CERUS CORP
Form 10-K
February 26, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 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.

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PART I

This report contains forward-looking statements that involve risks and uncertainties. When used herein, the words anticipate, believe, estimate, expect, plan and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including 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

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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.

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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

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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.

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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

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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

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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.

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

Our business faces significant risks. If any of the events or circumstances described in the following risks actually 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.

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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;

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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

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countries must obtain regulatory approv