CERUS CORP
Form 10-Q
November 14, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10 - Q

(Mark One)

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

For the quarterly period ended September 30, 2003

or

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

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 Number)

2411 Stanwell Dr.
Concord, California 94520
(Address of principal executive offices, including zip code)

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

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 ý NOo

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES ý NOo

As of October 31, 2003, there were 22,059,814 shares of the registrant s common stock outstanding.

CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q
THREE MONTHS ENDED SEPTEMBER 30, 2003
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PART I: **FINANCIAL INFORMATION**

ITEM 1. **FINANCIAL STATEMENTS**

CERUS CORPORATION

CONDENSED BALANCE SHEETS

UNAUDITED

(in thousands)

	September 30, 2003	December 31, 2002
Assets		
Current assets:		
Cash and cash equivalents	$ 52,878	$ 22,435
Short-term investments	70,247	41,883
Accounts receivable from related parties	25	46
Accounts receivable and other current assets	4,680	2,884
Total current assets	127,830	67,248
Furniture and equipment, net of depreciation	3,388	5,547
Other assets	151	152
Total assets	$ 131,369	$ 72,947
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable to a related party	$ 6,180	$ 8,538
Loan and interest payable to a related party	54,417	
Accounts payable	2,637	2,022
Accrued expenses	4,802	5,449
Deferred revenue	611	718
Current portion of capital lease obligations	28	35
Total current liabilities	68,675	16,762
Capital lease obligations, less current portion		16

Total stockholders equity		62,694		56,169
Total liabilities and stockholders equity	$	131,369	$	72,947

See notes to condensed financial statements.

CERUS CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	**2002**	**2003**	**2002**
Revenue:				
Milestone and development funding, related parties	$	$	$	$ 5,002
Development funding, other	257	167	539	306
Government grants and cooperative agreements	2,587	563	5,549	1,574
Product sales	24		52	
Total revenue	2,868	730	6,140	6,882
Operating expenses:				
Research and development	13,400	14,881	42,847	41,286
General and administrative	2,587	2,925	8,105	8,751
Total operating expenses	15,987	17,806	50,952	50,037
Loss from operations	(13,119)	(17,076)	(44,812)	(43,155)
Interest income (expense), net	(1,089)	485	(3,327)	1,733
Net loss	$ (14,208)	$ (16,591)	$ (48,139)	$ (41,422)
Net loss per share - basic and diluted	$ (0.64)	$ (1.05)	$ (2.61)	$ (2.62)
Shares used in computing net loss per share - basic and diluted	22,031	15,874	18,459	15,802

See notes to condensed financial statements.

CERUS CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Nine Months Ended September 30,	
	2003	**2002**
Operating activities:		
Net loss	$ (48,139)	$ (41,422)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,468	1,685
Issuance of common stock for services		33
Changes in operating assets and liabilities:		
Accounts receivable from a related party	21	(29)
Accounts receivable and other current assets	(1,796)	(556)
Other assets	1	35
Accounts payable to a related party	(2,358)	3,868
Accounts payable and accrued expenses	(32)	(1,801)
Accrued interest	4,417	
Deferred revenue	(107)	(173)
Net cash used in operating activities	(45,525)	(38,360)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(309)	(4,837)
Purchases of short-term investments	(128,345)	(77,034)
Sales of short-term investments	39,000	47,033
Maturities of short-term investments	60,981	49,292
Net cash used in investing activities	(28,673)	(14,454)
Financing activities:		
Net proceeds from issuance of common stock	54,664	1,554
Proceeds from loan payable to a related party	50,000	
Payments on capital lease obligations	(23)	(23)
Net cash provided by financing activities	104,641	1,531
Net increase (decrease) in cash and cash equivalents	30,443	(22,375)
Cash and cash equivalents, beginning of period	22,435	64,503

Cash and cash equivalents, end of period	$	52,878	$	42,128

See notes to condensed financial statements.

CERUS CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

UNAUDITED

Note 1 - Basis of Presentation

The accompanying unaudited condensed financial statements of Cerus Corporation have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accrual adjustments, considered necessary for a fair presentation have been included. Operating results for the three- and nine- month periods ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003 or for any future period.

These condensed financial statements and notes should be read in conjunction with Cerus audited financial statements and notes thereto for the year ended December 31, 2002 included in Cerus 2002 Annual Report on Form 10-K.

Note 2 Stock-Based Compensation

Cerus accounts for employee stock options in accordance with Accounting Principles Board Opinion No. 25, including Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation: An Interpretation of APB No. 25, and has adopted the disclosure only alternative described in Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation, as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (FAS 123).

Pro forma information regarding net loss and net loss per share is required by FAS 123, and has been determined as if Cerus had accounted for its employee stock options and employee stock purchase plan under the fair value method of FAS 123. The fair value for these options and shares was estimated at the date of grant using a Black-Scholes model with the following weighted-average assumptions for the three months ended September 30, 2003 and 2002, respectively: the expected volatility was 0.904 and 0.637 and the risk-free interest rate was 3.33% and 2.80%. The following weighted-average assumptions were used for the nine months ended September 30, 2003 and 2002, respectively: the expected volatility was 0.893 and 0.637 and the risk-free interest rate was 3.03% and 2.80%. The expected life of the option was five years for the stock option plans for both periods and six months for the employee stock purchase plan for both periods.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because Cerus employee stock options and purchased shares have

characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock awards.

The following table illustrates the effect on net loss and related net loss per share, had compensation expense for stock-based compensation plans been determined based on the fair value method prescribed under FAS 123 (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss:				
As reported	$ (14,208)	$ (16,591)	$ (48,139)	$ (41,422)
Add:				
Stock-based employee compensation expense included in reported net loss, net of related tax effects				
Less:				
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	2,419	4,391	6,672	11,252
Pro forma	$ (16,627)	$ (20,982)	$ (54,811)	$ (52,674)
Net loss per share - basic and diluted, as reported	$ (0.64)	$ (1.05)	$ (2.61)	$ (2.62)
Net loss per share - basic and diluted, pro forma	$ (0.75)	$ (1.32)	$ (2.97)	$ (3.33)

Note 3 - Comprehensive Income (Loss)

Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, requires that all items recognized under accounting standards as comprehensive income (revenue, expenses, gains and losses) be reported in a financial statement that is displayed with the same prominence as other financial statements. Cerus does not have material components of other comprehensive income. Therefore, comprehensive loss is equal to net loss for all periods presented.

Note 4 - Net Loss per Share

Cerus net loss per share has been calculated in accordance with Statement of Financial Accounting Standards No. 128, Earnings per Share. Basic and diluted net loss per share has been computed using the weighted average number of common shares outstanding during the period. The effects of outstanding stock options and other convertible securities are excluded from the calculation of diluted net loss per share, as inclusion would be antidilutive.

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Note 5 - Revenue and Research and Development Expenses

Development funding revenue includes amounts recognized under agreements with Baxter Healthcare Corporation (Baxter), a subsidiary of Baxter International Inc. (Baxter International), the National Marrow Donor Program, Kirin Brewery Company, Ltd. and the Consortium for Plasma Science. Baxter and the Consortium are related parties to Cerus. Development funding revenue is recognized as the related project costs are incurred. Research and development expenses are recognized as incurred. Revenue related to at-risk milestones specified under development contracts is recognized as the milestones are achieved. Payments for achieved milestones are non-refundable and are not subject to future performance. There was no milestone revenue recognized in the three and nine months ended September 30, 2003. In the second quarter of 2002, Cerus recognized $5,000,000 of milestone revenue from Baxter upon CE Mark approval of the disposable set for the platelet system.

Cerus receives certain United States government grants in support of its research efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred.

Note 6 Loan Payable to a Related Party

In January 2003, Cerus received proceeds from a $50 million loan from Baxter Capital Corporation (Baxter Capital), a subsidiary of Baxter International separate from Baxter. The interest rate on the loan is 12% per annum. Under the terms of the loan, no payment of principal or interest is due until 2008. The loan is secured by Cerus present and future accounts receivable from sales of the INTERCEPT Blood System for platelets.

In October 2003, Baxter Capital commenced legal proceedings against Cerus seeking immediate repayment of amounts outstanding under the loan, and has instructed Baxter to remit to Baxter Capital payments owing to Cerus for revenue sharing on platelet product sales. Baxter has informed Cerus that $24,000 was paid to Baxter Capital in November 2003 on Cerus behalf. Baxter Capital alleges that changes in Cerus business constitute a default under the loan agreement. Cerus does not agree that any default has occurred and therefore believes that, under the terms of the loan, no principal or interest payments are due until January 2008. Due to uncertainty as to the potential outcome of the legal proceedings, Cerus has reclassified amounts due to Baxter Capital under the loan as a current liability in the balance sheet.

Note 7 Preferred Stock

Baxter holds 3,327 shares of Cerus Series B preferred stock, which represents 100% of the total outstanding shares of Series B preferred stock. The holder of Series B preferred stock has no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B preferred stock as to voting, liquidation or conversion or with respect to the determination of fair market value of non-publicly traded shares received by the holder of Series B stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder may convert each share of Series B preferred stock into 100 common shares. If all shares of Series B preferred stock were converted to common stock, 332,700 shares would be issued, which represents 1.5% of the outstanding common shares of Cerus at

September 30, 2003. Cerus has the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million.

Note 8 - Capital Stock Transaction

In June 2003, Cerus completed a public offering of 6,000,000 shares of common stock and received net proceeds of $54.1 million, after deducting related expenses.

Note 9 - Clinical Trial Termination

In September 2003, Cerus and Baxter terminated Phase III clinical trials of pathogen-inactivated red blood cells after two study patients developed antibodies to red blood cells treated with S-303, the compound used in the companies investigational pathogen inactivation system for red blood cells. In October 2003, Cerus announced a restructuring due mostly to the clinical trial termination. The restructuring included a reduction in the workforce of approximately 25 percent and a significant reduction in research and development activities relating to the red blood cell program. Cerus expects that research and development expenses, including ongoing expenses related to terminating the red blood cell clinical trials, will be significantly reduced in 2004 as compared to 2003. Cerus expects that the restructuring will not affect current sources of development revenue.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and our 2002 audited financial statements and accompanying notes included in our 2002 Annual Report on Form 10-K. Operating results for the periods presented are not necessarily indicative of results for the year ending December 31, 2003 or any future period.

The following discussion includes forward-looking statements that involve risks and uncertainties. When used herein, the words believe, anticipate, expect, estimate 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 the risks and uncertainties of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development process, additional financing activities, manufacturing, reimbursement, market acceptance of any products, competitive conditions, our long term growth opportunity, legal proceedings, actions by Baxter and other factors discussed below and under the caption Risk Factors, 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.

The condensed balance sheet at December 31, 2002 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

Cerus and *Helinx* are United States registered trademarks of Cerus Corporation.

INTERCEPT and *INTERCEPT Blood* are trademarks of Baxter International Inc.

Overview

We are developing medical systems and therapeutics based on our proprietary Helinx® technology for controlling biological replication. Our most advanced programs are focused on systems to enhance the safety of blood products used for transfusion. The INTERCEPT Blood System, which is being developed in collaboration with subsidiaries of Baxter International Inc., is based on our Helinx technology. The INTERCEPT Blood System is designed to inactivate viruses, bacteria, other pathogens and white blood cells. We also are pursuing therapeutic and vaccine applications of Helinx technology to treat and prevent serious diseases.

We are developing the INTERCEPT Blood System for platelets, plasma and red blood cells with our development and commercialization partner, Baxter. The INTERCEPT Blood System targets and inactivates blood-borne pathogens, such as HIV and hepatitis B and C, as well as harmful white blood cells, while leaving intact the therapeutic properties of the blood components. The INTERCEPT Blood System inactivates a broad array of pathogens and has the potential to reduce the risk of transmission of pathogens for which testing is not completely effective or is

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not currently performed. We believe that the INTERCEPT Blood System also has the potential to inactivate new pathogens before they are identified and before tests are developed to detect their presence in donated blood.

The INTERCEPT Blood System for platelets has received CE Mark approval and has been commercially launched in Europe. The system also has received approval for use with buffy coat platelets in Canada. Baxter and we have submitted regulatory applications seeking marketing approval in Australia. 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 United States Food and Drug Administration, or FDA. Based on discussions with the FDA, we are performing additional analyses of the clinical trial data and plan to conduct a supplemental clinical trial. 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 are in late stage development of the INTERCEPT Blood System for plasma.

In September 2003, we terminated Phase III clinical trials of our INTERCEPT Blood System for red blood cells due to the detection of antibodies in two patients. The observations from this trial do not affect the development or commercialization of the pathogen inactivation programs for platelets and plasma, which use a different technology and mechanism of action. The red blood cell technology employs a compound called S-303, which is activated by the pH of blood. The platelet and plasma technology uses a compound called amotosalen, which is activated by light. There is extensive data on the profile of the platelet and plasma technology, including the amotosalen compound, indicating no associated antibody response. We have begun an evaluation of the antibody and are investigating process changes that could prevent antibody formation and allow the modified red blood cell system to undergo clinical trials. These activities may take a long time to complete and may not be successful.

We restructured our operations to focus on our pathogen inactivation products for platelets and plasma and our pipeline of therapeutics and vaccines. The restructuring was intended to reduce operating expenses and included a reduction in our workforce of approximately 25 percent.

Our allogeneic cellular immune therapy (ACIT) program, designed to improve the outcome of bone marrow transplantation procedures through use of T-cells treated with the Helinx technology, and Epstein-Barr virus (EBV) cellular vaccine program are in Phase I clinical trials.

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of medical systems based on our Helinx technology. We have been unprofitable since inception and, as of September 30, 2003, had an accumulated deficit of approximately $278.4 million. Except for the INTERCEPT Blood System for platelets, which has received CE Mark approval, all of our product candidates are in the research and development stage. We have not yet received significant revenue from product sales. Baxter and we must conduct significant research, development, pre-clinical and clinical evaluation, commercialization and regulatory compliance activities on these product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after commercialization of additional products. Our ability to achieve a profitable level of operations in the future will depend on our and Baxter s ability to successfully complete development and obtain additional regulatory approvals and on Baxter s ability to commercialize and achieve market acceptance of the INTERCEPT Blood System. We may never achieve a profitable level of operations. Further, under the agreements discussed below, Baxter provides significant funding for development of the INTERCEPT Blood System, based on an annual budgeting process, and is responsible for manufacturing and marketing the products following regulatory approvals. These agreements may be modified or terminated.

Agreement with Baxter for the Development of the INTERCEPT Blood System for Platelets. We have a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Blood System to inactivate viruses, bacteria and other infectious pathogens in platelets used for transfusion. This agreement provides for Baxter

and us generally to share system development costs equally, subject to mutually determined budgets established from time to time, and for us to receive approximately 33.5% of revenue from sales of inactivation system disposables after each party is reimbursed for its cost of goods to the extent the cost

exceeds specified amounts. Baxter has an exclusive, worldwide distribution license and is responsible for manufacturing and marketing the INTERCEPT Blood System for platelets.

Agreement with Baxter for the Development of the INTERCEPT Blood System for Red Blood Cells and INTERCEPT Blood System for Plasma. We also have a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Blood System to inactivate viruses, bacteria and other infectious pathogens in red blood cells and fresh frozen plasma for transfusion. This agreement provides for Baxter and us generally to share red blood cell system development costs equally, subject to mutually determined budgets established from time to time. We are solely responsible for funding the development costs of the INTERCEPT Blood System for plasma. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Blood System for red blood cells and INTERCEPT Blood System for plasma following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of red blood cell system disposables, and for us to receive 75% and Baxter to receive 25% of revenue from sales of plasma system disposables, in each case after each party is reimbursed for its cost of goods and a specified percentage, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses. The termination of Phase III clinical trials of the red blood cell system does not affect the terms of the agreement and is not expected to affect current sources of development funding revenue, but will significantly delay the development of, and any potential revenue from, sales of the red blood cell system.

This agreement also provides that Baxter and its affiliates will not acquire any of our capital stock if the acquisition would result in Baxter and its affiliates owning 5.4% or more of our outstanding voting shares. The provision excludes the conversion of preferred stock and will not apply in the event a third party makes a tender offer for a majority of our outstanding voting shares, the Board of Directors decides to liquidate or sell to a third party substantially all of our assets or a majority of our voting securities approve a merger in which our stockholders do not own a majority of the voting securities of the post-merger company. As of September 30, 2003, Baxter owned less than 5% of our outstanding common stock.

Funding from Baxter. From inception through September 30, 2003, we have received $46.7 million in equity investments from Baxter and $25.9 million in an equity investment from Baxter International Inc. and Subsidiaries Pension Trust, have received proceeds from a $50.0 million loan from Baxter Capital Corporation and have recognized $30.0 million in development funding revenue from Baxter. Baxter Capital has commenced legal proceedings against us seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleges that changes in our business constitute a default under the terms of the loan. Baxter has advised us that Baxter International Inc. and Subsidiaries Pension Trust is not an affiliate of Baxter. Development funding is in the form of balancing payments made by Baxter, if necessary, to reimburse us for development spending in excess of the levels determined by Baxter and us. Development funding revenue is recognized as the related project costs are incurred.

Agreement with Kirin. In January 2001, we entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on our Helinx technology. Under the terms of the agreement, we will jointly develop the products with Kirin. We received an initial license fee of $1 million. The license fee is being deferred and recognized as development funding ratably over the development period. We may not receive additional funding from Kirin. Although the agreement calls for Kirin to fund all development expenses for the Asia-Pacific region and a portion of our development activities aimed at obtaining product approval in the United

States, no such development activities co-funded by Kirin are currently ongoing. Upon product approval, Kirin has exclusive rights to market the products in the Asia-Pacific region, including Japan, China, Korea and Australia,

and we will receive a specified share of product revenue, including a royalty and reimbursement of our cost of goods. We retain all marketing rights for the rest of the world, including the United States and Europe.

Cooperative Agreement with the Armed Forces of the United States. In February 2001, we were awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002 and May 2003, we were awarded additional $6.5 million and $6.2 million cooperative agreements, respectively, both of which were awarded to continue funding of these projects. We received the awards to develop our pathogen inactivation technologies to improve the safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the conditions of the agreements, we are conducting research on the inactivation of infectious pathogens, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. We are collaborating with investigators at Walter Reed Army Institute of Research to investigate ways to improve the storage and shelf life of blood and blood components, which may be used for medical transfusion support in combat zones.

Agreement with the National Marrow Donor Program. In October 2001, we entered into an agreement with the National Marrow Donor Program, or NMDP, a non-profit corporation, under which the NMDP sponsors a clinical trial of our allogeneic cellular immune therapy in patients receiving matched unrelated bone marrow transplants. The agreement was amended in December 2002. Under the amended agreement, we provide our Helinx compound amotosalen, illumination devices, training of clinical sites and program oversight in exchange for reimbursement by the NMDP of our related costs.

Results of Operations

Three- and Nine- Month Periods Ended September 30, 2003 and 2002

Revenue. No development funding revenue from related parties was recognized in the three and nine months ended September 30, 2003. In the second quarter of 2002, a $5.0 million milestone payment from Baxter was earned upon CE Mark approval of the disposable set for the INTERCEPT Blood System for platelets.

Development funding from non-related parties (Kirin and the NMDP) increased 54% to $257,000 for the three months ended September 30, 2003 from $167,000 for the comparable period in 2002, and increased 76% to $539,000 for the nine months ended September 30, 2003 from $306,000 for the comparable period in 2002. The change was due to increased development funding from the NMDP for clinical trial expenses incurred by Cerus in 2003. The Phase Ib clinical trial funded by the NMDP was initiated in October 2003.

Revenue from government grants and cooperative agreements increased 360% to $2.6 million for the three months ended September 30, 2003 from $0.6 million for the comparable period in 2002, and increased 253% to $5.5 million for the nine months ended September 30, 2003 from

$1.6 million for the comparable period in 2002. The change was primarily due to increased research activities funded by the second cooperative agreement awarded in September 2002 and the timing of external contract research activities under the agreements. We have three three-year

cooperative agreements with the Armed Forces of the United States that were awarded in February 2001, September 2002 and May 2003.

During the three and nine months ended September 30, 2003, we recognized $24,000 and $52,000, respectively, of product sales revenue from sales of the INTERCEPT Blood System for platelets in Europe. The system is currently undergoing validation studies and regulatory and reimbursement review in many European countries. In-country approvals for sale and reimbursement in the larger European market countries may not be received until 2004, if at all. We do not expect product sales revenue in Europe to be significant at least until the system is approved for sale and reimbursement in the larger European market countries.

Research and Development Expenses. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, pre-clinical safety studies, compound manufacturing and other laboratory studies. Research and development expenses decreased 10% to $13.4 million for the three months ended September 30, 2003 from $14.9 million for the comparable period in 2002, and increased 4% to $42.8 million for the nine months ended September 30, 2003 from $41.3 million for the comparable period in 2002. The decrease for the three-month period was primarily due to greater development expenses in the platelet program in 2002 for the completion of the illumination device, which received CE Mark approval in October 2002. The increase for the nine-month period was primarily due to increased expenses in the red blood cell program, in support of the Phase III clinical trials.

Our total research and development costs included $11.7 million for the INTERCEPT Blood System and $1.7 million for all other programs for the three months ended September 30, 2003, and $12.6 million for the INTERCEPT Blood System and $2.3 million for all other programs for the comparable period in 2002. Our total research and development costs included $37.3 million for the INTERCEPT Blood System and $5.5 million for all other programs for the nine months ended September 30, 2003, and $35.4 million for the INTERCEPT Blood System and $5.9 million for all other programs for the comparable period in 2002.

We anticipate that our research and development expenses will decrease primarily as a result of the restructuring of our operations relating to the termination of red blood cell system Phase III clinical trials, which included a reduction in workforce of approximately 25 percent. Ongoing expenses relating to the termination of the red blood cell Phase III clinical trials will be reorganized as incurred over the next several quarters and will be significantly lower than expenses in prior quarters. In the longer term, we anticipate that our research and development expenses may increase as an additional planned clinical trial of the INTERCEPT Blood System for platelets is conducted, development is completed for the INTERCEPT Blood System for plasma and research and development activity relating to other clinical and pre-clinical programs increases. Due to the inherent uncertainties and risks associated with developing biomedical products, including but not limited to intense and changing government regulation, uncertainty of future pre-clinical and clinical study results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects; see Risk Factors below.

General and Administrative Expenses. General and administrative expenses decreased 12% to $2.6 million for the three months ended September 30, 2003 from $2.9 million for the comparable period in 2002, and decreased 7% to $8.1 million for the nine months ended September 30, 2003 from $8.8 million for the comparable period in 2002. We expect our general and administrative expenses to decrease slightly in 2004 as a result of our restructuring, due to the reduction in workforce. In the longer term, we expect our general and administrative expenses to increase moderately as development and commercialization activities progress.

Net Interest Income (Expense). Net interest expense was $1.1 million for the three months ended September 30, 2003 compared to net interest income of $0.5 million for the comparable period in 2002, and net interest expense was $3.3 million for the nine months ended September 30, 2003 compared to net interest income of $1.7 million for the comparable period in 2002. We received proceeds from a $50.0 million loan from Baxter Capital Corporation in January 2003 and recorded $1.5 million and $4.4 million of related interest expense for the three and nine months ended September 30, 2003, respectively. Interest income from investments was $0.4 million for the three months ended September 30, 2003 compared to $0.5 million for the comparable period in 2002, and was $1.1 million for the nine months ended September 30, 2003 compared to $1.7 million for the comparable period in 2002. The decreases in interest income for both periods were primarily due to reduced yields on investments as a result of declines in interest rates. We expect to earn interest at market rates in proportion to the balances we maintain.

Liquidity and Capital Resources

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, the loan from Baxter Capital Corporation, payments received under our agreements with Baxter, Kirin, the NMDP and the Consortium, United States government grants and cooperative agreements and interest income. To date, we have not received significant revenue from product sales, and we will not derive significant revenue from product sales unless and until one or more products under development receives regulatory approval and achieves market acceptance.

At September 30, 2003, we had cash, cash equivalents and short-term investments of $123.1 million. Net cash used in operating activities was $45.5 million for the nine months ended September 30, 2003, compared to $38.4 million for the same period in 2002, resulting primarily from the net loss of $48.1 million during the period and changes in other operating balances, including accrued interest at September 30, 2003 of $4.4 million. Net cash used in investing activities during the nine months ended September 30, 2003 of $28.7 million resulted principally from the purchases of $128.3 million of short-term investments and $0.3 million of furniture, equipment and leasehold improvements, offset by the sales and maturities of $100.0 million of short-term investments. Working capital increased to $59.2 million at June 30, 2003 from $50.5 million at December 31, 2002, primarily due to the receipt of $54.1 million of net proceeds for the public offering of common stock in June 2003.

We believe that our available cash balances, together with anticipated cash flows from existing development and grant arrangements, will be sufficient to meet our capital requirements for at least the next 24 months irrespective of the timing of repayment of any amounts due under the loan from Baxter Capital. These near-term capital requirements are dependent on various factors, including the development progress and costs of the INTERCEPT Blood System and other programs; payments to or from Baxter and the United States government; and costs related to

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creating, maintaining and defending our intellectual property position. Our long-term capital requirements will be dependent on these factors and on the outcome of the loan dispute with Baxter Capital whereby Baxter Capital is seeking immediate repayment of $54.4 million of outstanding principal and interest, our ability to raise capital through public or private equity or debt financings or through additional collaborative arrangements or government grants, regulatory approval and successful commercialization of the INTERCEPT Blood System and other product candidates, competitive developments and regulatory factors. If Baxter were to terminate its agreements with us, we might not be able to meet our long-term capital requirements. Future capital funding transactions may result in dilution to our investors, and may not be available on favorable terms or at all. In August 2001, we filed a shelf registration statement on Form S-3 to offer and sell up to $300 million of common stock and/or debt securities. In June 2003, we completed a public offering of 6,000,000 shares of common stock with gross proceeds, calculated for registration statement purposes, of $57.8 million under the shelf registration statement. We have no current commitments to offer or sell additional securities pursuant to this registration statement.

Financial Instruments

We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of stockholders equity, if material. Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our research and development activities. Unrealized gains and losses at September 30, 2003 and December 31, 2002 were not material. Our investments primarily consist of short-term money market mutual funds, United States government obligations and commercial paper. Of our investments balance of $120.9 million at September 30, 2003, approximately 42% have original maturity dates of less than 90 days, and approximately 28% have original maturities of 90 days to one year. We do not believe our exposure to interest rate risk to be material given the short-term nature of our investment portfolio.

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.

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 has received CE Mark approval and regulatory approval for use with platelets prepared by the buffy coat process in 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, stem cell transplantation and cellular vaccine 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 six months to complete.

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. Based on discussions with the FDA, we are performing additional analyses of the clinical trial data and plan to conduct a supplemental clinical trial. Data from the additional analyses and supplemental clinical trial will need to be submitted to the FDA before we can complete our regulatory submission. The additional analyses are blinded reviews of certain data by independent experts. The FDA may not find the results to be acceptable for approval. Before we begin the clinical trial, we will need to gain concurrence with the FDA on our trial design. We may not be able to reach concurrence on the size, scope or design of the study.

We have completed Phase IIIa 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 have not submitted any applications for regulatory approval of the INTERCEPT Blood System for plasma in the United States, Europe or any other regions.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibodies in two patients, we will need to conduct additional research activities on our red blood cell system to determine if the system can be reconfigured to prevent antibody formation and potentially undergo clinical testing. We may not be successful in this research. If we are successful, it is not known what stages of clinical testing would be necessary to be completed for the reconfigured system. If we are unsuccessful in developing a modified red blood cell system that can complete clinical testing, then we may never realize a return on our development expenses incurred to date in this program.

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 a Phase Ib clinical trial in the United States. 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. 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. 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.

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.

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. 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. Some blood product is consumed as a result of our pathogen inactivation process. If the reduction of blood product leads to increased costs, or requires changes in 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. Our products may be inappropriate for certain patients, which could reduce the potential market size. In addition, healthcare professionals may require further safety information or additional studies before adopting our products. 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. 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 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. In Germany, decisions on product adoption are expected to be on a blood center-by-blood center basis. We have not received in-country approvals to market our platelet system in

Germany or the United Kingdom. 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 September 30, 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 development funding 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 Baxter is unable to market the products successfully, we may need to develop our own capabilities to supplement Baxter s marketing efforts. If our agreements with Baxter are terminated, 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 increase our costs and, if our agreements with Baxter were terminated, would delay commercialization of our pathogen inactivation systems.

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

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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.

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. Delays or setbacks, such as the clinical trial termination that recently occurred in our red blood cell program, in any of our shared development programs might increase the risk that Baxter would terminate or reduce its funding commitments to one or more 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 dispute with Baxter Capital Corporation may affect our relationship with Baxter Healthcare Corporation. Baxter Capital Corporation and Baxter Healthcare Corporation are both subsidiaries of Baxter International Inc. Although these companies are separate subsidiaries within Baxter International Inc., our dispute with Baxter Capital over the repayment terms of the $50.0 million loan could adversely affect our joint efforts to develop and commercialize the INTERCEPT Blood System.

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. Before the FDA determines whether to approve our 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.

The BPAC will make a recommendation to the FDA for, or against, approval. If the BPAC were to recommend approval of one or more of our products, the FDA would not necessarily be required to approve those products. If the BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products.

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. For example, the FDA is considering implementing standards for the recovery and survival of stored platelets. Some platelets are consumed in our pathogen inactivation process. If we are unable to meet new or existing FDA standards for the recovery and survival of platelets, we will be unable to market our platelet system in the United States. 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 more than six months to complete. 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 September 30, 2003, we had an accumulated deficit of approximately $278.4 million. Except for the INTERCEPT Blood System for platelets, which has received CE Mark approval, all of our products are in the research and development stage, and we have not received significant revenue from product sales. We have received substantially all of our revenue from our agreements with 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 for at least the next 24 months. 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. In October 2003, Baxter Capital Corporation commenced legal proceedings against us seeking immediate repayment of $54.4 million of principal and interest outstanding under the loan. Baxter Capital alleges that changes in our business constitute a default under the loan agreement. We do not agree that any default has occurred. If we are unsuccessful in defending this legal action, or if we agree to repay all or part of the loan before January 2008, then we will require substantially greater funds to support our operations than currently anticipated. 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 September 30, 2003, we owned 66 issued or allowed United States patents and 58 issued or allowed foreign patents. Our patents expire at various dates between 2003 and 2018. In addition, we have 29 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 six of which 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 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 on the loan is 12% per annum. Under the terms of the loan, no payment of principal or interest is due until January 2008. The loan is secured by our present and future accounts receivable 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. Baxter Capital has commenced legal proceedings against us seeking immediate repayment of amounts outstanding under the loan.

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 September 30, 2003, the closing sale price of our common stock as quoted on the Nasdaq National Market fluctuated from a low of $4.64 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;

status of development partnerships;

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information called for by this item is provided under the caption Financial Instruments under Item 2 - Management s Discussion and Analysis of Financial Condition and Results of Operations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Based on their evaluation of our disclosure controls and procedures (as defined in the rules promulgated under the Securities Exchange Act of 1934), our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

Changes in Internal Controls. There were no significant changes in our internal control over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On October 14, 2003, Baxter Capital Corporation, a financial subsidiary of Baxter International Inc., filed a complaint in the Circuit Court of Cook County, Illinois against us seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleges that changes in our business constitute a default under the loan agreement. We do not agree that any default has occurred. If we are unsuccessful in defending this legal action, or if we agree to repay all or part of the loan before January 2008, then we will require substantially greater funds from other sources than currently anticipated to support our operations.

ITEM 2. **CHANGES IN SECURITIES AND USE OF PROCEEDS**

None.

ITEM 3. **DEFAULTS UPON SENIOR SECURITIES**

None.

ITEM 4. **SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

ITEM 5. **OTHER INFORMATION**

None.

ITEM 6. **EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits

31.1 Certification of the Chief Executive Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of the Chief Financial Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

On July 24, 2003, the Company filed a report on Form 8-K that included as an exhibit the press release announcing its second quarter 2003 financial results.

On September 4, 2003, the Company filed a report on Form 8-K that included as an exhibit the press release announcing that the Company and Baxter are voluntarily halting Phase III trials for their pathogen-inactivated red blood cell program.

SIGNATURES

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, thereunto duly authorized.

CERUS CORPORATION

Date: November 12, 2003 /s/ Gregory W. Schafer

Gregory W. Schafer
Chief Financial Officer
(Principal Financial and Accounting Officer)