in our decision as we believe it is more representative of future stock price. As such, we have calculated our estimated volatility by weighting both historical volatility and implied volatility. 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.

Risk-Free Interest Rate. We base the risk-free interest rate that we use in the option valuation model on U.S. 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 effect 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 by 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 carryforwards 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.

Table of Contents

Results of Operations

Years Ended December 31, 2006, and 2005

Revenue

(in thousands, except percentage)	Years Ended December 31, 2006	2005	Change	
Milestone and development funding	$ 22,760	$ 11,697	$ 11,063	95%
Government grant and cooperative agreements	9,845	12,189	(2,344)	(19)%
Product revenue	2,975	485	2,490	513%
Total revenue	$ 35,580	$ 24,371	$ 11,209	46%

Revenue increased 46% to $35.6 million for the year ended December 31, 2006, from $24.4 million for the comparable period in 2005.

Milestone and development funding from BioOne, Baxter and MedImmune increased 95% to $22.8 million during the year ended December 31, 2006, from $11.7 million during the year ended December 31, 2005. The increase was due primarily to the receipt and recognition of $9.5 million in milestone funding received from BioOne as a result of our receipt of the CE mark approval for the plasma system. The $9.5 million of milestone funding received from BioOne consisted of $4.5 million in cash consideration and BioOne equity securities valued at $5.0 million. Milestone and development funding from BioOne, Baxter, and MedImmune was 58%, 6% and 1%, respectively, of total revenue for the year ended December 31, 2006, as compared to 30%, 8% and 10% for the corresponding period in 2005. We do not anticipate recognizing significant future revenue from Baxter under our existing agreements.

Revenue from government grants and cooperative agreements decreased 19% to $9.8 million for the year ended December 31, 2006, from $12.2 million for the comparable period in 2005. The decrease was due primarily to the reduced awards from the Armed Forces for research activities for our immunotherapy program. We recognized $3.0 million in revenue for research and development activities under an agreement with the Armed Forces for the year ended December 31, 2006, as compared to $6.5 million for the corresponding period in 2005. 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 Small Business Administration. As a result, we will not be eligible to apply for any new grants that meet the criteria for those certain types of grants.

For the year ended December 31, 2006, we recognized $3.0 million of product revenue from sales of the INTERCEPT Blood System for platelets in Europe, compared to $0.5 million during the same period in the prior year. Prior to the February 2006 agreements with Baxter, product revenue represented our share of adjusted gross margins on platelet system sales. Subsequent to February 1, 2006, product revenue represents the sales from platelet systems. The results may not be indicative of platelet system revenue in the future. We anticipate product revenues for both the platelet and plasma systems to increase in future periods as the INTERCEPT Blood System gains market acceptance in Europe and other geographies where commercialization efforts are underway.

For the year ended December 31, 2005, we recognized $0.5 million of product sales revenue from our share of gross margins from sales of the INTERCEPT Blood System for platelets in Europe, pursuant to the terms of the agreement with Baxter then in place.

Cost of Product Revenue.

(in thousands, except percentage)	Years Ended December 31, 2006	2005	Change	
Cost of product revenue	$ 1,541	$	$ 1,541	100%

42

Table of Contents

Prior to the February 2006 agreement with Baxter, we did not record cost of product revenue or gross margins from product sales. Subsequent to February 1, 2006, the effective date of the agreement, and through December 31, 2006, our cost of product revenue consisted primarily of platelet system inventory sold. Inventory is accounted for on a first-in, first-out basis. These results may not be indicative of future costs of product sales or gross margins. We anticipate our cost of product revenue to increase in the future as a result of increased product sale volume, royalties that will be owed to Baxter on platelet and plasma system sales, and as we perform or find alternative service providers for supply chain and back-office order fulfillment services.

Research and Development.

Our research and development expenses include salaries and related expenses for our scientific personnel, payments to consultants, costs to prepare and conduct preclinical and clinical trials, third-party costs for development activities, certain regulatory costs, costs for licensed technologies, and costs associated with our infrastructure, and laboratory chemicals and supplies. Beginning January 1, 2006, our research and development expenses also include non-cash stock-based compensation as a result of adopting FAS 123R.

	Years Ended December 31,			
(in thousands, except percentage)	**2006**	**2005**	**Change**	
Research and development	$ 29,507	$ 24,134	$ 5,373	22%

Research and development expenses for the year ended December 31, 2006, increased $5.4 million to $29.5 million from $24.1 million for the corresponding period in 2005. Of the $29.5 million in research and development expenses recognized during the year ended December 31, 2006, $1.1 million was due to non-cash stock-based compensation recognized in accordance with the adoption of FAS 123R. Additional factors for the increase in research and development expenses during 2006 compared to 2005 include costs incurred to initiate and maintain Phase I clinical trials for the red blood cell system and CRS-100 product candidates, costs associated with the development of the plasma system, and an increase in the number of research and development personnel employed. Our total research and development costs included $16.2 million for our blood safety programs and $13.3 million for our immunotherapy programs for the twelve months ended December 31, 2006, and $11.0 million for our blood safety programs and $13.1 million for our immunotherapy programs for the comparable period in 2005. We anticipate that our research and development spending will continue and at times, may increase in the future as a result of ongoing and later stage preclincal and clinical trials, and as potential products move from discovery to preclinical and clinical trials. Due to the inherent uncertainties and risks associated with developing biomedical and biopharmaceutical products, including but not limited to intense and changing government regulation, uncertainty of future preclinical and clinical study results and uncertainty associated with manufacturing it is not possible to reasonably estimate the costs to complete our research and development projects.

Selling, General, and Administrative.

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, expenses for our commercialization efforts underway in Europe, expenses for accounting, tax, and internal control, legal and facility related expenses, and insurance premiums. Beginning January 1, 2006, our selling, general, and administrative expenses also include non-cash stock-based compensation as a result of adopting FAS 123R.

	Years Ended December 31,			
(in thousands, except percentage)	**2006**	**2005**	**Change**	
Selling, general, and administrative	$ 14,012	$ 9,578	$ 4,434	46%

Table of Contents

Selling, general, and administrative expenses increased 46% to $14.0 million for the year ended December 31, 2006, from $9.6 million for the comparable period in 2005. Of the $14.0 million of selling, general, and administrative expense recognized during the year ended December 31, 2006, $1.4 million was due to non-cash stock-based compensation recognized under FAS 123R. Additional factors for the increase in selling, general, and administrative expenses during 2006 compared to 2005 include costs associated with establishing and building our commercial operations in Europe, as well as increased legal and accounting fees. We anticipate our selling, general, and administrative expenses will continue to increase as we ramp up our INTERCEPT commercialization efforts and continue to work toward broader market acceptance in Europe.

Gain on Loan Settlement.

	Years Ended December 31,			
(in thousands, except percentage)	**2006**	**2005**	**Change**	
Gain on loan settlement	$	$ 22,089	$ (22,089)	(100)%

Under an agreement entered into with Baxter Capital in 2005, we repaid $34.5 million and concurrently entered into a promissory note for $4.5 million payable with 8% interest as full satisfaction of a loan obligation during the year ending December 31, 2005. As a result of the 2005 agreement, during the twelve months ended December 31, 2005, we recorded a non-operating gain of $22.1 million. In February 2006, we repaid the $4.5 million promissory note plus the accrued interest. As of December 31, 2006, we have no further loan obligations.

Interest Income (Expense) and Other, Net.

	Years Ended December 31,			
(in thousands, except percentage)	**2006**	**2005**	**Change**	
Interest income (expense) and other, net	$ 4,701	$ 316	$ 4,385	1,388%

Interest income (expense) and other, net was $4.7 million for the year ended December 31, 2006, and $0.3 million for the corresponding period in 2005. We recognized a non-operating gain of $1.8 million during the year ended December 31, 2006, from cash consideration received from Baxter as a result of the February 2006 commercialization transition agreement. Net interest income increased to $3.0 million for the year ended December 31, 2006 from $1.1 million for the comparable period in 2005. The increase from 2005 was primarily due to consistently higher cash balances maintained during 2006 from 2005, primarily as a result of our public offerings in 2006. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain.

Years Ended December 31, 2005, and 2004

Revenue.

	Years Ended December 31,			
(in thousands, except percentage)	**2005**	**2004**	**Change**	
Milestone and development funding	$ 11,697	$ 4,187	$ 7,510	179%
Government grant and cooperative agreements	12,189	9,724	2,465	25%
Product revenue	485		485	100%
Total revenue	$ 24,371	$ 13,911	$ 10,460	75%

Revenue increased 75% to $24.4 million for the year ended December 31, 2005, from $13.9 million for the comparable period in 2004.

44

Table of Contents

For the year ended December 31, 2005, milestone and development funding, which includes amounts received from Baxter, BioOne, MedImmune and Kirin, increased 179% to $11.7 million from $4.2 million for 2004. The increase in these revenues during 2005 compared to 2004 is primarily due to revenue recognized from up-front payments received from BioOne and MedImmune originally received and deferred in 2004 and recognized ratably over respective development terms. Additionally, the increase in milestone and development funding recognized in 2005 compared to 2004 is attributable to increased development funding and a milestone payment received from MedImmune under the April 2004 agreement. Milestone and development funding from Baxter, BioOne, MedImmune and Kirin was 14%, 62%, 21% and 3%, of milestone and development funding respectively for the year ended December 31, 2005.

Revenue from government grants and cooperative agreements increased 25% to $12.2 million in the year ended December 31, 2005, from $9.7 million for 2004, due primarily to increased government funding for both blood safety and vaccines programs.

For the year ended December 31, 2005, we recognized $0.5 million of product sales representing our share of margins of the platelet system in Europe. As a result of a loan dispute with Baxter Capital that was subsequently resolved, we also recognized approximately $0.2 million in product sales revenue from 2004 that was deferred until February 2005. We did not record any product revenue in 2004.

Research and Development.

During the years ended 2005 and 2004, research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, payments for licensed technologies, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, manufacturing development and other laboratory studies.

	Years Ended December 31,			
(in thousands, except percentage)	**2005**	**2004**	**Change**	
Research and development	$ 24,134	$ 27,651	$ (3,517)	(13)%

Research and development expenses decreased 13% to $24.1 million in the year ended December 31, 2005, from $27.7 million for 2004. Increased spending on vaccine programs, particularly in support of development of CRS-100 and CRS-207, was offset by reduced spending for our blood safety programs during 2005. Our total research and development costs included $11.0 million for our blood safety programs and $13.1 million for our immunotherapy programs for the year ended December 31, 2005, and $17.9 million for our blood safety programs and $9.8 million for our immunotherapy programs for the comparable period in 2004.

Selling, General, and Administrative.

	Years Ended December 31,			
(in thousands, except percentage)	**2005**	**2004**	**Change**	
Selling, general, and administrative	$ 9,578	$ 10,225	$ (647)	(6)%

General and administrative expenses decreased 6% to $9.6 million for the year ended December 31, 2005, from $10.2 million for 2004, due principally to reduced headcount costs in 2005 which are directly attributable to the 2004 restructuring of our operations.

Table of Contents

Restructuring.

(in thousands, except percentage)	Years Ended December 31, 2005	2004	Change	
Restructuring	$	$ 2,861	$ (2,861)	(100)%

On June 30, 2004, we announced that we realigned our operations to better match our cost structure to our operations. As a result of the realignment, we reduced our workforce by approximately 35% and reduced our operating expenses. We recorded aggregate charges of $2.9 million during the second and third quarters of 2004 related to this restructuring. Restructuring costs primarily include severance benefits to employees terminated as part of the restructuring. We do not expect to record further costs related to the 2004 restructuring.

Gain on Loan Settlement.

(in thousands, except percentage)	Years Ended December 31, 2005	2004	Change	
Gain on loan settlement	$ 22,089	$	$ 22,089	100%

Concurrent with the 2005 restructured agreements between Baxter and us, Baxter Capital and we entered into an agreement under which we immediately paid $34.5 million to Baxter Capital and entered into a promissory note for $4.5 million, payable with 8% interest in December 2006. 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, we recorded a non-operating gain of $22.1 million that reflected the difference between loan principal and accrued interest balances recorded through 2004, less amounts paid in February 2005 and remaining accrued liabilities as a result of the settlement, and long-term debt of $4.5 million, representing the note due to Baxter Capital in December 2006, which accrues interest at 8%. The gain on the loan settlement was recognized in the period ending March 31, 2005, when the settlement occurred.

Net Interest (Expense) and Other, Net.

(in thousands, except percentage)	Years Ended December 31, 2005	2004	Change	
Interest income (expense) and other, net	$ 316	$ (4,327)	$ 4,643	107%

Net interest (expense) and other, net resulted in income of $0.3 million for the year ended December 31, 2005, compared to an expense of $4.3 million for 2004. Net interest income was $1.1 million and $1.6 million for the year ended December 31, 2005, and 2004, respectively. The reduced interest income in 2005 compared to 2004 was due to lower investment account balances. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. In 2005, interest was accrued at 8% on the $4.5 million note payable to Baxter Capital. In 2004, interest was accrued at 12.0% on the $50.0 million loan from Baxter Capital.

Liquidity and Capital Resources

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, payments received under our agreements with Baxter, BioOne, MedImmune and others, United States government grants and cooperative agreements, and interest income. To date, we have not derived a significant amount of capital from product sales, and we will not derive significant capital from product sales unless and until more of our products receive regulatory approval and achieve market acceptance.

46

Table of Contents

At December 31, 2006, we had cash, cash equivalents and short-term investments of $93.4 million. Net cash used in operating activities was $14.7 million for the year ended December 31, 2006, compared to $14.9 million for the same period in 2005. The decrease in net cash used in operating activities was primarily due to increases in our revenues and related cash collections in 2006 compared to 2005, as well as changes in our operating assets and liabilities, notably decreases in our accounts payable balances. Net cash used in investing activities during the year ended December 31, 2006, was $7.9 million, primarily due to purchases of short-term investments, partially offset by the maturity of short-term investments. Net cash provided by financing activities during the year ended December 31, 2006, was $63.1 million, compared to cash used in financing activities of $33.8 million for the same period in 2005. The increase in 2006 compared to 2005 was largely due to the issuance of 5,175,000 shares of common stock in a public offering in March 2006, providing net proceeds of $42.4 million, and the issuance of 3,903,952 shares of common stock in a registered direct offering in December 2006, providing net proceeds of approximately $24.3 million, offset by the repayment of a loan from Baxter Capital of $4.5 million plus accrued interest. During the same period in 2005, we repaid $34.5 million on the note due to Baxter. Working capital increased to $87.9 million at December 31, 2006, from $27.7 million at December 31, 2005, primarily due to the receipt of proceeds from our stock offerings and, to a lesser degree, from the gain from the February 2006 commercialization transition agreement with Baxter recognized during the period.

We believe that our available cash balances, together with anticipated cash flows from product sales and existing development and grant arrangements, will be sufficient to meet our capital requirements through 2008. These near-term capital requirements are dependent on various factors, including the progress and costs of development and commercialization of the INTERCEPT Blood System and research and development of our immunotherapy programs, payments from our development and commercialization partners, including BioOne, cash collected from product sales, and from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will be dependent on these factors and on our ability to raise capital through public or private equity or debt financings or through additional collaborative arrangements or government grants, development progress in our immunotherapy programs, regulatory approval and successful commercialization of the INTERCEPT Blood System and other product candidates, competitive developments and regulatory factors. Future capital funding transactions may result in dilution to our investors, and may not be available on favorable terms or at all. In August 2001, we filed a shelf registration statement on Form S-3 to offer and sell up to $300.0 million of common stock and/or debt securities. In June 2003, we completed a public offering of 6,000,000 shares of common stock with gross proceeds, calculated for registration statement purposes, of $57.8 million under the shelf registration statement. In March 2006, we completed a public offering of 5,175,000 shares of common stock with gross proceeds, calculated for registration statement purposes, of $45.3 million under the shelf registration statement. In December 2006, we completed a registered direct offering of 3,903,952 shares of common stock with gross proceeds, calculated for registration purposes, of $26.1 million under the shelf registration statement.

Commitments

The following is a summary of our contractual obligations as of December 31, 2006 (in thousands):

	Payments Due by Period, from December 31, 2006				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Contractual obligations:					
Minimum purchase requirements	$ 150	$ 50	$ 100	$	$
License fees and sponsored research	67	67			
Operating leases	1,995	1,080	904	11	
Total contractual cash obligations	$ 2,212	$ 1,197	$ 1,004	$ 11	$

Table of Contents

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

Interest Rate Risk

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.

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 dated of less than three months 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, 2006 (dollar amounts in thousands):

	Fair Value	Weighted Average Interest Rate
Cash and Cash equivalents (0 90 days)	$ 46,287	4.55%
Short-term investments (91 days 1 year)	18,589	5.87
Short-term investments (1 3 years)	28,540	5.17%
Total investments	$ 93,416	5.00%

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 typically made in Europe and generally are invoiced to customers typically in Euros. In addition, we incur operating expenses in 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 (Expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. 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***

Not applicable.

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

48

Table of Contents

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, 2006, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in this Annual Report on Form 10-K was (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and (ii) accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. During the last quarter of our fiscal year ended December 31, 2006, 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, 2006, is discussed in the Management s Report on Internal Control Over Financial Reporting included on page 54.

Item 9B. ***Other Information***

Not applicable.

Table of Contents

PART III

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

Information regarding our directors and officers, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, will be set forth under the captions Election of Directors, 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 4, 2007, 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 2006 fiscal year.

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference to the information set forth under the captions Executive Compensation, Compensation Committee Interlocks and Insider Participation, and Compensation Committee Report 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***

The information required by this item is incorporated herein by reference to the information set forth under the captions Transactions with Related Persons, and Independence of the Board 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 Principal Accountant Fees and Services, and Pre-Approval Policies and Procedures in the proxy statement.

Table of Contents

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

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

(a) *Financial Statements*.

	Page
Management s Report on Internal Control Over Financial Reporting	54
Reports of Ernst & Young LLP, Independent Registered Public Accounting Firm	56
Balance Sheets as of December 31, 2005 and 2006	57
Statements of Operations for the three years ended December 31, 2006	58
Statements of Stockholders Equity for the three years ended December 31, 2006	59
Statements of Cash Flows for the three years ended December 31, 2006	60
Notes to Financial Statements	61

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

(b) Exhibits.

Exhibit Number	Description of Exhibit
3.1.1(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2(1)	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.
10.6(1)	Series E Preferred Stock Purchase Agreement, dated April 1, 1996, between Cerus and Baxter Healthcare Corporation.
10.7(1)	Common Stock Purchase Agreement, dated September 3, 1996 between Cerus and Baxter Healthcare Corporation.
10.8(1)	Amended and Restated Investors Rights Agreement, dated April 1, 1996, among Cerus and certain investors.
10.9(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.
10.10(1)	Real Property Lease, dated August 8, 1996, between Cerus and S.P. Cuff.
10.11(1)	Lease, dated February 1, 1996, between Cerus and Holmgren Partners.
10.12(1)	First Amendment to Common Stock Purchase Agreement, dated December 9, 1996, between Cerus and Baxter Healthcare Corporation.

51

Table of Contents

10.13(2)	License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation.
10.14(3)	Series A Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.15(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.16(4)	Stockholder Rights Plan, dated November 3, 1999.
10.17(15)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999
10.18(6)*	Employment Agreement with Howard G. Ervin.
10.19(7)	Collaborative License Agreement between Cerus and Kirin Brewery Company, Limited.
10.20(8)	Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P.
10.21(8)	Lease, dated October 12, 2001 between Cerus and California Development, Inc.
10.22(9)	Loan Agreement, dated November 15, 2002, between Cerus and Baxter Capital Corporation.
10.23(9)	Letter of Understanding between Cerus and Baxter, dated November 1, 2002.
10.24(10)*	1999 Non-Employee Directors Stock Option Sub-Plan, amended December 4, 2002.
10.25(11)	Collaboration and License Agreement, dated April 20, 2004, between Cerus Corporation and MedImmune, Inc.
10.26(11)*	Employment Agreement, dated August 5, 2004, between Cerus Corporation and Claes Glassell.
10.27(12)*	Employment Agreement, dated July 22, 2004, between Cerus Corporation and William J. Dawson.
10.28(16)*	Bonus Plan for Senior Management of Cerus Corporation, dated April 1, 2003, as amended on December 9, 2004, January 18, 2005, and February 28, 2005.
10.29(13)	Amendment, Mutual Release and Settlement Agreement, dated as of February 2, 2005, between Cerus and Baxter Capital Corporation.
10.30(13)	Amended and Restated Note, dated as of February 3, 2005, payable to the order of Baxter Capital Corporation.
10.31(13)	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.32(13)	License Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.33(13)	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.34(14)*	Bonus Plan for Senior Management of Cerus Corporation, dated January 1, 2006.
10.35(14)	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
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.

Table of Contents

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.

* 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	Annual Report on Form 10-K, for the year ended December 31, 2000.
(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, 2004.
(12)	Incorporated by reference to Cerus	Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
(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	Current Report on Form 8-K, dated June 5, 2006.
(16)	Incorporated by reference to Cerus	Annual Report on Form 10-K for the year ended December 31, 2004.

Table of Contents

MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining effective internal control over the Company s financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Management assessed the effectiveness of the Company s internal control over financial reporting as of December 31, 2006. 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, 2006, the Company s internal control over financial reporting is effective.

The Company s independent registered public accounting firm, Ernst & Young LLP, has audited management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2006. Ernst and Young s attestation report on management s assessment of internal control over financial reporting is included at page 55.

The Company s internal control system was designed to provide reasonable assurance to the Company s management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Table of Contents

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM, ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Stockholders of Cerus Corporation

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that Cerus Corporation maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of 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, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management s assessment that Cerus Corporation maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Cerus Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006, and 2005, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2006, and our report dated February 9, 2007, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 9, 2007

Table of Contents

REPORT OF ERNST & YOUNG LLP, 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, 2006, and 2005, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2006. 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, 2006, and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U. S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, in fiscal year 2006, Cerus Corporation changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), Share-Based Payment .

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Cerus Corporation s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organization of the Treadway Commission and our report dated February 9, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 9, 2007

Table of Contents

CERUS CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,287	$ 5,780
Short-term investments	47,129	40,025
Accounts receivable, net of allowance of $0 at December 31, 2006 and 2005	5,279	4,700
Inventories	1,833	
Prepaid and other current assets	2,215	500
Total current assets	102,743	51,005
Property and equipment, net	1,627	1,235
Long-term investments	11,175	6,175
Other assets	272	245
Total assets	$ 115,817	$ 58,660
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,665	$ 2,092
Current loan and interest payable		4,826
Accrued liabilities	7,479	5,197
Deferred revenue		11,135
Deferred gain	586	
Current portion of capital lease obligations	84	67
Total current liabilities	14,814	23,317
Long term portion of capital lease obligations	32	68
Total liabilities	14,846	23,385
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value: issuable in series; 3 shares issued and outstanding at December 31, 2006, and 2005; aggregate liquidation preference of $9,496 at December 31, 2006, and 2005	9,496	9,496
Common stock, $0.001 par value; 50,000 shares authorized: 31,735 and 22,458 shares issued and outstanding at December 31, 2006, and 2005, respectively	32	23
Additional paid-in capital	402,888	332,694
Accumulated other comprehensive loss	(23)	(295)
Accumulated deficit	(311,422)	(306,643)
Total stockholders equity	100,971	35,275
Total liabilities and stockholders equity	$ 115,817	$ 58,660

See accompanying notes.

57

Table of Contents

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	2006	2005	2004
Revenue:			
Milestone and development funding	$ 22,760	$ 11,697	$ 4,187
Government grants and cooperative agreements	9,845	12,189	9,724
Product revenue	2,975	485	
Total revenue	35,580	24,371	13,911
Operating expenses:			
Cost of product revenue	1,541		
Research and development	29,507	24,134	27,651
Selling, general, and administrative	14,012	9,578	10,225
Restructuring			2,861
Total operating expenses	45,060	33,712	40,737
Loss from operations	(9,480)	(9,341)	(26,826)
Interest and other income (expense):			
Gain on loan settlement		22,089	
Interest income (expense) and other, net	4,701	316	(4,327)
Net interest and other income (expense)	4,701	22,405	(4,327)
Income before income taxes	(4,779)	13,064	(31,153)
Income taxes			
Net income (loss)	$ (4,779)	$ 13,064	$ (31,153)
Net income (loss) per common share:			
Basic	$ (0.18)	$ 0.58	$ (1.41)
Diluted	$ (0.18)	$ 0.55	$ (1.41)
Weighted average common shares outstanding used for basic and diluted net income (loss) per share:			
Basic	26,870	22,350	22,143
Diluted	26,870	23,950	22,143

See accompanying notes.

Table of Contents

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share data)

	Preferred Stock		Common Stock						
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Comprehensive Income	Accumulated Deficit	Total Stockholders Equity
Balances at December 31, 2003	3	9,496	22,060	22	331,564			(288,554)	52,528
Issuance of common stock under stock option and employee stock purchase plans			150		438				438
Net change in unrealized loss on investments						(324)	(324)		(324)
Net loss							$ (31,153)	(31,153)	(31,153)
Total comprehensive income (loss)							(31,477)		
Balances at December 31, 2004	3	9,496	22,210	22	332,002	(324)		(319,707)	21,489
Issuance of common stock under stock option and employee stock purchase plans			247	1	692				693
Net change in unrealized loss on investments						29	$ 29		29
Net income							13,064	13,064	13,064
Total comprehensive income (loss)							$ 13,093		
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
Equity compensation					2,535				2,535
Net change in unrealized gain (loss) on investments						272	$ 272		272
Net loss							(4,779)	(4,779)	(4,779)
Total comprehensive income							$ (4,507)		
Balances at December 31, 2006	3	$ 9,496	31,734	$ 32	$ 402,888	$ (23)		$ (311,422)	$ 100,791

See accompanying notes.

Table of Contents

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	2006	2005	2004
Operating activities			
Net income (loss)	$ (4,779)	$ 13,064	$ (31,153)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	716	652	2,152
Gain on settlement of loan		(22,089)	
Stock-based compensation	2,535	206	212
Non-cash equity in satisfaction of milestone and development funding	(10,000)	(5,000)	
Gain on sale of equipment			48
Loss on long-term investment			62
Changes in operating assets and liabilities:			
Accounts receivable and other current assets	(4,126)	(664)	1,207
Other assets	(27)	(160)	71
Accounts payable	4,573	616	(3,167)
Accrued interest payable	(326)	326	5,986
Accrued compensation and related expenses	(552)	(74)	674
Accrued contract research and other accrued expenses	3,436	258	(1,462)
Deferred revenue	(6,135)	(2,082)	12,642
Net cash used in operating activities	(14,685)	(14,947)	(12,728)
Investing activities			
Purchases of furniture and equipment	(1,108)	(856)	(594)
Proceeds from sale of equipment		51	
Investments in BioOne Corporation			(1,237)
Purchases of short-term investments	(42,310)	(5,000)	(76,835)
Sales of short-term investments		8,000	95,725
Maturities of short-term investments	35,478	13,169	11,466
Net cash provided by (used in) investing activities	(7,940)	15,364	28,525
Financing activities			
Net proceeds from issuance of common stock	67,668	693	226
Loan repayments	(4,500)	(34,500)	
Payments on capital lease obligations	(36)		(19)
Net cash provided by (used in) financing activities	63,132	(33,807)	207
Net increase (decrease) in cash and cash equivalents	40,507	(33,389)	16,004
Cash and cash equivalents, beginning of period	5,780	39,169	23,165
Cash and cash equivalents, end of period	$ 46,287	$ 5,780	$ 39,169

See accompanying notes.

Table of Contents

CERUS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2006

1. Nature of Operations

Cerus Corporation (the Company) was incorporated on September 19, 1991, and is developing novel products for blood safety, cancer and infectious disease. The Company is developing the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen inactivation. The Company is also developing cancer immunotherapies based on its *Listeria* vaccine platform, often combined with disease antigens. The Company has collaboration agreements with Baxter Healthcare Corporation (Baxter, a subsidiary of Baxter International Inc.) and BioOne Corporation (BioOne) for the INTERCEPT Blood System and with MedImmune, Inc. (MedImmune) and The Johns Hopkins University for cancer immunotherapy.

The Company has received only modest revenue to date from product sales of the INTERCEPT platelet system in Europe. Substantially all revenue recognized by the Company to date has resulted from the Company s collaboration agreements with MedImmune, Baxter, BioOne and others and Federal research grants and collaborative agreements. The Company will be required to conduct significant research, development, testing and regulatory compliance activities on its product candidates that, together with anticipated selling, general, and administrative expenses, are expected to result in substantial additional losses, and the Company may need to adjust its operating plans and programs based on the availability of cash resources. The Company s ability to achieve a profitable level of operations will depend on successfully completing development, obtaining additional regulatory approvals and achieving market acceptance of its products. There can be no assurance that the Company will ever achieve a profitable level of operations.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying audited consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (collectively hereinafter Cerus or the Company) after elimination of all intercompany accounts and transactions.

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. The Company records accrued liabilities for certain contract research activities, including clinical trials, preclinical safety studies, external laboratory studies and development activities performed by third-parties. Some of those accrued liabilities are based on estimates because billings for these activities do not occur on a timely basis consistent with the performance of the services.

Revenue and Research and Development Expenses

The Company recognizes revenue in accordance with Securities and Exchange Commission published Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) and Emerging Issues Task Force (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; (iii) pricing is fixed or determinable; and (iv) collection is probable.

Table of Contents

CERUS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2006

The Company s main sources of revenues through December 31, 2006, have come from its research and development activities and agreements and commercialization agreements. Development funding for the Company consists of payments made (i) by Baxter to the Company to reimburse the Company for development spending in excess of the levels determined by Baxter and the Company and (ii) by MedImmune to reimburse the Company for certain fee-for-service development activities. Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to substantive at-risk milestones specified under development contracts is recognized as the milestones are achieved. Payments for achieved milestones are non-refundable and are not subject to future performance. Commercialization agreements for the Company consist of agreements for the commercialization of its blood safety products. Revenue related to substantive at-risk milestones specified under commercialization contracts is recognized as the milestones are achieved. The Company evaluates the fair value of equity consideration received as consideration for agreements using several criteria including, but not limited to, third-party investor participation in and pricing of recent equity offerings and the business and financial outlook of the issuer. These criteria require the use of estimates using the best information available to the Company at the time the evaluation is made. The Company evaluates licenses and research and development agreements that contain multiple elements in accordance with EITF 00-21 and accordingly allocates revenue to each element of the agreement based on their relative fair values.

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 Statement of Financial Accounting Standards No. 2, Accounting for Research and Development Expenses, research and development costs are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

Effective February 1, 2006, the Company entered into an agreement with Baxter, which gave the Company the exclusive commercialization rights to the INTERCEPT Blood Safety System for platelets and plasma (the platelet system and the plasma system). As a result of the agreement, the Company now records product sales of the platelet system, rather than the negotiated share of gross profits from such sales under the prior agreement with Baxter. Also as a result of the February 2006 agreement, the Company records cost of revenues, which, for the year ended December 31, 2006, consisted primarily of the value of platelet system inventory sold.

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 three months or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments and commercial paper.

In accordance with Statement of Financial Accounting Standards (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

Table of Contents

CERUS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2006

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 U.S. government agency securities and corporate debt securities.

Unrealized gains and losses at December 31, 2006, and 2005 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. As of December 31, 2006, there were no other-than-temporary declines in fair value and the Company has the intent and ability to hold its investments to maturity. The cost of securities sold is based on the specific identification method.

As of December 31, 2006, 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 balance sheet at December 31, 2006.

Concentration of Credit Risk

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

Substantially all of the Company s cash, cash equivalents and short-term investments are maintained pursuant to the Company s investment policy by two major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and type of investments that exist within its investment portfolio. All of the Company s investments carry high credit quality ratings, in accordance with its investment policy. At December 31, 2006, 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.

Inventories

At December 31, 2006, inventory consists of finished goods of INTERCEPT disposable kits and illumination devices. Inventory is recorded at the lower of cost or market value, determined on a first in, first-out basis. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise unsaleable items. To the extent unsaleable items are observed and there is no alternative use, we will record a write-down to net realizable value in the period that the impairment is first recognized. There has been no write-down of inventory to date.

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.

Table of Contents

CERUS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2006