CERUS CORP
Form 8-K
June 09, 2003

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 5, 2003**

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**0-21937**	**68-0262011**
(State of jurisdiction)	(Commission File No.)	(IRS Employer Identification No.)

2411 Stanwell Drive

Concord, California 94520

(Address of principal executive offices and zip code)

Registrant s telephone number, including area code: **(925) 288-6000**

Item 5. Other Events.

On June 5, 2003, Cerus Corporation (the Company) and Morgan Stanley & Co. Incorporated (Morgan Stanley) entered into an underwriting agreement (the Underwriting Agreement) pursuant to which the Company issued and sold to Morgan Stanley 6,000,000 shares of the Company s common stock and granted to Morgan Stanley an over-allotment option for an additional 900,000 shares (the Offering). The Underwriting Agreement is attached hereto as Exhibit 1.1.

On June 6, 2003, the Company announced gross proceeds in the Offering, before expenses and not including possible proceeds in connection with the exercise of the over-allotment option, of $54,300,000. A copy of the Company s press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

The Company hereby updates its Risk Factors as follows:

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus supplement and the accompanying prospectus and incorporated by reference into the accompanying prospectus before purchasing our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business

If our pre-clinical and clinical trials are not successful or the data are not considered sufficient by regulatory authorities to grant marketing approval, Baxter and we will be unable to commercialize our products and generate revenue.

Except for the INTERCEPT Blood System for platelets, which is approved for sale in Europe and Canada, we have no products that have received regulatory approval for commercial sale. 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 products must satisfy rigorous standards of safety and efficacy before the United States Food and Drug Administration and international regulatory authorities can approve them for commercial use. Our INTERCEPT Blood System and stem cell transplantation programs are undergoing clinical testing. We must provide the FDA and foreign regulatory authorities with pre-clinical, 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 INTERCEPT Blood System for platelets received CE Mark approval in Europe. Our development and marketing partner, Baxter Healthcare Corporation, will need to complete validation studies and obtain reimbursement approvals in some individual European countries to market our products in those countries. In certain countries, including the United Kingdom, France and Germany, the system must be approved for purchase or use by a specific governmental or non-governmental (such as the Paul Ehrlich Institute in Germany) entity or entities in order for it to be adopted by a specific customer. The level of additional product testing varies by country, but could take more than a year to complete

after CE Mark approval. We completed our Phase III clinical trial of the INTERCEPT Blood System for platelets 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. We plan to perform additional analyses of the clinical trial data and conduct an additional clinical trial to provide supplemental data. Data from the additional analyses and supplemental clinical trial will need to be submitted to the FDA before we can complete our regulatory submission. We have completed Phase IIIa and Phase IIIb clinical trials of the INTERCEPT Blood System for plasma in the United States and are conducting a Phase IIIc clinical trial. We are conducting Phase III clinical trials of INTERCEPT red blood cells in the United States. Our allogeneic cellular immune therapy (referred to as ACIT) program, designed to improve the outcome of bone marrow transplantation procedures through use of T-cells treated with the Helinx technology, is in Phase I clinical trials in the United States. Last, our Epstein-Barr virus (referred to as EBV) cellular vaccine program is in a Phase I clinical trial in the United States. We will have to conduct significant additional research and pre-clinical (animal) and clinical (human) testing before we can file additional applications for product approval with the FDA and foreign regulatory authorities. Clinical trials in particular are expensive and have a high risk of failure. In addition, to compete effectively, our products must be easy to use, cost-effective and economical to manufacture on a commercial scale. Any of our product candidates may fail in the testing phase or may not attain market acceptance, which could prevent us from achieving profitability.

It may take us several years to complete our clinical testing, and failure can occur at any stage of testing. 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. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical 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 may fail to complete our clinical trials on time or be unable to complete the trials at all.

Significant clinical trial delays would impair our ability to commercialize our products and could allow competitors to bring products to market before we do. Some of our clinical trials involve patient groups with rare medical conditions, which has in the past made, and may continue to make, it difficult to identify and enroll a sufficient number of patients to complete the trials on time. Our Phase III clinical trials of the INTERCEPT Blood System for red blood cells involve patient groups that include a significant percentage of children, which has made, and may continue to make, it difficult to obtain consent to enroll these patients in our trials. Other factors, including the unavailability of blood products or delays in the supply of clinical product material, could also delay our clinical trials. Clinical trials of our ACIT and EBV vaccine programs are sponsored by other organizations, which will further reduce our ability to control the progress of these trials. Our product development costs will increase if we have additional delays in testing or approvals.

We are using prototype components in our pre-clinical studies and clinical trials and have not completed the components commercial design.

If we fail to develop commercial versions of the systems on schedule, our potential revenue would be delayed or diminished and our competitors may be able to bring products to market before we do. The system disposables and instruments we use in our pre-clinical studies and clinical trials are prototypes of those to be used in the final products. As a result, we plan to perform studies, both pre-clinical and clinical, to demonstrate the acceptability of the commercial configuration and the equivalence of the prototype and the commercial design. However, regulatory authorities may require us to perform additional studies, both pre-clinical and clinical, using the commercial versions of the systems, which may increase our expenses and delay the commercialization of our products.

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. For example, in the system for plasma, fluid leakage was discovered in some components during the scale-up process for commercial manufacturing, resulting in a delay in expected commercialization. The solution to this issue remains under study, and the time required to identify and implement a solution remains uncertain. Additional unforeseen design, engineering and manufacturing issues may arise in the future, which could increase the development cost and delay commercialization of our products.

Because our product candidates have not been manufactured on a commercial scale, we face manufacturing uncertainties that could limit their commercialization. If our third-party manufacturers fail to produce our compounds and other product components satisfactorily and in sufficient quantities, we may incur delays, shortfalls and additional expenses.

Our product candidates, including many of the components, have never been manufactured on a commercial scale. We intend to use third-party manufacturers to produce commercial quantities of the chemical compounds and other components to be used in our products. These compounds and other components have never been produced in commercial quantities. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, which is the compound used in our platelet and plasma systems. We currently do not have any other third-party manufacturing agreements in place for commercial production of other compounds or components. Any 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. It may be difficult or impossible to economically manufacture our products on a commercial scale.

A limited number of suppliers manufacture our inactivation compounds for our use in product development, including clinical trials. We are pursuing contracts with manufacturers to produce intermediates to our S-303 compound, which is used in our red blood cell system, and to produce S-303 itself. If any of these manufacturers cannot produce our compounds in the required quantities or to the required standards, we may face delays and shortfalls before we are able to identify alternate or additional manufacturers to meet these requirements. Contracts have not yet been signed for the long-term supply in commercial quantities of the compounds used in our red blood cell system. While alternative suppliers for the inactivation compounds exist, any new manufacturer will have to prove both to us and to the FDA and foreign regulatory authorities that its manufacturing process complies with government regulations. Identifying and qualifying such new suppliers could be expensive and time-consuming.

Baxter is responsible for manufacturing and assembling our pathogen inactivation systems. Baxter intends to rely on third parties to manufacture and assemble some of the system components, many of which are customized and have not been manufactured on a commercial scale. Baxter has not produced the pathogen inactivation systems in commercial quantities and may not be able to manufacture and assemble them, or do so economically. 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. Efforts to modify the design for manufacturing of our plasma system continue, and the timing of our regulatory submission for the plasma system is dependent on the successful completion of this design, which is uncertain.

Baxter has advised us that it intends to purchase certain key components of the pathogen inactivation systems from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. While we believe there are alternative suppliers for these components, it would be expensive and time-consuming to establish additional or replacement suppliers for these components. If Baxter were unable to find adequate suppliers for these components, we may be required to redesign the systems, which could lead to additional testing and clinical trials. If we were required to redesign the products, our development costs would increase, and our programs could be delayed significantly.

We will need to establish a sufficient shelf life for the components of our products before the FDA will approve our products for sale.

Product stability studies to establish the shelf life of our system disposables have not yet demonstrated a sufficient shelf life. Certain platelet and plasma system disposables and packaging are being redesigned, and product stability will need to be validated through additional studies, which are expensive and time consuming. If sufficient shelf life cannot be demonstrated, the products may not achieve customer acceptance and may not receive regulatory approval in the United States.

Our products may not achieve acceptance in, or be rapidly adopted by, the health care community.

Even if our product candidates receive regulatory approval for commercial sale, physicians, patients and healthcare payors may not believe that the benefits of using our systems justify their additional cost, because the blood supply has become safer or for other reasons. Baxter s ability to successfully commercialize our products will depend in part on the availability of adequate reimbursement for product costs and related treatment of blood components from governmental authorities and private health care insurers (including health maintenance organizations), which are increasingly attempting to contain health care costs by limiting both the extent of coverage and the reimbursement rate for new tests

and treatments. In addition, our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may inhibit their 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. Our products may require significant changes to our potential customers space and staffing requirements and require significant capital investment. If our products fail to achieve market acceptance, we may never become profitable.

We will need to develop and test additional configurations of our pathogen inactivation systems to address the entire market.

In the United States, our efforts to develop our systems to inactivate viruses, bacteria and other pathogens in platelets have focused almost entirely on apheresis platelets collected on Baxter s automated collection platform. Apheresis platelets are platelets that are collected from a single donor using an automated collection machine. Currently, we estimate that the majority of platelets used in the United States are collected by apheresis, with the remainder prepared from pooled random donor platelets. Blood centers in the United States preparing random donor platelets may be reluctant to switch to apheresis collection, and the FDA may require us to make our systems to inactivate viruses, bacteria and other pathogens in platelets compatible with random donor platelets. In order to develop a platelet pathogen inactivation system compatible with random donor platelets, we will need to perform additional product development and testing, including clinical trials. These development activities would increase our costs significantly, and may not be successful. In addition, FDA regulations limit the time from pooling to transfusion to four hours to minimize the proliferation of bacterial contamination in the pooled product. As a result, most pooling occurs in hospitals. Our platelet system is designed for use in blood centers, not at hospitals, and is intended to permit storage and transfusion of treated platelets for up to five days after pooling. The FDA s time limit between pooling and transfusion currently precludes the use of our system with pooled random donor platelets. Although our system is designed to reduce the risk of bacterial contamination, we cannot predict whether the FDA would remove this process time constraint to allow our system to be used with pooled random donor platelets, and we have not yet made a formal request for the FDA to do so.

Baxter is one of three primary manufacturers of equipment for the collection of apheresis platelets in the United States. The equipment, design and materials used to collect the platelets vary from manufacturer to manufacturer. We have conducted our pre-clinical and clinical studies in the United States for apheresis platelets collected using only Baxter s equipment and materials. Under an agreement with Haemonetics Corporation, Baxter has agreed to provide Haemonetics with a platelet storage solution proprietary to Cerus and Baxter, with the objective that platelets collected on certain future Haemonetics apheresis collection equipment may be directly treated using our platelet system. Baxter and we also are adapting our platelet system to allow compatibility with other manufacturers equipment. Such adaptations will require additional product development and testing, including clinical trials. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the platelet system in the United States may be delayed until the system receives regulatory approval for use on such other equipment.

In Europe, platelets also are typically prepared from several units of whole blood using a semi-automated process known as the buffy coat process. For platelets prepared by the buffy coat process, our platelet system is approved for use only with Baxter s platelet collection and pooling materials. As a result, market acceptance in Europe of our platelet system for platelets prepared by the buffy coat process will depend on market acceptance of Baxter s platelet collection and pooling sets or on our ability to develop products compatible with other manufacturers platelet collection and pooling sets. Our platelet system is also approved in Europe for use with Baxter s apheresis collection equipment as well as the apheresis collection equipment of two other manufacturers through the use of preparation kits.

In Canada, our platelet system is approved for use with platelets prepared by the buffy coat process. Blood centers in Canada currently use the platelet rich plasma and single donor collection methods, and do not use the buffy coat process. The primary difference between the methods is the centrifugation process for separating the component from whole blood to obtain a therapeutic dose of platelets. Baxter and we intend to apply for the license to use the platelet system in Canada with single-donor platelets. We will not have product sales in Canada unless we apply for and receive approval for our system in Canada for use with single-donor platelets or Canadian blood centers implement the buffy coat method.

Fresh frozen plasma and red blood cells are also collected by different methods and equipment and in different volumes. Our systems for plasma and red blood cells being developed and tested will not be suitable for all methods, equipment and volumes used to collect these blood components. We will need to develop and test additional configurations of these systems in order to address the entire market.

A small number of customers will determine market acceptance of our pathogen inactivation systems.

Even if our products receive regulatory approval to be commercialized and marketed, due to the intense market concentration, failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenue. The market for our pathogen inactivation systems is dominated by a small number of blood collection organizations. In the United States, the American Red Cross collects and distributes approximately 50% of the nation s supply of blood and blood components. Other major United States blood collection organizations include the New York Blood Center and United Blood Services, each of which distributes approximately 6% of the nation s supply of blood and blood components. In many countries of Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations blood and blood components supply. In Europe, the largest markets for our products are in Germany, the United Kingdom and France. Decisions on product adoption are centralized in the United Kingdom and France. In Germany, decision on product adoption is expected to be on a blood center-by-blood center basis. We have not received in-country approvals to market our platelet system in these countries. If we do not receive approvals to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue in Europe will be significantly decreased.

We rely heavily on Baxter for development funding, product engineering, manufacturing, marketing and sales.

We have two development and commercialization agreements with Baxter for our systems to inactivate viruses, bacteria and other pathogens in each of the three commonly transfused blood components: platelets, fresh frozen plasma and red blood cells, and we rely on Baxter for significant financial and technical contributions to these programs. Since the beginning of our relationship with Baxter in 1993 through March 31, 2003, we have received $46.7 million in equity investments from Baxter and $25.9 million from Baxter International Inc. and Subsidiaries Pension Trust, a $50.0 million loan from Baxter Capital Corporation and we have recognized $30.0 million in revenue from Baxter. Our ability to develop, manufacture and market these products successfully depends significantly on Baxter s performance under these agreements.

We rely on Baxter for engineering, manufacturing and supplying components of our pathogen inactivation systems. Under the terms of our agreements, Baxter is responsible for manufacturing or supplying the disposable units, such as blood storage containers and related tubing, as well as any device associated with the inactivation processes. If these agreements were terminated or if Baxter otherwise failed to design or deliver an adequate supply of components, we would be required to identify other third-party component manufacturers. We cannot assure you that we would be able to identify such manufacturers on a timely basis or enter into contracts with such manufacturers on reasonable terms, if at all. Any delay in the availability of devices or disposables from Baxter could delay the submission of the INTERCEPT Blood System for regulatory approval or the 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.

We rely on Baxter for the marketing, sales and distribution of our pathogen inactivation systems. We currently have a small marketing group that helps support Baxter s marketing organization; however, we do not intend to develop our own independent marketing and sales organization and expect to continue to rely on Baxter to market and sell the INTERCEPT Blood System. If our joint development agreements with Baxter are terminated or if Baxter is unable to market the products successfully, we will be required to find another marketing, sales and distribution partner or develop these capabilities ourselves. We may not be able to find a suitable partner on favorable terms or on a timely basis, if at all. Developing marketing, sales and distribution capabilities ourselves would delay commercialization of our pathogen inactivation systems and increase our costs.

We share control over management decisions. Baxter and we share responsibility for managing the development programs for the pathogen inactivation systems. Management decisions are made by a governance committee, which has equal representation from both Baxter and us. Our interests and Baxter s may not always be aligned. Disagreements with Baxter may be time-consuming to resolve and cause significant delays in the development of our products. If we disagree with Baxter on

program direction, a neutral party will make the decision. The neutral party may not decide in our best interest. Under the agreements, Baxter may independently develop a pathogen inactivation system for fresh frozen plasma using a pre-existing technology. Such an effort by Baxter could create conflicts in our joint program for the development of a pathogen inactivation system for fresh frozen plasma.

Baxter can terminate our agreements or fail to perform. Any development program under the agreements may be terminated by either party, with 90 days notice in the case of the platelet program, or 270 days written notice in the case of the plasma or red blood cell programs. If Baxter terminates the agreements or fails to provide adequate funding to support the product development efforts, we will need to obtain additional funding from other sources and will be required to devote additional resources to the development of our products. We cannot assure you that we would be able to find a suitable substitute partner in a timely manner, on reasonable terms or at all. If we fail to find a suitable partner, our research, development or commercialization of certain planned products would be delayed significantly, which would cause us to incur additional expenditures.

Our products are subject to extensive regulation by domestic and foreign governments.

Our products under development, and anticipated future products, are subject to extensive and rigorous regulation by United States local, state and federal regulatory authorities and by foreign regulatory bodies. These regulations are wide-ranging and govern, among other things:

product development;

product testing;

product manufacturing;

product labeling;

product storage;

product premarket clearance or approval;

product sales and distribution;

product use standards and documentation;

product advertising and promotion; and

product 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. The time required for regulatory approvals is uncertain, and the process 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.

Even 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 practices. The failure to comply with these requirements could result in enforcement action, which could harm our business. 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. Regulatory authorities may also require post-marketing testing, which can involve significant expense. The government may impose new regulations 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 addition to CE Mark approval in Europe, we will need to obtain regulatory approvals in individual European countries to market our products. The level of additional product testing varies by country, but could take up to six months or more to complete after CE Mark approval. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in reduced revenue and earnings. In some countries, we may also need to obtain government approvals for reimbursement in order for our product to be adopted. Reimbursement levels in some countries are determined by annual budgeting processes which, in addition to affecting product adoption, will affect the price we will be able to charge for our products.

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; and
- manufacturing and stability studies.

We have conducted many toxicology studies to demonstrate our product candidates safety, and we plan to conduct additional toxicology studies 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. 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. In addition, our clinical development plan assumes that we will not be required to perform human clinical studies to demonstrate our systems ability to inactivate pathogens. Although we have discussed this plan with the FDA and other regulatory authorities, they may find it unacceptable at any time and may require human clinical trials to demonstrate efficacy in inactivating pathogens. Trials of this type may be too large and expensive to be practical.

Regulatory agencies may limit the uses, or indications, for which any of our products are approved. For example, we believe that we 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, 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 products processed with our pathogen inactivation systems. This requirement or FDA 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.

Customer adoption of our products will be affected by the availability of reimbursement from governments or other third parties.

Sales of our products may be affected by the availability of reimbursement from governments or other third parties, such as insurance companies. It is difficult to predict the reimbursement status of newly approved, novel medical products. In certain foreign markets, governments have issued regulations relating to the pricing and

profitability of medical products and medical products companies. There have been proposals in the United States, at both the federal and state government level, to implement such controls. The growth 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 Baxter and we can obtain for our products.

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 general and administrative expenses have resulted in substantial losses each year since our inception, including net losses of $36.0 million in 2000, $49.4 million in 2001 and $57.2 million in 2002. As of March 31, 2003, we had an accumulated deficit of approximately $247.4 million. Except for our platelet system, which is approved for sale in Europe, 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 Baxter and other 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 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 expect to continue to spend substantial funds for our operations for the foreseeable future. We believe that our existing capital resources, together with anticipated product revenue, funding from Baxter and the United States government and projected interest income, will support our current and planned operations until at least mid-2004. Our cash, liquidity and capital requirements will depend on many factors, including the development progress and costs of our programs, payments by Baxter and 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.

We expect to require substantial additional funds for our long-term product development, marketing programs and operating expenses. We do not know if we will be able to raise additional funds on acceptable terms. If we are unable to obtain sufficient additional capital, we may need to delay or cease certain development programs. If we raise additional funds by issuing equity securities, our existing stockholders may experience substantial dilution.

If our competitors develop and market products that are more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We expect our products to encounter significant competition. Our products may compete with other approaches to blood safety and improving the outcome of stem cell transplantation currently in use, as well as with future products developed by biotechnology and pharmaceutical companies, hospital supply companies, national and regional blood centers and governmental organizations and agencies. 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 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. Competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in pre-clinical testing, human clinical trials and other regulatory approval procedures. Our ability to compete successfully will depend, in part, on our ability to:

attract and retain skilled scientific personnel;

develop technologically superior products;

develop lower cost products;

obtain patent or other proprietary protection for our products and technologies;

obtain required regulatory approvals for our products;

be early entrants to the market; and

manufacture, market and sell our products, independently or through collaborations.

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 various blood components. In Europe, several companies, including Grifols, Octapharma AG and Maco Pharma International GmbH, are developing or have developed commercial systems to treat fresh frozen plasma.

Other groups are developing synthetic blood product substitutes and products to stimulate the growth of platelets, and new methods of testing blood for specific pathogens have recently been approved by the FDA, including tests for bacteria. Several companies are developing tests for West Nile Virus in blood products, although none have been approved for sale to date. Development of any of these technologies could impair the potential market for our products.

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 by others 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.

As of March 31, 2003, we owned 65 issued or allowed United States patents and 46 issued or allowed foreign patents. Our patents expire at various dates between 2003 and 2018. In addition, we have 26 pending United States patent applications and have filed 17 corresponding patent applications under the Patent Cooperation Treaty, which are currently pending in Europe, Japan, Australia and Canada, and of which seven are also pending in China and five are also pending in Hong Kong. In addition, we are a licensee under a license agreement with respect to two United States patents covering inventions pertaining to psoralen-based photochemical decontamination treatment of whole blood or blood components and four United States patents relating to vaccines, as well as related foreign patents. 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 patent has recently issued to a third-party covering 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. 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 declared by 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. However, these agreements may be breached, 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 may also arise as to the rights in related or resulting know-how and inventions.

We may be liable if our products harm people.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and products. We may be liable if any of our products cause injury, illness or death. 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.

We may be liable if hazardous materials used in the development of our products harm the environment, our employees or other people.

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 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.

If we do not generate sufficient cash flow through product sales revenue or by raising additional capital, then we may not be able to meet our debt obligation in 2008.

In January 2003, we received a $50.0 million loan from Baxter Capital Corporation. The interest rate for the loan is 12% per annum. No repayment of principal and interest is due until January 2008. The loan is secured with collateral based on future revenue from sales of the

INTERCEPT Blood System for platelets. Our substantial indebtedness will result in a significant amount of interest expense in future periods. Our indebtedness could have significant additional negative consequences, including limiting our ability to obtain additional financing and to plan for, or react to, changes in our business and the industry in which we compete. If we are unable to satisfy our debt obligation, substantial liquidity problems could result, which would negatively impact our future prospects.

Risks Related to Our Common Stock and this Offering

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, 2001 to March 31, 2003, the closing sale price of our common stock as quoted on the Nasdaq National Market fluctuated

from a low of $5.59 to a high of $75.35. 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;
- 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. In the past, following periods of volatility in the market price of a company s stock, securities class action litigation has occurred against the issuing company. Such litigation could result in substantial costs and a diversion of management s attention and resources, which could have a material adverse effect on our revenue and earnings. Any adverse determination in such litigation could also subject us to significant liabilities.

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

We have not designated the amount of net proceeds we will use for any particular purpose. Accordingly, our management will have broad discretion as to the application of the net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase our profitability or our market value.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $9.63 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $5.39 per share in the net tangible book value of the common stock. See Dilution below for a more detailed discussion of the dilution you will incur in this offering.

Item 7. Exhibits.

Exhibit Number		Description of Exhibit
1.1		Underwriting Agreement, dated June 5, 2003, by and between the Company and Morgan Stanley.
99.1		Press Release, dated June 6, 2003, entitled Cerus Announces Pricing of Public Offering.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CERUS CORPORATION

Dated: June 9, 2003

By: /s/ Gregory W. Schafer
Gregory W. Schafer
Vice President, Finance and
Chief Financial Officer

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