

CERUS CORP  
Form 10-Q  
May 02, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10 - Q**

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(Mark One)

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

For the quarterly period ended March 31, 2007

or

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

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

Commission File Number 0-21937

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**CERUS CORPORATION**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction  
of incorporation or organization)

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

2411 Stanwell Drive

Concord, California 94520

(Address of principal executive offices, including Zip Code)

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(925) 288-6000

(Registrant's telephone number, including area code)

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

As of April 20, 2007, there were 31.8 million shares of the registrant's common stock outstanding.

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**CERUS CORPORATION**

**QUARTERLY REPORT ON FORM 10-Q**

**THREE MONTHS ENDED MARCH 31, 2007**

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**Table of Contents****PART I: FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****CERUS CORPORATION****CONDENSED CONSOLIDATED BALANCE SHEETS****UNAUDITED**

(in thousands)

	<b>March 31,</b>	<b>December 31,</b>
	<b>2007</b>	<b>2006</b>
	<b>(Unaudited)</b>	<b>(see Note 1)</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 39,192	\$ 46,287
Short-term investments	40,422	47,129
Accounts receivable	9,304	5,279
Inventories	2,577	1,833
Prepaid and other current assets	1,576	2,215
<b>Total current assets</b>	<b>93,071</b>	<b>102,743</b>
<b>Non-Current assets:</b>		
Property and equipment, net	1,550	1,627
Long-term investment in related party	11,175	11,175
Other assets	368	272
<b>Total assets</b>	<b>\$ 106,164</b>	<b>\$ 115,817</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 3,194	\$ 6,665
Accrued liabilities	7,655	7,479
Deferred revenue	126	
Deferred gain	91	586
Capital lease obligation	72	84
<b>Total current liabilities</b>	<b>11,138</b>	<b>14,814</b>
Capital lease obligation	27	32
<b>Total liabilities</b>	<b>11,165</b>	<b>14,846</b>
<b>Stockholders' equity</b>		
Preferred stock	9,496	9,496
Common stock	32	32
Additional paid-in capital	403,701	402,888
Accumulated other comprehensive (loss)		(23)
Accumulated deficit	(318,230)	(311,422)

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Total stockholders' equity	\$ 94,999	100,971
Total liabilities and stockholders' equity	\$ 106,164	\$ 115,817

See notes to condensed consolidated financial statements.

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**CERUS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

UNAUDITED

(in thousands, except per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Revenue:</b>		
Government grants and cooperative agreement	\$ 3,511	2,701
Product revenue	1,187	479
Milestone and development funding		\$ 379
Milestone and development revenue from related party		3,438
<b>Total revenue</b>	<b>4,698</b>	<b>6,997</b>
<b>Operating expenses:</b>		
Cost of product revenue	824	182
Research and development	6,448	6,638
Selling, general and administrative	5,322	3,160
<b>Total operating expenses</b>	<b>12,594</b>	<b>9,980</b>
Loss from operations	(7,896)	(2,983)
Interest income and other, net	1,088	2,053
<b>Net income (loss)</b>	<b>\$ (6,808)</b>	<b>\$ (930)</b>
<b>Net income (loss) per common share:</b>		
Basic	\$ (0.21)	\$ (0.04)
Diluted	\$ (0.21)	\$ (0.04)
<b>Weighted average common shares outstanding used for basic and diluted net income (loss) per share:</b>		
Basic	31,760	23,040
Diluted	31,760	23,040

See notes to condensed consolidated financial statements.

**Table of Contents****CERUS CORPORATION****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****UNAUDITED**

(in thousands)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
Operating activities:		
Net income (loss)	\$ (6,808)	\$ (930)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	213	164
Stock-based compensation to employees	523	642
Changes in operating assets and liabilities:		
Accounts receivable	(4,025)	(5,796)
Inventories	(744)	(2,068)
Other assets	544	3,907
Deferred gain	(495)	5,753
Accounts payable and accrued expenses	(3,295)	702
Accrued interest		(326)
Deferred revenue	126	(3,563)
Net cash used in operating activities	(13,961)	(1,515)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(136)	(179)
Purchases of short-term investments	(7,457)	
Sales of short-term investments		
Maturities of short-term investments	14,186	10,116
Net cash provided by investing activities	6,593	9,937
Financing activities:		
Net proceeds from issuance of common stock public offering		42,353
Net proceeds from issuance of common stock, ESPP, stock options and restricted stock units	290	747
Repayment of loan		(4,500)
Payments on capital lease obligations	(17)	(15)
Net cash provided by financing activities	273	38,585
Net increase (decrease) in cash and cash equivalents	(7,095)	47,007
Cash and cash equivalents, beginning of period	46,287	5,780
Cash and cash equivalents, end of period	\$ 39,192	\$ 52,787

See notes to condensed consolidated financial statements.

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**CERUS CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**UNAUDITED**

**Note 1. Summary of Significant Accounting Policies**

**Principles of Consolidation**

The accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and its wholly-owned subsidiary, Cerus Europe B.V. (collectively, the Company), after elimination of all intercompany accounts and transactions. These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 and reclassifications, considered necessary for a fair presentation have been included. The Company reclassified certain legal costs from research and development to selling, general and administrative for the three months ended March 31, 2006. Operating results for the three-month period ended March 31, 2007, are not necessarily indicative of the results that may be expected for the year ending December 31, 2007, or for any future period.

These condensed consolidated financial statements and notes should be read in conjunction with our audited financial statements and notes thereto for the year ended December 31, 2006, included in our 2006 Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2006, has been derived from our audited financial statements as of that date.

**Use of Estimates**

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions. The Company records accrued liabilities for certain contract research activities, including clinical trials, preclinical safety studies, external laboratory studies and development activities performed by third parties. Some of those accrued liabilities are based on estimates because billings for these activities do not occur on a timely basis consistent with the performance of the services.

**Revenue and Research and Development Expenses**

The Company recognizes revenue in accordance with Securities and Exchange Commission published Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) and Emerging Issues Task Force (EITF) 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

The Company's main sources of revenues through March 31, 2007, have come from its research and development activities and agreements, United States government grants and awards, and commercialization agreements. Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to up-front license payments are deferred and recognized ratably over the period of the Company's substantive performance obligation. Revenue related to substantive at-risk milestones specified under development contracts is recognized as the milestones are achieved. Payments for achieved milestones are non-refundable and are not subject to future performance. Commercialization agreements for the Company consist of agreements for the commercialization of its blood safety products. Revenue related to up-front license payments are deferred and recognized ratably over the period of the Company's substantive performance obligation. Revenue related to substantive at-risk milestones specified under commercialization contracts is recognized as the milestones are achieved.

The Company receives certain United States government grants that support the Company's efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In accordance with Statement of Financial Accounting Standards No. 2, Accounting for Research and Development Expenses, research and development costs are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house



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laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

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

The Company's use of estimates in recording accrued liabilities for research and development activities (described previously in this Note under the heading Use of Estimates ) affects the amounts of research and development expenses recorded and revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

### **Cash, Cash Equivalents and Short-Term Investments**

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments and commercial paper.

In accordance with Statement of Financial Accounting Standards (FASB) No. 115, Accounting for Certain Investments in Debt and Equity Securities, the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at estimated fair value based on quoted market prices. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income (expense) and other, net. The Company's available-for-sale securities consist primarily of U.S. government agency securities and corporate debt securities.

Unrealized gains and losses at March 31, 2007, and December 31, 2006, are reported in accumulated other comprehensive income (loss) on the Company's consolidated balance sheets. The Company reviews all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. As of March 31, 2007, there were no other-than-temporary declines in fair value. The cost of securities sold is based on the specific identification method.

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As of March 31, 2007, the Company also maintained a certificate of deposit for approximately \$0.2 million with a domestic bank. The Company holds this certificate of deposit for any potential decommissioning resulting from the Company's possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded within Other long-term assets on the Company's balance sheet at March 31, 2007.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents and short-term investments. Substantially all of the Company's cash, cash equivalents and short-term investments are maintained pursuant to the Company's investment policy by two major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and type of investments that exist within its investment portfolio. All of the Company's investments carry high credit quality ratings, in accordance with its investment policy. At March 31, 2007, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

**Inventories**

At March 31, 2007, inventory consists of finished goods of INTERCEPT disposable kits, illumination devices, and certain replacement parts for the illumination devices. Inventory is recorded at the lower of cost or market value, determined on a first in, first-out basis. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise unsaleable items. To the extent unsaleable items are observed and there is no alternative use, we will record a write-down to net realizable value in the period that the impairment is first recognized. There has been no write-down of inventory to date. Sales of certain products carry a one-year warranty for any defect in material or workmanship. The Company accrues costs associated with warranty obligations when claims become probable and estimable. There have been no warranty costs incurred through March 31, 2007. Accordingly, at March 31, 2007, the Company has not accrued for any potential warranty costs.

**Property and Equipment, net**

Property and equipment is comprised of furniture, equipment, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated on a straight-line basis over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements.

**Long-Term Investments**

The Company accounted for its long-term investments under the either the cost method of accounting or equity method of accounting in accordance with Accounting Principles Bulletin No.18, "The Equity Method of Accounting for Investments in Common Stock" (APB 18), and Financial Accounting Standards Board Interpretation No. 35, "Criteria for Applying the Equity Method of Accounting for Investment in Common Stock" (FIN 35). At March 31, 2007 and December 31, 2006, the Company held approximately 20% interest in the voting securities of BioOne Corporation (BioOne) and accounts for its investment in BioOne under the cost method. The Company regularly evaluates several criteria in determining whether or not it has the ability to exercise significant influence over the operating and financial policies of BioOne. These criteria include but are not limited to: availability and frequency financial information of BioOne, majority shareholder mix in BioOne, and the Company's lack of representation on BioOne's board of directors. As a result of its evaluation, at March 31, 2007 and December 31, 2006, the Company has accounted for its investment under the cost method, as it has concluded that predominant evidence exists to support this conclusion. As of March 31, 2007, the Company's investment in BioOne is recorded as \$11.2 million and is included in long-term investments in related party on its balance sheets. Based on third-party participation in recent equity offerings of BioOne, the Company has determined that there is no impairment of this investment as of March 31, 2007. However, to the extent that the criteria used to support the carrying value of the investment at March 31, 2007, deteriorates, or if BioOne is unable raise additional capital to fund operations in the near term, the Company will need to reassess the recorded basis of its investment in BioOne.

**Foreign Currency Remeasurement**

The functional currency of the Company's foreign subsidiary, Cerus Europe B.V. is the U.S. Dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. Dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. Dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company's consolidated statements of operations as a

component of interest income and other, net.

### **Stock-Based Compensation**

The Company maintains stock compensation plans as long-term incentives for employees, contractors, members of the Board of Directors, and Scientific Advisory Board. These plans allow for the issuance of non-statutory and incentive stock options, rights to acquire restricted stock, and stock bonuses. The Company also maintains an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code.

Beginning January 1, 2006, we adopted the provisions of, and account for stock-based compensation in accordance with, the FASB's Statement of Financial Accounting Standards No. 123R ( FAS 123R ), Share-Based Payment, which replaced Statement of Financial Accounting Standards No. 123 ( FAS 123 ), Accounting for Stock-Based Compensation and supersedes APB Opinion No. 25 ( APB 25 ), Accounting for Stock Issued to Employees. Under the fair value recognition provisions of FAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. The Company elected the modified-prospective method, which requires that compensation expense be recorded for the vesting of all non-vested stock options and other stock-based awards at the beginning of the first quarter of adoption of FAS 123R. In accordance with the modified-prospective method, no prior period amounts have been restated to reflect our adoption of FAS 123R.

See Note 6 for further information regarding our stock-based compensation assumptions and expenses, including pro forma disclosures for prior periods as if we had recorded stock-based compensation expense.

We continue to apply the provisions of EITF 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services ( EITF 96-18 ) for our non-employee stock-based awards. Under EITF 96-18, the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of (1) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (2) the date at which the counter party's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of the non-employee awards in our consolidated statements of operations.

**Table of Contents****Other Comprehensive Income (Loss)**

Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, establishes the standards of reporting and displaying comprehensive income (loss) and its components in the consolidated financial statements. The components of comprehensive income (loss) include net income (loss) and other comprehensive income (loss). The Company's only component of other comprehensive income (loss) has consisted of unrealized gains or losses from the Company's available-for-sales short-term investments. Other comprehensive income (loss) is reported as a separate component of stockholders' equity.

**Income Taxes**

The Company accounts for income taxes based upon Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes (FAS 109). Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Effective January 1, 2007, Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), became effective for the Company. FIN 48 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in FAS 109 is not an appropriate substitute for the derecognition of a tax position. The adoption of FIN 48 did not result in any significant impact to the Company. The Company continues to carry a full valuation allowance on all of its deferred tax assets. The tax years 2003 through 2006 remain subject to examination by the taxing jurisdictions to which the Company is subject.

**Net Income (Loss) Per Share - Basic and Diluted**

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per share reflects the assumed conversion of all dilutive securities, such as options, restricted stock units and convertible preferred stock.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income (loss) per common share (in thousands, except per share amounts):

	Three months ending March 31,	
	2007	2006
<b>Numerator:</b>		
Net income (loss)	\$ (6,808)	\$ (930)
<b>Denominator:</b>		
Basic weighted average number of common shares outstanding	31,760	23,040
Effect of dilutive potential common shares resulting from stock options, unvested restricted common stock and ESPP shares		
Diluted weighted average number of common shares outstanding	31,760	23,040
Basic net income (loss) per common share	\$ (0.21)	\$ (0.04)
Diluted net income (loss) per common share	\$ (0.21)	\$ (0.04)

The table below presents stock options, preferred stock and restricted stock units that are excluded from the diluted net income (loss) per common share due to their anti-dilutive effect (shares in thousands):

	2007	2006
Antidilutive securities weighted average shares	5,721	4,707

**Guarantee and Indemnification Arrangements**

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company after December 31, 2002, if these arrangements are within the scope of Financial Accounting Standards Board Interpretation No. 45, Guarantors' Accounting and

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Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others ( FIN 45 ). In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications, as required under previously existing generally accepted accounting principles, in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the development arrangements of the Company contain provisions that indemnify the counterparty of the Company's technology from damages and costs resulting from claims alleging that the Company's technology infringes the intellectual property rights of a third party. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions. Accordingly, the Company has not recorded a liability related to these indemnification provisions. The Company does not have any guarantees or indemnification arrangements other than the indemnification clause in some of its development arrangements.

### **New Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 ( SFAS 157 ), Fair Value Measurements, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided the reporting company has not yet issued financial statements, including for interim periods, for that fiscal year. The Company is currently evaluating the impact of SFAS 157, but does not expect the adoption of SFAS 157 to have a material impact on its consolidated financial position, results of operations or cash flows.

**Table of Contents****Note 2 Comprehensive Income (Loss)**

Comprehensive income (loss) comprises net income (loss) and other comprehensive loss. Other comprehensive loss for all periods presented comprises unrealized holding losses on our available-for-sale securities, which are excluded from net loss and included as a component of stockholders' equity. Comprehensive income (loss) and its components are as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Net income (loss):		
As reported	\$ (6,808)	\$ (930)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale securities	1	133
<b>Comprehensive income (loss)</b>	<b>\$ (6,807)</b>	<b>\$ (797)</b>

**Note 3 Development and License Agreements****Agreement with MedImmune**

In April 2004, the Company entered into an agreement with MedImmune, Inc. ( "MedImmune" ) to co-develop a therapeutic vaccine designed to target antigens expressed in breast, prostate and colon cancer, as well as metastatic melanoma. A vaccine is being developed using the Company's Listeria vaccine platform and MedImmune's EphA2 cancer antigen. Under the terms of the agreement, MedImmune is responsible for clinical testing, manufacturing and commercialization of any product resulting from this collaboration. The Company has been responsible for preclinical development of a therapeutic vaccine candidate. Under this agreement, the Company has received development funding cost reimbursement, up-front payments, at-risk milestone payments, and the right to receive royalties on future product sales. Upon achievement of an at-risk preclinical milestone, the Company has the option to require MedImmune to purchase \$5.0 million of its common stock at a per share price of 115% of the average closing price of the Company's stock for 30 days prior to achievement of the at-risk milestone.

Under the agreement with MedImmune, the Company received a non-refundable, up-front payment of \$1.0 million in April 2004, and a non-refundable at-risk milestone payment of \$0.5 million in 2005. The \$1.0 million up-front payment was received upon bi-lateral execution of the agreement and was deferred upon receipt and recognized ratably over the period of Company performance ending in May 2006. During the three months ended March 31, 2006, the Company recognized revenue of \$0.1 million associated with this payment. The \$0.5 million at-risk milestone payment was received upon selection of a candidate strain to move into late-stage preclinical development and was recognized upon receipt in 2005, as the Company's substantive performance obligations associated with this payment had been satisfied.

The Company also received and recognized \$0.2 million in development funding related to cost reimbursement during the three months ended March 31, 2006 and nothing during the three months ended March 31, 2007. The Company has no further development commitments under the current agreement with MedImmune. On April 23, 2007, MedImmune announced that it had entered into a definitive agreement to be acquired by AstraZeneca Plc., with closing of the transaction expected in June 2007.

**Restructured Agreements with Baxter**

Effective February 1, 2006, the Company entered into a restructuring of its agreements with Baxter related to the INTERCEPT Blood System. Under terms of the 2006 agreement, the Company gained worldwide rights to the INTERCEPT Blood System for platelets (the "platelet system" ) and the INTERCEPT Blood System for plasma (the "plasma system" ) previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. The Company will pay Baxter royalties on future product sales, replacing terms of the previous agreement, in which the Company received a defined share of gross profit from product sales. The royalty rates vary by product, with a rate of 10% of net sales for the platelet system, 3% for the plasma system and 5% for the INTERCEPT Blood System for red blood cells (the "red blood cell system" ). Baxter agreed to supply certain transition services, including regulatory, technical and administrative support, in 2006 at our expense and to conduct certain continued development efforts relating to the plasma system at Baxter's expense. The Company recorded net gains and deferred gains in excess of \$6.5 million in the period ending March 31, 2006, resulting largely from the disbursement to us of funds that remained from a \$13.1 million escrow account established in the February 2005 agreement with Baxter (as described below) to fund commercialization of the platelet and plasma systems in Europe. The majority of the disbursed funds were to be spent on certain specified activities associated with the European

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commercialization of the platelet and plasma systems, and any such funds that remain unspent by the end of 2006 were to be split evenly between Baxter and the Company. As part of the agreement, the Company purchased UVA illumination devices from Baxter's inventory for use with the platelet and plasma systems. The Company also repaid in February 2006 the \$4.5 million promissory note plus accrued interest owed to Baxter Capital that was originally due in December 2006. During the three months ended March 31, 2007, the Company recognized \$0.5 million in operating gains from the deferred gain balance. These gains offset operating expenses incurred for INTERCEPT commercialization activities. During the three months ended March 31, 2006 the Company recognized non-operating gains of \$1.8 million associated with the 2006 agreement. At March 31, 2007 and March 31, 2006, the Company had \$0.1 million and \$5.8 million, respectively, in deferred gains recorded on its condensed consolidated balance sheets. The \$0.1 million remaining deferred gain balance at March 31, 2007 will be utilized to offset the amortization of prepayments the Company made in 2006 for INTERCEPT commercialization activities.

Prior to February 2005, Baxter and the Company shared development expenses for the platelet and red blood cell systems under the parties existing development and commercialization agreements. The agreements provided for us to be solely responsible for funding development expenses for the plasma system. Under the agreements, Baxter had been responsible for manufacturing and marketing the platelet system, which is approved for sale in some countries in Europe. The agreements provided for us to receive approximately 33.5% of revenue from sales of system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts. Recognition of product sales revenue was deferred from the fourth quarter of 2003 through December 31, 2004, as a result of revenue sharing payments being withheld by Baxter due to a dispute over the timing of repayment of a loan from Baxter Capital.

In February 2005, Baxter and the Company entered into agreements that reaffirmed the previous agreements in certain respects and modified them in other respects (the 2005 agreements). Under the 2005 agreements, Baxter remained solely responsible for sales and marketing expenses for the products/countries as to which it maintained commercialization rights. For 2005 and 2006, Baxter agreed to fund \$13.1 million of expenses for platelet and plasma system sales and marketing and for activities directed toward CE mark approval of the plasma system. Baxter also agreed to furnish specified levels of personnel to conduct sales and marketing of the platelet system and, upon approval, plasma system in Europe.

Our arrangement with Baxter to equally fund development work for the platelet system and the red blood cell system also was terminated by the 2005 agreements. Commencing January 1, 2005, each company agreed to bear its own expenses regarding ongoing discussions with the United States Food and Drug Administration (FDA) to gain clarity on the remaining steps in the U.S. regulatory process for the platelet system. Effective February 1, 2006, the Company became primarily responsible for all regulatory expenses incurred in support of the INTERCEPT Blood System.

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Under the 2005 and 2006 agreements, the Company remained responsible for funding 100% of development expenses for the plasma system, except that \$3.2 million of Baxter's \$13.1 million commitment (described above) was to be applied to activities directed toward obtaining CE mark approval of and launch preparation for the plasma system. Baxter agreed to cooperate with the Company to complete certain activities required for the CE mark application. Such activities were at the Company's expense, except for the right to apply such \$3.2 million for plasma development. The Company recognized \$0.1 million of the \$3.2 million as development funding cost reimbursement during the three months ended March 31, 2006 and had recognized the balance of the \$3.2 million development funding for cost reimbursement by December 31, 2006.

Baxter has agreed to manufacture systems and components of the INTERCEPT Blood System, on a cost-plus basis, through 2008. Since the agreements do not require Baxter to manufacture in an FDA-approved facility, the Company will need to undertake additional validation steps before use of such items in the United States. Baxter has agreed to supply only very limited types of components for the prototype red blood cell system.

On March 1, 2007, Baxter announced that it had sold its Transfusion Therapies business to an investment group led by Texas Pacific Group, which was then renamed Fenwal Inc. (Fenwal). The Company has been informed that Baxter assigned its rights and obligations under its agreements with Baxter to Fenwal as of March 1, 2007.

**Agreements with BioOne**

In June 2004, Baxter and the Company entered into an agreement with BioOne for commercialization of the INTERCEPT Blood System for platelets in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for platelets in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. In July 2004 and October 2004, the Company received non-refundable up-front license payments totaling \$10.0 million in the aggregate from BioOne. The Company deferred the revenue associated with these payments and recognized the revenue ratably over the period of Company performance which ended in June 2006. For the three months ended March 31, 2006, the Company recognized \$1.4 million of revenue associated with the up-front payments. The agreement also provides for at-risk milestone payments and royalties on future product sales, which would be shared equally by Baxter and the Company.

In December 2004, Baxter and the Company signed a letter of intent with BioOne to enter into a definitive agreement for commercialization of the INTERCEPT Blood System for plasma in parts of Asia. Under the letter of intent, the Company received a non-refundable up-front payment of \$3.0 million from BioOne. A definitive agreement with BioOne for the plasma system was signed by Baxter and the Company in June 2005, and in December 2005 the Company received additional non-refundable up-front payments of \$2.0 million in cash and \$5.0 million worth of BioOne's equity. The number of BioOne shares the Company received was based on the current price per share third-party investors paid for BioOne equity with the same rights as the equity received by the Company divided by \$5.0 million. All non-refundable up-front payments received from BioOne were deferred upon receipt and recognized ratably over the period of the Company's performance obligations which ended in December 2006. During the three months ended March 31, 2006, the Company recognized \$0.8 million in revenue associated with the non-refundable up-front plasma agreement payments.

In December 2006, the Company received a payment from BioOne for an at-risk milestone of \$4.5 million in cash and \$5.0 million worth of BioOne's equity. The combined \$9.5 million at-risk milestone payment was received upon the Company's receipt of a CE mark for the plasma system. The Company recognized the combined \$9.5 million as revenue upon receipt as its substantive performance obligations were complete and there were no further performance obligations required of the Company.

The Company evaluated several criteria to determine the fair value of the BioOne equity received in both December 2005 and December 2006 and to conclude whether or not the facts and circumstances support a fair value for revenue recognition and investment balance. These criteria included, but are not limited to: third-party investor interest and participation in equity offerings at current pricing, business outlook of BioOne, and available financial information. Based on this evaluation, the Company recognized both \$5.0 million equity payments received as revenue. Since BioOne is a privately-held Japanese company, it is only obligated to provide the Company with annual financial information at the end of its fiscal year which ends in May. Therefore, although the Company uses the best available information at the time, there can be no assurance that facts and circumstances will not change in the future. Revenues recognized from BioOne represented 0% and 49% of total revenue for the three months ended March 31, 2007 and 2006, respectively.

**Cooperative Agreements with the U.S. Armed Forces**

Since February 2001, the Company has received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received these awards in order to develop its pathogen inactivation technologies for the improved safety and availability of blood that may be used by the U.S. armed forces for medical transfusions. Under the conditions of the



agreements, the Company is reimbursed for development funding expenses incurred for conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that are of concern to the U.S. armed forces. This funding also supports advanced development of the Company's blood safety technologies. The Company recognized \$1.1 million and \$0.4 million of revenue under these agreements during the three months ended March 31, 2007 and 2006, respectively.

The Company has also received awards from the Army Medical Research Acquisition Activity division of the Department of Defense for the research and development of vaccines for biodefense and cancer. The Company recognized \$1.8 million and \$2.0 million of revenue from these awards during the three months ended March 31, 2007 and 2006, respectively.

#### **Note 4 Litigation**

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

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

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

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On February 16, 2007, the federal district court granted final approval to the class action settlement. On February 21, 2007, the state court granted final approval to the derivative settlement. Both settlements have now become final and effective.

**Note 5 Preferred Stock**

Baxter holds 3,327 shares of our 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 common shares would be issued, which represents 1.0% of our outstanding common shares as of March 31, 2007. We have the right to redeem the Series B preferred stock prior to conversion for a payment of \$9.5 million.

**Note 6 Stock-Based Compensation**

We maintain stock compensation plans as long-term incentives for employees, contractors, and members of our Board of Directors and Scientific Advisory Boards. Currently, our active stock option plans include the 1996 Equity Incentive Plan (the 1996 Plan ), the 1998 Non-Officer Stock Option Plan (the 1998 Plan ), and the 1999 Equity Incentive Plan (the 1999 Plan ).

*The 1996 Plan*

The 1996 Plan provides for grants of Incentive Stock Options ( ISOs ) to employees and Nonstatutory Stock Options ( NSOs ), restricted stock purchase awards, stock appreciation rights and stock bonuses to our employees, directors and consultants. The ISOs may be granted at a price per share not less than the fair market value at the date of grant. The NSOs may be granted at a price per share not less than 85% of the fair market value at the date of grant. The option term is ten years. Vesting, as determined by our Board of Directors, generally occurs ratably over four years. In the event option holders cease to be employed by us, except in the event of death or disability or as otherwise provided in the option grant, all unvested options are forfeited and all vested options must be exercised within a three-month period, otherwise the options are forfeited.

*The 1998 Plan*

Under the terms of the 1998 Plan, options may be granted to employees or consultants at an exercise price of at least 85% of the fair market value per share at the date of grant. The option term is ten years.

*The 1999 Plan*

The 1999 Plan provides for grants of ISOs to employees and NSOs, stock bonuses and restricted stock purchase awards to our employees, directors and consultants. The option term is ten years.

*Employee Stock Purchase Plan*

We also maintain an Employee Stock Purchase Plan (the Purchase Plan ). The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, our Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings following the adoption of the Purchase Plan. The offering period for any offering will be no more than 27 months.

*Restricted Stock Units*

In March 2004, we granted restricted stock units to certain then-current employees. Subject to each grantee's continued employment, shares underlying restricted stock unit grants vest in four semi-annual installments. We recorded compensation expense based on the fair value of the underlying common stock as of the grant date, recognized over the vesting period on a straight-line basis. In the quarter ended March 31, 2007, we granted restricted stock units to the Chief Executive Officer and Vice Presidents in accordance with the Bonus Plan for Senior Management of Cerus Corporation. Subject to each grantee's continued employment shares underlying the grants vest in three annual installments and are issuable at the end of the three-year vesting term. As of March 31, 2006, all restricted stock units granted in 2004 were valued at \$3.38 per share and were fully vested. We granted 37,098 restricted stock units during the three months ended March 31, 2006, valued at \$10.32 per share, of

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which 12,366 were vested as of March 31, 2007. We granted 60,620 restricted stock units during the three months ended March 31, 2007, valued at \$5.54 per share, of which none were vested as of March 31, 2007.

### *Stock-based Compensation*

Beginning with our first quarter of 2006, we adopted FAS 123R. See Note 1 for a description of our adoption of FAS 123R. We currently use the Black-Scholes option pricing model to determine the fair value of stock options and employee stock purchase plan shares. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. The variables used to calculate the fair value of stock based payment awards using the Black-Scholes option pricing model, include our expected stock price volatility, actual and projected employee stock option exercise behaviors, including forfeitures, the risk-free interest rate and expected dividends.

### *Expected Term*

We estimate the expected term of options granted using a variety of factors. Where possible, we estimate the expected term of options granted by analyzing employee exercise and post-vesting termination behavior. To make this estimation, we analyze the population of options granted by discreet, homogeneous groups. If we are unable to obtain sufficient information to estimate the expected term for a particular group, we estimate the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in SAB 107. The expected term of employee stock purchase plan shares is the term of each purchase period.

### *Estimated Forfeiture Rate*

We estimate the forfeiture rate of options at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. We estimate the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

### *Estimated Volatility*

We estimate the volatility of our common stock by using both historical volatility of our common stock and implied volatility in market traded options in accordance with SAB 107. Our decision to use both historical volatility and implied volatility was based upon the limited availability of actively traded options on our

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common stock and our assessment that due to the limited availability of actively traded options, historical volatility should be given greater prominence in our decision as we believe it is more representative of future stock price. As such, we have calculated our estimated volatility by weighting both historical volatility and implied volatility. We have used significant judgment in making these estimates and we will continue to monitor the availability of actively traded options on our common stock.

*Risk-Free Interest Rate*

We base the risk-free interest rate that we use in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Expected Dividend*

We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option valuation model.

The assumptions used to value option grants for the three months ended March 31, 2007, and 2006 are as follows:

	2007	2006
Expected term (in years)	5.00-5.48	3.77-6.28
Volatility	61.5%	64.9%
Risk free interest rate	4.32%	4.55%

The assumptions used to value employee stock purchase rights for the quarters ended March 31, 2007, and 2006 are as follows:

	2007	2006
Expected term (in years)	0.50	0.50
Volatility	58.68%	59.82%
Risk free interest rate	5.12%	4.58%

Total stock-based compensation recognized on our consolidated statement of income for the three months ended March 31, 2007 and 2006, is as follows:

	2007	2006
	Option Grants and Stock	
<b>Income Statement Classifications</b>	<b>Purchase Rights</b>	
Research and development	\$ 253	\$ 267
Selling, general and administrative	270	375
<b>Total</b>	<b>\$ 523</b>	<b>\$ 642</b>

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

	Number of Options Outstanding	Weighted Average Exercise Price per Share (\$)
Balances at December 31, 2006	5,255	12.058

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Granted	134	5.728
Cancelled	(64)	18.271
Exercised	(34)	3.292
Balances at March 31, 2007	5,291	11.879

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At March 31, 2007, the total aggregate intrinsic value of options outstanding and of options exercisable was \$5.1 million. The weighted average fair value of options granted during the three months ended March 31, 2007 and 2006 were \$3.27. The weighted average remaining term of options exercisable at March 31, 2007 is 6.18 years. As of March 31, 2007, we had stock-based compensation expense of \$1.8 million related to nonvested stock options not yet recognized, which is expected to be recognized over an estimated weighted average period of 1.22 years. The following table depicts the population of stock options at range of exercise prices outstanding at March 31, 2007:

<i>(Shares in thousands)</i>	Options Outstanding			Options Vested	
	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Range of Exercise Prices					
\$1.950 2.050	152	7.36	\$ 2.049	97	\$ 2.050
\$2.100 2.280	658	7.25	\$ 2.274	325	\$ 2.271
\$2.360 2.890	482	7.37	\$ 2.512	234	\$ 2.546
\$2.950 3.250	542	7.12	\$ 3.235	389	\$ 3.233
\$3.430 4.740	439	7.29	\$ 4.313	306	\$ 4.266
\$5.310 5.550	584	9.51	\$ 5.546	76	\$ 5.546
\$5.570 8.560	573	8.16	\$ 7.110	244	\$ 7.074
\$8.600 8.600	3	8.47	\$ 8.600	1	\$ 8.600
\$8.860 8.860	548	8.51	\$ 8.860	195	\$ 8.860
\$9.010 75.250	1,310	4.64	\$ 33.587	1,235	\$ 35.002
	5,291	7.09	\$ 11.879	3,102	\$ 16.506

**Note 7 Disclosures About Segments of an Enterprise**

We have two reportable segments: blood safety programs and immunotherapies. The blood safety segment primarily comprises development and commercialization of the INTERCEPT Blood Systems. The immunotherapies segment primarily comprises research and development of vaccines using our Listeria and KBMA platforms. The accounting policies of the reportable segments are the same as those under which our financial statements are prepared. There are no transactions between reportable segments.

Our senior management do not evaluate segment results below operating income (loss) from each reportable segment and, therefore, interest income, expense and other non-operating expenses are not allocated to reportable segments. For the periods presented, revenue from Baxter, BioOne and the units of the United States Department of Defense ( Armed Forces ) are included in blood safety programs, and revenue from MedImmune and the Armed Forces are included in immunotherapies. Segment information for the three months ended March 31, 2007, and 2006, is presented below (in thousands):

	Three Months Ended March 31, 2007	
	Revenue	Operating Income (Loss)
Blood safety programs	\$ 2,252	\$ (5,282)
Immunotherapies	2,446	(2,614)
Totals	\$ 4,698	\$ (7,896)

Three Months Ended March 31, 2006	
Revenue	Operating Income (Loss)

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Blood safety programs	\$ 4,419	\$ (601)
Immunotherapies	2,578	(2,382)
Totals	\$ 6,997	\$ (2,983)

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

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

#### **Overview**

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of blood safety systems and, more recently, immunotherapies for cancer and infectious disease. With the exception of a non-recurring gain recognized during the three months ended March 31, 2005, and receipt and recognition of an at-risk milestone during the three months ended December 31, 2006, we have been unprofitable since inception and, as of March 31, 2007, had an accumulated deficit of approximately \$318.2million. Except for the platelet and plasma systems, for which the European Union approved issuance of CE marks, all of our product candidates are in the research and development stage.

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

Through December 31, 2006, in addition to the product revenues from sales of our platelet and plasma systems, we have recognized revenue from an ongoing development agreement with MedImmune and commercialization agreements with BioOne, as well as from grants and cooperative agreements from the Armed Forces and the NIH. Under the agreements with MedImmune and BioOne, we have received up-front license payments, at-risk milestone payments and development funding and may receive additional at-risk milestone payments and royalties on future product sales. Up-front payments received under the agreements with MedImmune and BioOne were deferred upon receipt and recognized as revenue over our required performance period. At March 31, 2007, we no longer had any remaining deferred revenues or performance obligations under our current agreements with MedImmune or BioOne.

As of March 31, 2007, we had cumulatively received \$1.5 million of non-refundable up-front and at milestone payments from MedImmune under the terms of our agreement with them, consisting of a \$1.0 million non-refundable up-front payment and a \$0.5 million at-risk milestone payment, and had received a total of \$1.5 million in development funding for cost reimbursement. In accordance with our revenue recognition policy, we deferred the up-front payment upon receipt and recognized the related revenue ratably over the period of our performance. We received the at-risk milestone payment upon selection of a candidate strain to move into late-stage preclinical development and recognized the revenue associated with the payment upon receipt as we had no further substantial performance obligations under the agreement. As of March 31, 2007, we have no further development commitments under the current agreement with MedImmune.

As of March 31, 2007, we have received a total of \$29.5 million in cash payments and equity securities from BioOne for up-front and at-risk milestone payments. Of the \$29.5 million, \$15 million related to up-front cash payments which we deferred upon receipt and recognized over the period of our required performance. The remaining \$14.5 million we received from BioOne was composed of \$5.0 million worth of equity in BioOne for an up-front payment, \$5.0 million worth of BioOne equity for payment upon receipt of the CE mark for the plasma system, and \$4.5 million cash payment upon of the CE mark for the plasma system. We determined the value of BioOne equity we received by comparing the price of the shares we received to concurrent third-party investor participation in the BioOne equity offerings. The at-risk milestone payments received were recognized upon receipt as we had completed our substantial performance obligations under the agreement with BioOne. The up-front payments we received were deferred upon receipt and recognized as revenue over the period with which we had performance obligations for development. Our performance obligations for development with BioOne ended in December 2006. As such, for the three months ended March 31, 2007, we did not recognize any revenue and do not have any remaining deferred revenues associated with our BioOne agreements. During the three months ended March 31, 2006, we recognized \$3.4 million in revenue from our BioOne agreements.

We also have entered into cooperative agreements with the Armed Forces and received grants and contracts from the NIH to conduct certain research and development activities. These cooperative agreements and grants are related to both our blood safety and immunotherapy and infectious disease platforms. The following table summarizes the revenues recognized from government grants and cooperative agreements and



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the programs which the revenues related for the three months ended March 31, 2007, and 2006:

(in thousands, except percentage)	Three Months Ended	
	March 31,	
	2007	2006
Blood Safety	\$ 1,065	\$ 382
Immunotherapy	2,446	2,319
<b>Total revenue</b>	<b>\$ 3,511</b>	<b>\$ 2,701</b>

Effective February 1, 2006, we entered into a new agreement with Baxter related to the INTERCEPT Blood System. Under terms of the February 2006 agreement, we gained worldwide rights to the INTERCEPT platelet and plasma systems previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. We previously acquired worldwide commercialization rights for the red blood cell system from Baxter. Beginning in 2007, we will pay Baxter royalties on product sales, at a rate of 10% of net sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. This royalty structure replaces the terms of previous agreements with Baxter under which we had received a defined share of the gross profits from product sales. Under the terms of the February 2006 agreement, Baxter agreed to supply certain transition services to us through 2006 at our expense, including regulatory, technical and back-office support, and to conduct certain continued development efforts relating to the plasma system at its expense. Baxter also agreed to manufacture systems for the platelet and plasma systems on a cost-plus basis through December 31, 2008, and components through December 31, 2009, and agreed to supply only very limited types of components for the prototype of the red blood cell system. On March 1, 2007, Baxter announced that it had sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to a new company (renamed Fenwal) formed by an investment group led by Texas Pacific Group. Baxter has informed us that Fenwal has assumed Baxter's obligations under our agreements with Baxter.

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As a result of the February 2006 agreement with Baxter, we recorded net gains and deferred gains in excess of \$6.5 million and also repaid the \$4.5 million promissory note plus accrued interest owed to Baxter Capital that had originally been due in December 2006. At December 31, 2006, we had \$0.6 million in remaining deferred gains, all of which are associated with payments made to vendors by December 31, 2006, in support of INTERCEPT commercialization efforts. During the three months ended March 31, 2007, we recognized \$0.5 million of the remaining deferred gain as vendors completed delivery of prepaid services. We anticipate recognizing the remainder of the deferred gain balance in 2007 as vendors complete delivery of the prepaid services.

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

On April 26, 2007, we announced that we are exploring alternative funding sources for our cancer and infectious disease immunotherapy programs. We will consider several possible business structures, including partnering some or all of the programs within our immunotherapy business with companies having established programs in immunology or in cancer and infectious disease indications, combining our immunotherapy business with another public or private company, or spinning out the business for an equity interest in a newly-formed immunotherapy company. This potential corporate realignment may provide opportunities for our immunotherapy business to more fully realize its potential value, while allowing us to focus resources on creating value in our commercial-stage blood safety business. We may be unable to consummate a transaction involving our immunotherapy and infectious disease programs, which would then require that we either fund increased operations internally or curtail operations.

**Critical Accounting Policies and Management Estimates**

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to collaborative arrangements, contract research and other contingencies, and non-cash stock compensation assumptions. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies, require us to make significant judgments and estimates used in the preparation of our financial statements:

**Revenue and research and development expenses** Revenue is recognized when (i) a written agreement with the funding party exists; (ii) services have been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable. Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects are incurred. Revenue related to substantive at-risk milestones specified under development contracts is recognized as the milestones are achieved. To date, we have not received license fees or milestone payments that are refundable. To the extent that they are subject to future performance criteria, we recognize revenue ratably over the estimated license or development period. We have received up-front payments from collaboration agreements. These up-front payments are deferred and recognized over the period we estimate we are likely to have involvement. We have also received equity in a privately held company in addition to cash as consideration for up-front and at-risk milestone payments. We evaluate several criteria to determine the fair value of the equity received and to conclude whether the facts and circumstances support a fair value for revenue recognition and the investment balance. These criteria include, but are not limited to, third-party investor interest and participation in recent equity offerings at current pricing, business outlook of the privately held company, and available financial information of the privately held company. The financial information we receive is generally only available on an infrequent basis. Although management uses the best available information at the time, there can be no absolute assurance that facts and circumstances will not change in the future. Should these facts and circumstances change, they may negatively impact our consolidated financial statements. We receive certain United States government grants and contracts that support our research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred.

**Accrued expenses** We record accrued liabilities for certain contract research activities and development services, including those related to clinical trials, preclinical safety studies and external laboratory studies, as well as transition services and development activities being performed by third parties. Some of those accrued liabilities are based on estimates because billings for these activities may not occur on a timely basis consistent with the performance of the services. Specifically, accruals for clinical trials require us to make estimates surrounding costs associated with patients at various stages of the clinical trial, pass through costs to clinical sites, contract research organization costs including fees, database development, and reporting costs, among others.

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

The Black-Scholes option pricing model calculates the grant-date fair value using certain variables. These variables are impacted by our stock price, award exercise behaviors, the risk free interest rate and our expected dividends and many of these variables require us to use significant judgment.

**Expected Term.** We estimate the expected term of options granted using a variety of factors. Where possible, we estimate the expected term of options granted by analyzing employee exercise and post-vesting termination behavior. To make this estimation, we analyze the population of options granted by discreet homogeneous groups. For those homogeneous groups where we are unable to obtain sufficient information to estimate the expected term in this manner, we estimate the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in the Securities and Exchange Commission Staff Accounting Bulletin No. 107, or SAB 107. The expected term of employee stock purchase plan shares is the average of the remaining purchase periods under each offering period.

**Estimated Forfeiture Rate.** We estimate the forfeiture rate of options at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. We estimate the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term.

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

*Risk-Free Interest Rate.* We base the risk-free interest rate that we use in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Expected Dividend.* We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option valuation model.

If factors change and we utilize different assumptions in determining the grant-date fair value of stock compensation expense in the future, or if we utilize a different option pricing model in the future, then those results may differ significantly from what we have recorded in the current period and could materially effect our operating results. There is significant risk that the Black-Scholes option pricing model and the judgment we have used in ascertaining the variables will yield results that differ materially from the actual values realized upon the exercise, expiration, termination or forfeitures of the awards in the future. Historical results were utilized in deriving our variables, which may not be indicative of the future.

*Income Taxes* Since our inception we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carryforwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. Effective January 1, 2007, Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ), became effective for us. FIN 48 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in FAS 109 is not an appropriate substitute for the derecognition of a tax position. The adoption of FIN 48 did not have a significant impact on us. We continue to carry a full valuation allowance on all of our deferred tax assets. There can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed.

**Table of Contents****Results of Operations****Three-Month Periods Ended March 31, 2007, and 2006***Revenue.*

(in thousands, except percentage)	Three months ended March 31,		Change	
	2007	2006		
Milestone and development revenue	\$	\$ 3,817	\$ (3,817)	(100)%
Government grant and cooperative agreements		3,511	2,701	810 30%
Product revenue		1,187	479	708 148 %
Total revenue		\$ 4,698	\$ 6,997	\$ (2,299) (33)%

During the three months ended March 31, 2007, we did not recognize any development funding revenue from our collaborative partners. During the three months ended March 31, 2006, we recognized \$3.8 million in milestone and development funding revenue. The decrease was due primarily to revenue recognized in the first quarter of 2006 from up-front consideration received from BioOne in June 2005, which was initially deferred and was recognized ratably through 2006. At January 1, 2007, we did not have any remaining deferred revenue from our current agreements with BioOne or MedImmune. In addition, as of January 1, 2007, we no longer receive development funding for cost reimbursement from either Baxter or MedImmune. During the three months ended March 31, 2006, we recognized \$0.1 million in cost reimbursement development funding for the plasma system from Baxter under the February 2005 agreements, and \$0.1 million in cost reimbursement development funding from MedImmune. We have no further development obligations under our existing agreements with BioOne or MedImmune. We do not expect significant revenues to be generated from BioOne until such time as BioOne may successfully commercialize the products licensed from us, which we expect will be no earlier than 2009, if ever.

Revenue from government grants and cooperative agreements increased 30% to \$3.5 million for the three months ended March 31, 2007, from \$2.7 million for the comparable period in 2006. The increase was due primarily to higher levels of reimbursed activities under the blood safety and immunotherapy awards in 2007. We no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the NIH and regulated by the Small Business Administration. As a result, we will not be eligible to apply for any new grants for which only small businesses are eligible.

During the three months ended March 31, 2007, we recognized \$1.2 million of product sales revenue almost entirely from sales of the INTERCEPT Blood System for platelets in Europe. Prior to the February 2006 agreement with Baxter, product revenue represented our share of platelet system gross profits; subsequent to February 1, 2006, product revenue represents all of the INTERCEPT Blood System revenues. These quarterly results may not be indicative of INTERCEPT Blood System revenue in the future.

*Cost of Product Revenue*

Prior to the February 2006 agreement with Baxter, we did not record cost of product sales or gross margins from product sales. Subsequent to the February 1, 2006, effective date of the agreement, our cost of product sales consists of the cost of the INTERCEPT Blood System inventory sold, . Inventory is accounted for on a first-in, first-out basis.

(in thousands, except percentage)	Three months ended March 31,		Change	
	2007	2006		
Cost of product revenue	\$ 824	\$ 182	\$ 642	353 %

Cost of product revenue increased \$0.6 million, to \$0.8 million during the three months ended March 31, 2007, from \$0.2 million during the three months ended March 31, 2006. The increase in cost of revenue is a primarily due to a higher number of platelet system sets sold during the three months ended March 31, 2007. In addition, effective January 1, 2007, we became solely responsible for supply chain costs, including warehouse and order fulfillment costs, and in some instances these costs were higher in the three months ended March 31, 2007, than those costs

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incurred during the same period in 2006. During the three months ended March 31, 2006, Baxter performed these services as a component of the February 2006 agreement. These results may not be indicative of future costs of product sales or gross margins. We anticipate our cost of product revenue to increase in the future as a result of increased product sale volume, royalties that will be owed to Baxter on platelet and plasma system sales, and as we perform or utilize third-party service providers for supply chain services.

### *Research and Development Expenses*

Our research and development expenses include salaries and related expenses for our scientific personnel, non-cash stock based compensation, payments to consultants, costs to prepare and conduct preclinical and clinical trials, third-party costs for development activities, certain regulatory costs, costs for licensed technologies, and costs associated with our infrastructure, and laboratory chemicals and supplies.

(in thousands, except percentage)	<b>Three months ended March 31,</b>		<b>Change</b>	
	<b>2007</b>	<b>2006</b>	<b>\$</b>	<b>(%)</b>
Research and development expenses	\$ 6,448	\$ 6,638	\$ (190)	(3)%

Research and development expenses decreased 3% to \$6.4 million for the three months ended March 31, 2007, from \$6.6 million for the comparable period in 2006. Of our total research and development costs incurred, non-cash stock based compensation represented \$0.3 million for the three months ended March 31 in both 2007 and 2006. Overall, our research and development expenses remained relatively consistent when comparing the three months ended March 31, 2007 and March 31, 2006, primarily due to continued design and development spending related to the red blood cell system, increased costs incurred to conduct Phase I clinical trials for the red blood cell system and CRS-100 product candidates, offset by a decrease in development spending for our plasma system.

Our total research and development costs included \$3.3 million for our blood safety programs and \$3.1 million for our immunotherapy programs for the three months ended March 31, 2007, and \$3.4 million for our blood safety programs and \$3.2 million for our immunotherapy programs for the comparable period in 2006.

We anticipate our research and development spending will continue and at times may increase as a result of ongoing and later stage preclinical and clinical trials, and as potential new products move from discovery to preclinical and clinical trials. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, uncertainty of future pre-clinical and clinical study results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects; see [Risk Factors](#) in Part II, Item 1A below.

**Table of Contents***Selling, General, and Administrative Expenses.*

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, non-cash stock based compensations, expenses for our commercialization efforts underway in Europe, expenses for accounting, tax, and internal control, legal and facility related expenses, and insurance premiums.

(in thousands, except percentage)	Three months ended March 31,			Change
	2007	2006		
Selling, general, and administrative	\$ 5,322	\$ 3,160	\$ 2,162	68%

Selling, general, and administrative expenses increased 68% to \$5.3 million for the three months ended March 31, 2007, from \$3.2 million for the comparable period in 2006. Of the \$5.3 million and \$3.2 million of selling, general and administrative expense recognized during the three months ended March 31, 2007 and 2006, respectively, \$0.3 million and \$0.4 million was due to non-cash stock-based compensation recognized during the respective periods. Overall, the increase in selling, general and administrative from the three months ended March 31, 2006, was principally attributable to costs incurred in establishing and expanding our operations in Europe, including increases in salaries and related personnel costs, and legal, accounting, and marketing expenses. We anticipate continuing to increase selling, general, and administrative spending to achieve commercial sustainability of our INTERCEPT Blood Systems.

*Interest Income(Expense) and Other, Net*

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

(in thousands, except percentage)	Three months ended March 31,			Change
	2007	2006		
Interest income (expense) and other, net	\$ 1,088	\$ 2,053	\$ (965)	(47)%

Net interest income (expense) and other, net was \$1.1 million for the three months ended March 31, 2007, compared to \$2.1 million during the comparable period in 2006. Interest income was \$1.1 million and \$0.3 million for the three months ending March 31, 2007, and 2006, respectively. During the three months ended March 31, 2006, we recognized non-recurring non-operating gains of \$1.8 million in connection with our February 2006 agreement with Baxter. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. In March and December 2006, we completed public offerings of our common stock, which resulted in increased cash balances. We invested these proceeds in marketable securities pursuant to our investment policy, and generally hold such investments until such time as we liquidate them to meet an operating cash need.

**Liquidity and Capital Resources**

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

At March 31, 2007, we had cash, cash equivalents and short-term investments of \$79.6 million. Net cash used in operating activities was \$14.0 million for the three months ended March 31, 2007, compared to \$1.5 million for the same period in 2006. The increase in net cash used in operating activities was primarily due to changes in our operating assets and liabilities, notably decreases in our accounts payable and accrued liability balances and decreases in our other assets. Net cash provided by investing activities during the three months ended March 31, 2007, was \$6.6 million compared to \$9.9 million from the same period in 2006. The decrease is primarily due to a larger number of maturities of short-term investments in 2007, offset by purchases of short-term investments in 2007. Net cash provided by financing activities during the three months ended March 31, 2007, was \$0.3 million, compared to cash provided by financing activities of \$38.6 million for the same period in 2006, due to the issuance of 5,175,000 shares of common stock in a public offering in March 2006, providing net proceeds of \$42.4 million, offset by the repayment of a loan from Baxter Capital \$4.5 million plus accrued interest. Working capital decreased to \$81.9 million at March 31, 2007, from

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\$87.9 million at December 31, 2006, primarily due to lower cash, cash equivalents and short-term investments.

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



**Table of Contents****Commitments**

Our commitments are as follows (in thousands):

	Payments Due by Period from March 31, 2007				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
<b>Contractual obligations:</b>					
Minimum purchase requirements	2,651	795	1,856		
License fees and sponsored research	64	64			
Operating leases	1,686	893	793		
<b>Total contractual cash obligations</b>	<b>\$ 4,401</b>	<b>\$ 1,752</b>	<b>\$ 2,649</b>	<b>\$</b>	<b>\$</b>

**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 at March 31, 2007, totaled \$0.0 million and unrealized losses at December 31, 2006 totaled \$0.1 million. Our investments primarily consist of short-term money market mutual funds, general corporate obligations notes, United States government obligations and commercial paper. Of our cash, cash equivalent, and short-term investments balance of \$79.6 million at March 31, 2007, approximately 49% have original maturity dates of less than 90 days, and approximately 14% 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 and the consistent yields we have experienced and anticipate experiencing across our portfolio, regardless of maturity date. We do not believe our unrealized losses reflect more than a temporary decline in value of our marketable securities held.

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**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.* Our chief executive officer and chief financial officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in the rules promulgated under the Securities Exchange Act of 1934, as amended), for our company. Based on their evaluation of disclosure controls and procedures as of March 31, 2007, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2007.

*Changes in Internal Control Over Financial Reporting.* During the three months ended March 31, 2007, we implemented internal controls relating to inventory management, product sales, cash collections, and reporting. The implementation of these controls is a direct result of the cessation of administrative transition services that Baxter had been performing for us through December 31, 2006, as required under our February 2006 Commercialization Transition Agreement with Baxter. Our internal controls relating to inventory management, product sales, cash collections, and reporting are designed to provide reasonable assurance that our financial statements are properly stated and are in accordance with accounting principles generally accepted in the United States.

*Limitations on the Effectiveness of Controls.* A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and the chief executive officer and 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 August 31, 2006, we announced that we had reached agreement to settle the class action lawsuit, pending since 2003 in the United States District Court for the Northern District of California, against certain of our current and former directors, officers and us. The amended and consolidated complaint alleged that the defendants had violated the federal securities laws by making allegedly false and misleading predictions regarding the initiation and completion of clinical trials, submission of regulatory filings, receipt of regulatory approval and other milestones in the development of the platelet, plasma and red blood cell systems. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our securities during the period from December 9, 2000, through January 30, 2003.

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

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

On February 16, 2007, the federal district court granted final approval to the class action settlement. On February 21, 2007, the state court granted final approval to the derivative settlement. Both settlements have become final and effective.



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**Table of Contents****ITEM 1A. RISK FACTORS****Risk Factors**

*Our business faces significant risks. If any of the events or circumstances described in the following risks actually occur, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this report. There may be additional risks faced by our business. All references to Baxter in these Risk Factors should be read, as to future contingencies, to include Fenwal or any other assignee of Baxter's obligations under our agreements.*

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

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

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those with the potential to improve the safety of the blood supply, such as the INTERCEPT Blood System. Our products may require significant changes to our potential customers' blood component collection methods, space and staffing requirements and require upfront investment in UVA illuminators, disposable kit inventory and staff training. Even if our product candidates receive regulatory approval for commercial sale, blood centers, physicians, patients and healthcare payors may not believe that the benefits of using the INTERCEPT Blood System justify their additional cost. If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced. For example, if adverse events arise from incomplete inactivation of pathogens, improper processing or user error, or if testing of INTERCEPT Blood System-treated blood samples fails to reliably confirm pathogen inactivation, whether or not directly attributable to a shortcoming of the INTERCEPT Blood System, customers may refrain from purchasing the products.

Market acceptance of our products may also be affected by the availability of reimbursement from governments, managed care payors, such as insurance companies, or other third parties. In many cases, due to the structure of the blood products industry, we will have little control over reimbursement discussions, which generally occur between blood centers and national or regional ministries of health and private payors. For example, while the platelet system has been approved in France for use by blood centers in treating platelets, commercial adoption has been delayed pending negotiation of contracts with the French national blood service, Etablissement Francais du Sang (the EFS), pursuant to a public tender process. We may be required to seek explicit reimbursement in European countries for our plasma system, even though other competing pathogen inactivation products for plasma have been approved and are being reimbursed in Europe presently. It is difficult to predict the reimbursement status of newly approved, novel medical device or biopharmaceutical products. In certain foreign markets, governments have issued regulations relating to the pricing and profitability of medical products and medical products companies. There also have been proposals in the United States, at both the Federal and state government level, to implement such controls.

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The widespread adoption of managed care in the United States has also placed pressure on the pricing of medical products. These pressures can be expected to continue and may limit the prices we can obtain for our products.

We believe that future product sales in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products, nor are we prioritizing seeking such approval. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable. In addition, failure to advance the red blood cell system toward regulatory approval and commercialization may have a negative impact on customers' willingness to adopt the platelet and plasma systems. Deferring pursuit of regulatory approval of the INTERCEPT Blood System in the United States due to strategic priorities favoring Europe may have adverse consequences on market acceptance of the INTERCEPT Blood System globally.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even if our products receive regulatory approval and reimbursement is available, failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenue in those geographies. The market for our pathogen inactivation systems in the United States is highly concentrated, dominated by a small number of blood collection organizations. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nation's blood and blood components supply. In Europe, the largest markets for our products are in England, Germany and France. Decisions on product adoption in England are centralized with the National Blood Service, where general cost containment pressures have delayed consideration of the INTERCEPT Blood System to date. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a blood center-by-blood center basis, but depend on both local and centralized regulatory approvals. While the platelet system has received in-country regulatory approval in France, adoption has been delayed in the absence of negotiated contracts with regional EFS blood centers. In-country regulatory approval in France for the plasma system was obtained in early 2007. However, adoption may be delayed until the existing national reimbursement rates for pathogen inactivated plasma are extended to the INTERCEPT plasma system. The Japanese Red Cross controls a significant majority of blood transfusions in Japan. If approvals are not obtained to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue will be significantly decreased.

***Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities.***

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

development;

testing;

manufacturing;

labeling;

storage;

pre-market clearance or approval;

sales and distribution;

use standards and documentation;

post-launch surveillance;

quality;

advertising and promotion; and

reimbursement.

The FDA and other agencies in the United States and in foreign countries impose substantial requirements upon the manufacturing and marketing of products such as those we are developing. The process of obtaining FDA and other required regulatory approvals is long, expensive and uncertain, and typically takes a number of years, depending on the type, complexity and novelty of the product. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC. BPAC would then make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily approve those products. If BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products. Before entering human clinical trials, product candidates in our immunotherapy programs beyond CRS-100 likely will be subject to review by the Recombinant DNA Advisory Committee, or RAC, of the NIH, which could delay initiation of clinical trials.

If our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with Good Manufacturing Practice and ISO 13485, a quality management system standard applicable to the products we sell in Europe. We were found to be in compliance with ISO 13485 quality management system requirements in an audit conducted by European Union regulators in late 2006. The failure to comply with these requirements on an ongoing basis could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result in enforcement action, which could harm our business. The current manufacturing sites we rely upon for producing the platelet and plasma system products for European distribution are not FDA-qualified facilities. Regulatory authorities may also require post-marketing testing, which can involve significant expense. Governments or regulatory authorities may impose new regulations or other changes that could further delay or preclude regulatory approval of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

Distribution of our products outside the United States also is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In some countries, we may be required to register as a medical device manufacturer, even though we outsource manufacturing to third parties. In addition, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation with which we have no familiarity.

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We will be required to obtain a CE mark extension in our name from European Union regulators for our platelet system, originally obtained by Baxter in 2002, by May 2007 and every five years thereafter. In addition to European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries, including France, Germany, Switzerland and England, to market our products. In addition, our customers in many countries must obtain regulatory approval to sell blood components treated with the INTERCEPT Blood System. Our customers may lack the resources or capability to obtain such regulatory approvals. The level of additional product testing varies by country, but could take a long time to complete. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in lost product sales and profitability.

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

toxicology studies to evaluate product safety;

laboratory and animal studies to evaluate product effectiveness;

human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components or immunotherapies; and

manufacturing and stability studies.

We have conducted many toxicology studies to demonstrate the INTERCEPT platelet and plasma systems' safety, and we have conducted and plan to conduct toxicology studies for the INTERCEPT red blood cell system and our vaccine candidates throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay commercialization. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate our having to redesign our product candidates or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. We believe the FDA and other regulatory authorities are likely to weigh the potential risks of using our pathogen inactivation products against the incremental benefits, which may be less compelling in light of improved safety in the blood supply. With respect to an additional Phase III trial of the platelet system in the United States, we expect the FDA to require us to demonstrate a very low level of potential side effects. Trials of this type may be too large and expensive to be practical.

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

Regulatory delays can also materially impact our product development costs. If we experience delays in testing or approvals, our product development costs will increase. For example, we may need to repeat clinical trials to address regulatory or clinical questions. We may also need to make additional payments to third-party investigators and organizations to retain their services. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed.

Regulatory agencies may limit the uses, or indications, for which any of our products are approved. For example, we believe that the INTERCEPT Blood System products will be able to claim the inactivation of particular pathogens only to the extent we have laboratory or animal data to support such claims. After regulatory approval for the initial indications, further studies may be necessary to gain approval for the use of the product for additional indications.

In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements applicable to our prospective customers of INTERCEPT Blood System products, the blood centers that process and distribute blood and blood products. Blood centers and

others will likely be required to obtain approved license supplements from the FDA or European regulatory authorities before making available blood products processed with our pathogen inactivation systems to hospitals and transfusing physicians. This requirement or regulators' delays in approving these supplements may deter some blood centers from using our products. Blood centers that do submit supplements may face disapproval or delays in approval that could provide further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

***If our preclinical and clinical data are not considered sufficient by regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue. Our red blood cell system requires extensive additional testing and development.***

Except for the INTERCEPT platelet and plasma systems, which have received CE mark approval and regulatory approval in certain countries in Europe, we have no products that have received regulatory approval for commercial sale and are being marketed. Our product candidates are in various stages of development, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our product candidates must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes before the FDA and international regulatory authorities can approve them for commercial use. We must provide the FDA and international regulatory authorities with preclinical, clinical and manufacturing data that demonstrate our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale.

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

We completed our Phase III clinical trial of the platelet system in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we performed an additional blinded analysis of the clinical trial data, under the direction of an independent expert physician panel, to determine if apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to inconsistent event reporting. The reassessment of primary patient records by the expert physician panel showed no statistically significant differences between groups. This reassessment differed from the earlier analysis of adverse events that was based on clinical trial case report forms, which showed statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. The report included conclusions from the expert physician panel. Based upon further discussions with the FDA following submission of that report, we continue to expect that the FDA will require an additional, significantly larger Phase III clinical trial to evaluate the hemostatic efficacy and safety of the platelet system, using the Company's final commercial product design, as compared to conventional platelets. We also understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the apparent differences observed in that trial between the treatment groups in the category of pulmonary adverse events, and that an additional Phase III trial would have to be designed to demonstrate no greater frequency in the incidence of such adverse events relative to a control group on a statistically significant basis. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. The additional Phase



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III clinical trial would need to be completed and data from the trial submitted to the FDA before we could complete our regulatory submission. The FDA may not find the data from any additional clinical trials to be acceptable for approval. Before we begin an additional clinical trial, we will need to gain concurrence with the FDA on our trial design. We may not be able to reach concurrence on the size, scope or design of the study or we may conclude that the cost of such a study are unacceptable or logistically unachievable.

We have completed Phase IIIa, Phase IIIb and Phase IIIc clinical trials of the plasma system, in the United States, reports for which were filed with the FDA during 2005. We obtained a CE mark approval in Europe of the plasma system in November 2006. We have not submitted any applications for regulatory approval of the plasma system in the United States or any other regions other than Europe. In some countries, including several in Europe, we may be required to perform additional clinical studies using the commercial configuration of the system in order to obtain regulatory approval.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibody reactivity to red blood cells treated with the INTERCEPT red blood cell system in two patients, we have been conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce the potential for antibody reactivity to treated red blood cells. Based upon an internal evaluation of the results to date from these additional research activities and after consulting with regulatory authorities, we initiated a new Phase I trial in 2006 in the United States using a modified red blood cell system before potentially progressing to later-stage clinical trials. We are utilizing a manual processing system in the Phase I trial, which system is not in a commercially feasible form. Interim results of the Phase I trial suggest that the modified process in combination with a conventional additive solution results in conditions not suitable for long-term storage of red blood cells treated with the INTERCEPT system, adversely impacting their lifespan. Consequently, we will likely continue with Phase I studies to optimize the red blood cell system by investigating alternate additive solutions in combination with other changes to the process. A number of trial design, process and product design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials and while those clinical trials are being conducted, including determining the appropriate design of additional Phase I or subsequent Phase II clinical trials, if deemed necessary, and Phase III clinical trials, and developing a commercially feasible red blood cell system, including disposables, hardware and software for implementing the process in blood collection centers. These development initiatives may be costly and time consuming. Even if the project proceeds on course, we would not expect to initiate a Phase III trial for our red blood cell system prior to 2009. A delay in completing such activities could result in a delay in the timely progression to later stage trials. If we are unsuccessful in advancing a modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system program.

Clinical trials in particular are expensive and have a high risk of failure. Any of our product candidates may fail in the testing phase or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we or our collaborators will begin and conduct planned clinical trials on schedule, if at all. Significant delays in clinical testing could materially impact our clinical trials. We also do not know whether planned clinical trials will need to be revamped or will be completed on schedule, if at all. Criteria for regulatory approval in cancer and infectious disease indications are evolving with competitive advances in the standard of care against which new product candidates are judged, as well as with changing market needs and reimbursement levels. Clinical trial design, including enrollment criteria, endpoints, and anticipated label claims are thus subject to change, even if original objectives are being met. In addition to the reasons stated above, clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board approval to conduct a study at a prospective clinical site and delays in recruiting subjects to participate in a study. We do not know whether any clinical trials will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical and clinical trials and product candidates emerging from any successful trials would not reach the market for several years.

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

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

## Edgar Filing: CERUS CORP - Form 10-Q

Upon reaching agreements with Baxter in February 2006, we became fully responsible for sales, marketing and distribution support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. As a consequence, we no longer rely upon Baxter for sales, marketing, distribution, or regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop such internal competencies or establish acceptable relationships with third parties on a timely basis, our attempts to commercialize the INTERCEPT Blood System may be irreparably harmed.

*We must develop, build and manage marketing, sales, distribution, customer service and back office functions necessary to support commercialization of the INTERCEPT Blood System in Europe.* Historically, we had a small scientific affairs group that helped support Baxter's European sales and marketing organization; however, we did not maintain our own independent sales and marketing organization. We may be unable to maintain existing customer relationships established by Baxter as we take on responsibility for sales, marketing and customer service. Beginning in early 2006, we began to recruit a small European organization dedicated primarily to selling and marketing the platelet system and more recently, the plasma system, in Europe. We may be unable to recruit suitable sales, marketing, regulatory, and quality assurance personnel on a timely basis, if at all. We also need to continue developing distribution, customer service, and back office capabilities either internally or by contracting with third parties, which we may be unable to accomplish on a timely or maintain on an affordable basis. In addition to adding sales and marketing capabilities, we have needed to develop appropriate inventory and logistics management, receivables and collections, foreign exchange, risk management, human resources, information and quality systems capabilities. Generally, such capabilities must be built in compliance with European standards and practices, with which we have little experience. We also have had to develop customer service capabilities to insure uninterrupted supply, timely calibration and servicing of UVA illuminators, and appropriate and timely resolution of customer complaints. We may be unable to operate a European organization effectively and efficiently, even after Cerus Europe B.V. is fully staffed. Developing sales, marketing and operational capabilities ourselves will increase our costs and may delay commercialization of our pathogen inactivation systems.

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*We must develop regulatory capabilities for clinical-stage and Phase IV trials involving the INTERCEPT Blood System globally.* Following our February 2006 agreements with Baxter, we have taken on worldwide responsibility for regulatory activities regarding the INTERCEPT Blood System, except in territories covered by our agreement with BioOne for the platelet and plasma systems, provided that Baxter remained as the registrant or applicant under European registrations and applications for a transition period in 2006. We will need to complete the transition from Baxter, where we must gain regulatory approval to switch product labels to our brand. Failure to do so may slow the rate of sales of the platelet system or delay the launch of our plasma system. We need additional resources to support regulatory activities and post-approval trials relating to these products. We may not have adequate internal resources and capabilities to manage Phase IV and post-approval trials and to respond appropriately to possible customer complaints or required regulatory reporting of adverse events arising from the use of the platelet system. We will need to increase our regulatory and trial management resources or contract with independent regulatory consultants, which we may be unable to do on a timely basis. Adding regulatory and trial management resources will result in increased costs and may potentially delay regulatory filings. Delays or inability to complete regulatory filings and obtain approvals will also delay or prevent us from being able to recognize sales of our products and attaining profitability.

***We will continue to rely on Fenwal for manufacturing and supplying components of our platelet and plasma systems for a limited period of time. Over a longer period, we will need to identify, select and qualify third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system.***

*We rely on third parties for manufacturing and supplying components of our platelet and plasma systems.* Under the terms of our agreements and subsequent to its assumption of Baxter's obligations, Fenwal is currently responsible for manufacturing and supplying illuminators and disposable kits associated with the platelet and plasma systems for commercial use through 2008 and certain components of the platelet and plasma systems through 2009. We will also be dependent on Fenwal to transfer know-how relevant to the INTERCEPT Blood System; however, certain of Fenwal's materials, manufacturing processes and methods are proprietary to Fenwal or Baxter. We may be unable to establish alternate sources of supply to Fenwal without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review, which would delay our ability to commercialize the platelet and plasma systems. If Fenwal fails to manufacture an adequate supply of components or devices within quality specifications, we may be unable to supply products to our customers. Fenwal is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Any delay in the availability or disruption in supply from Fenwal of devices, components or Intersol, a proprietary platelet storage solution manufactured by Fenwal, could delay further regulatory approvals, market introduction and subsequent sales of the systems. If we conclude that supply of the INTERCEPT Blood System or components from Fenwal is uncertain, we may choose to build inventories of raw materials or work-in-process components, which would consume capital resources and may cause our supply chain to be less efficient. 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. Fenwal manufactures our platelet and plasma systems in facilities that are not FDA-approved. Our agreements do not require Fenwal to validate these manufacturing facilities with the FDA. In order to be sold in the United States, our systems would be required to be manufactured in an FDA-approved facility. FDA validation of a manufacturing facility, whether owned by Fenwal or by another party, will be costly and time-consuming.

*Baxter has sold its Transfusion Therapies business unit and, under that agreement, the buyer will assume Baxter's manufacturing obligations to Cerus.* On March 1, 2007, Baxter announced that it had sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to a new company, Fenwal Inc. formed by an investment group led by Texas Pacific Group. We have been informed by Baxter that Fenwal has assumed Baxter's obligations to us under the manufacturing agreement. However, Fenwal may fail to manufacture an adequate supply of components, Intersol additive solution or devices of the INTERCEPT Blood System, which would subject us to the risks described above. Certain components of the INTERCEPT Blood System are currently manufactured or assembled at facilities not owned by Fenwal. Under our agreements, Fenwal will continue to be obligated to supply illuminators, disposable kits and the Intersol additive solution associated with the platelet and plasma systems to us generally through 2008 and for certain components through 2009. Failure to supply an adequate supply of components or devices of the INTERCEPT Blood System, would subject us to the risks described above. In addition, because the components of the INTERCEPT Blood System are manufactured and assembled at multiple facilities owned by both Fenwal and Baxter leading up to final assembly, Fenwal and Baxter will remain interdependent with respect to the INTERCEPT Blood System supply chain. Fenwal and Baxter may fail to coordinate or meet interdependent supply chain obligations, leading to a failure to manufacture an adequate supply of components or devices of the INTERCEPT Blood

System, which would also subject us to the risks described above.

*We will be required to identify and enter into agreements with third parties to manufacture the INTERCEPT Blood System products and related blood component storage solutions.* Fenwal's manufacturing responsibilities for illuminators and disposable kits associated with the platelet and plasma systems in general extend through 2008 and for certain components of the platelet and plasma systems through 2009, after which we will assume manufacturing responsibilities. Except for very limited manufacturing of disposable components, Fenwal is not obligated to provide manufacturing services related to the red blood cell system. We will need to identify parties to provide those manufacturing services related to our red blood cell system. It may be difficult to enter into these types of agreements on reasonable terms. In particular, it will be time-consuming for other manufacturers to develop the capability to manufacture the INTERCEPT Blood System products and blood component storage solutions economically and to gain regulatory approval to do so for commercial use. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to commercialize our products.

*Our potential remedies against Fenwal and Baxter may be inadequate in assuring that Fenwal and Baxter meet their contractual obligations.* In the event of a failure by Fenwal or Baxter to perform their obligations to supply components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Our supply agreement with Baxter, assumed by Fenwal, contains limitations on incidental and consequential damages that we may recover. Fenwal's and Baxter's potential liability in the event of non-performance may not be sufficient to compel Fenwal and/or Baxter to continue to act in conformity with our agreements.

***The platelet system is not compatible with some commercial platelet collection methods and platforms and platelet storage solutions.***

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the United States and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe and Canada, and the pooled random donor method, which is used in the United States and to a more limited extent in Europe.

Our system for platelets is designed to work with platelets collected using a proprietary platelet storage solution, called Intersol, manufactured by Fenwal. For

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platelets collected by apheresis, the INTERCEPT platelet system is most compatible with Fenwal's apheresis platelet collection system, because it facilitates the use of Intersol. For platelets prepared from whole blood, our platelet system is most compatible with the buffy coat collection method, again because this method facilitates the use of Intersol as an additive solution to the platelet concentrate. As a result, we have conducted most of our clinical studies using either Fenwal's equipment or buffy coat platelets. More recently, we have begun conducting studies in Europe supporting the use of the platelet system in combination with other collection and preparation platforms.

In order to address the entire market in the United States, we would need to develop and test additional configurations of the INTERCEPT platelet system. Our efforts to develop the platelet system to date have focused almost entirely on apheresis platelets collected on Fenwal's automated collection platform. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. We may be required to make our systems compatible with random donor platelets. In order to develop a platelet pathogen inactivation system compatible with random donor platelets, we would need to perform additional product development and testing, including additional clinical trials. These development activities would increase our costs significantly, and may not be successful.

Fenwal has committed to us to make Intersol collection and pooling products and conversion kits available to customers. However, Fenwal may not make such products or its apheresis collection system available for sale in certain countries and has elected to discontinue sales efforts for its apheresis collection system in Japan.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System compatible with their platforms. Making our platelet system readily compatible with the apheresis collection system manufactured by Haemonetics Corp., a supplier of automated blood collection systems, will require certain changes in the Haemonetics device, and there can be no assurance that Haemonetics will undertake this effort on a timely basis or be commercially successful. Gambro, Inc., or Gambro, another major supplier of automated platelet collection systems, is conducting clinical trials of its own system for pathogen inactivation of platelets. For competitive reasons, Gambro may have little or no incentive to make its apheresis collection system compatible with our platelet system. Attaining compatibility with collection platforms manufactured by others would require adaptations to either our platelet system or to the collection platforms, which may be difficult to engineer, expensive to implement and test, require additional clinical trials, cause delays in regulatory approval and/or be commercially unattractive to pursue. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the platelet system may be delayed until the system receives regulatory approval for use on such other equipment.

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

The INTERCEPT Blood System products, including many of the components, have been manufactured on a commercial scale on only a limited basis. Fenwal relies on third parties, including Baxter, to manufacture and assemble some of the platelet and plasma system components, many of which are customized and have not been manufactured on a commercial scale. Fenwal has produced some pathogen inactivation systems in modest commercial quantities, but may not be able to manufacture and assemble other systems or in larger quantities, or do so economically. Because of low sales volumes and other reasons, Fenwal's costs to manufacture commercial components for the platelet system have been greater than we previously anticipated and may continue to rise. This may reduce our potential gross profit margin from platelet and plasma system sales.

We may be unable to contract with third parties to supply the INTERCEPT Blood System in adequate quantities or to manufacture the system or its components at acceptable cost. We are in the initial stages of commercializing the INTERCEPT Blood System in Europe and may not accurately forecast demand for the INTERCEPT Blood System. We may be unable to contract with third parties to supply adequate numbers of platelet and plasma systems and components to meet demand and, as a result, supply to our customers may be interrupted. If Fenwal or third-party manufacturers fail to produce our products or Intersol products satisfactorily, at acceptable costs and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations. 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.

Fenwal and we purchase certain key components of the INTERCEPT Blood System from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. It would be expensive and time-consuming to establish additional or replacement suppliers for these components. Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require Fenwal or us to identify and qualify replacement components and may require that we conduct additional studies, which could include clinical trials, to demonstrate equivalency or validate any required design or

component changes. If Fenwal or we are unable to identify and supply replacement components, we may be unable to supply products to our customers. If we were required to redesign the products, our development costs would increase, and our programs and commercialization efforts could be delayed significantly.

We intend to use third-party manufacturers to produce commercial quantities of the chemical compounds to be used in our products. These compounds have not yet been produced in quantities sufficient to support commercialization for all regions in which we may market our products. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, a proprietary compound used in our platelet and plasma systems. We currently do not have any third-party manufacturing agreements in place for commercial production of compounds used in our red blood cell system. Any new or additional commercial manufacturer will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that its commercial scale manufacturing processes comply with government regulations and that its compounds are equivalent to originally licensed compounds in order for us to maintain commercial licensure of our products. It may be difficult or impossible to economically manufacture our products on a commercial scale.

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

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

***We have used prototype components in our preclinical studies and clinical trials of the INTERCEPT red blood cell system and have not completed the components commercial design.***

The system disposables and instruments of our red blood cell system that we used in our preclinical studies and clinical trials in the United States historically and those we are now using in our new Phase I red blood cell trial are prototypes of systems to be used in the final products. As a result, we expect regulatory authorities will require us to perform additional preclinical and clinical studies using the commercial versions of the systems to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial products design, which may increase our expenses and delay the commercialization of our products. If we fail to develop commercial versions of the INTERCEPT red blood cell system on schedule, our potential revenue would be delayed or diminished and our competitors may be able to bring products to market before we do.

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

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

Baxter and we have licensed to BioOne, rights to commercialization of the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in those countries. We understand Fenwal has assumed the rights and obligations of Baxter with regard to Baxter's agreements with BioOne. We also understand that Fenwal does not intend to maintain its CE mark registration for the platelet system after it expires in mid-2007. In addition, we received CE mark approval for the plasma system independently from Fenwal, and Fenwal is not intending to apply for a CE mark for the plasma system. However, BioOne is dependent on Fenwal for the manufacture and supply of the platelet and plasma systems well beyond the time when Fenwal intends to let its CE mark registration for the platelet system lapse. BioOne is also dependent on Fenwal for providing certain regulatory support and the timely transition of regulatory files and dossiers. BioOne may be unable to qualify the platelet and plasma systems for sale in certain countries in its territory in the absence of CE marks being held by Fenwal, even if CE marks are held by us. BioOne has made only limited progress to date in commercializing the platelet and plasma systems in Asian territories. Because we only have a minority investment interest in BioOne, we lack the ability to significantly influence BioOne, and are dependent on BioOne's performance to realize milestone and royalty revenue from commercialization of our platelet and plasma systems in those countries. In Japan, regulatory authorities may require our platelet and plasma systems to be widely adopted commercially in Europe or approved by the FDA before the platelet and plasma systems are considered for approval in Japan, which would delay or prevent BioOne from achieving significant product sales. We understand that BioOne will need to raise additional capital in the first half of 2007 in order to fund its operations. There is no assurance that BioOne will be able to attract additional required capital to successfully commercialize those products licensed from Baxter and us. BioOne may not be successful in commercializing the platelet and plasma systems in its Asian territories or may raise equity capital at a valuation lower than that our carrying value, in which case the value of BioOne's equity likely would decline and may give rise to an impairment in the carrying value of our equity interest in BioOne.

***Our vaccine programs are in an early stage of development.***

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

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

Because our vaccine candidates use novel platforms, the FDA or foreign regulators may require studies that we have not anticipated. In addition, we have contracted with third-party manufacturers to produce our vaccines for research, preclinical and clinical testing. We have manufactured CRS-100 for toxicology studies and Phase I clinical trials, but have not engaged in scale-up of the manufacturing process or the development of

a commercial formulation. We also rely on third parties to conduct aspects of preclinical and clinical development on our behalf, including contract manufacturing and research services. These third parties may encounter delays, over which we have significantly less control than research and development activities performed in-house, or experience unexpected results. We may experience numerous unforeseen events during, or as a result of, the preclinical research and development process that could delay or prevent clinical testing, regulatory approval and commercialization of our potential products.

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

The development and commercialization of product candidates employing our *Listeria* and KBMA platform technologies will be expensive, lengthy and uncertain. To date, we have relied not only upon internal scientific, development and financial resources, but also upon third parties. We have licensed our *Listeria* platform to MedImmune for use in developing a product candidate potentially applicable to cancers expressing EphA2, a proprietary antigen owned by MedImmune. On April 12, 2007, MedImmune announced that it was investigating strategic alternatives, up to and including the sale of the company. Sponsorship of MedImmune's immunotherapy program involving EphA2 and our *Listeria* may be lost as a consequence of changed strategic direction or ownership of MedImmune. We are collaborating with investigators at Johns Hopkins University on other cancer and infectious disease programs. We also rely on advice and insights from our scientific advisory board, a group of independent clinicians, professors and investigators, regarding our research and development activities. These relationships provide us with external perspectives and independent validation that may be critical to our future success. Loss of these relationships or failure to attract others may result in additional expense, delays in development and regulatory approval and failure to commercialize products. We have received significant funding from United States government agencies for research and development in both cancer and infectious disease, as well as funding from MedImmune under our license agreement relating to development of MEDI-543 (EphA2); however, development funding from MedImmune to us ceased at the completion of contracted work we had performed through early 2006. Due to budgetary constraints, funding from the Federal government, particularly funding from the Department of Defense and National Institutes of Health, is expected to be reduced from prior years and is subject to political and economic forces beyond our control. Additionally, we no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the National Institutes of Health and regulated by Small Business Administration.

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



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

We expect our products to encounter significant competition. The INTERCEPT Blood System products may compete with other approaches to blood safety currently in use, as well as with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to medical and technological changes brought about by the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures.

Several companies are developing technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in platelets and plasma. In Europe, several companies, including Grifols S.A., Octapharma AG and Maco Pharma International GmbH, are developing or have developed and are selling commercial pathogen inactivation systems to treat fresh frozen plasma. Navigant Biotechnologies, a wholly owned subsidiary of Gambro Group, is developing a pathogen inactivation system for blood products.

New methods of testing blood for specific pathogens have been approved by the FDA and in Europe, as have tests for bacteria in platelets. Continued delays in commercialization of the platelet system in France and Germany may impact our ability to compete with bacterial testing for platelets. Tests have recently been approved to detect West Nile Virus in blood products. Other groups are developing rapid, point-of-care bacterial tests, synthetic blood product substitutes and products to stimulate the growth of platelets. Development and commercialization of any of these or other related technologies could impair the potential market for our products.

There are many companies pursuing programs for the treatment of cancer and treatment and prevention of infectious disease. Some are large pharmaceutical companies, such as Pfizer Inc., GlaxoSmithKline Inc., Sanofi-Aventis, Bristol-Myers Squibb Company, Genentech, Inc. and Gilead Sciences, Inc., which have greater experience and resources in product development, preclinical testing, human clinical trials, obtaining FDA and other regulatory approvals and in manufacturing and marketing new therapies. We are also competing with other biotechnology companies, such as Cell Genesys, Inc., Coley Pharmaceutical Group, and Dendreon Corporation, that have cancer vaccine programs that are in more advanced stages of development than ours. In addition, other companies are pursuing early-stage research and development of *Listeria*-based immunotherapies. If any of these companies' products are shown to be more efficacious than ours, our *Listeria*-based products may fail to gain regulatory approval or commercial acceptance. If these companies' products fail in human clinical trials, we may be required to overcome more significant regulatory barriers prior to gaining approval, face more challenging impediments to market acceptance and may be unable to raise capital to fund development of our *Listeria* or KBMA programs.

***We may be liable and we may need to withdraw our products from the market if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials.***

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and pharmaceutical products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in clinical and preclinical testing could be discovered in clinical trials or after a marketing approval has been received. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations would be harmed and we would incur unforeseen losses. We maintain product liability insurance, but do not know whether the insurance will provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis viruses. Although we believe that our safety procedures for handling and disposing of hazardous materials are adequate and comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result.

***Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from at a single site that may be subject to lengthy business interruption in the event of a severe earthquake.***

Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from our facilities in Concord, California, which are within an active earthquake fault zone. Should a severe earthquake occur, we might be unable to occupy our facilities or conduct research and development and general and administrative activities in support of our business and products until such time as our facilities could be repaired and made operational. Our property and casualty and business interruption insurance in general does not cover losses caused by earthquakes. While we have taken certain measures to protect our scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us.

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

We may never achieve a profitable level of operations. To date, we have engaged primarily in research and development. Our development and selling, general, and administrative expenses have resulted in substantial losses each year since our inception with the exception of the year ended December 31, 2005. In 2005, we realized a \$22.1 million nonrecurring gain associated with the restructuring of a loan payable in 2005 and, as a result of this gain, we recorded net income of \$13.1 million in 2005. At March 31, 2007, we had an accumulated deficit of approximately \$318.2 million. Except for the platelet and plasma systems, which have received European Union CE mark approval, all of our products are in the research and development stage, and we have not received significant revenue from product sales. We may be required to reduce the sales price for our products in order to make them economically attractive to our customers and to governmental and private payors, which would reduce and may eliminate our gross profit on sales. Pricing levels may differ widely from country to country, depending on economic, social and industry practices specific to each country. At our present low unit sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer the systems are in excess of revenue. We may be unable to increase sales to a level sufficient to generate profit contribution. Because the contracts with large, public-sector customers, such as the EFS, for the INTERCEPT Blood System may not be confidential due to the public tender process, their terms may set contractual precedents that would not be acceptable to us if applied to contracts with our other customers. We have received substantially all of our revenue from our agreements with our development partners and from federal research grants and cooperative agreements. We will be required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. We expect our losses to continue at least until more of our product candidates are commercialized and achieve significant market acceptance.

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

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

Through March 31, 2007, we had been awarded \$41.7 million in funding under cooperative agreements with the Department of Defense, and have received \$35.1 million in proceeds from these awards. We also have received funding under grants from the National Institutes of Health. Further funding awarded under federal grants and cooperative agreements is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment, coupled with tight Federal budgets, has led to a general decline in the amount of government funding. Additionally, we no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the National Institutes of Health and regulated by Small Business Administration. If we are unable to obtain Federal grant and cooperative agreement funding for future activities at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs. In addition, we are required separately to administer and account for our work under government contracts and grants on an on-going basis as a condition to accepting government funding which places administrative, accounting and reporting burdens on us beyond those we have assumed as a public company. If we fail to comply with applicable governmental administrative, accounting and reporting regulations with respect to these grants and cooperative agreements, funds currently available to us may be reduced or lost. These conditions may also result in increased selling, general, and administrative spending beyond what we have experienced.

***We may be unable to consummate a transaction involving our immunotherapy programs.***

On April 26, 2007, we announced that we are exploring strategic alternatives for our cancer and infectious disease immunotherapy programs. We will consider several possible business structures, including partnering some or all of the programs within our immunotherapy business with companies having established programs in immunology or in cancer and infectious disease indications, combining our immunotherapy business with another public or private company, or spinning out the business for an equity interest in a newly-formed immunotherapy company. This potential corporate realignment would allow us to focus resources on our commercial-stage blood safety business. We may be unable to consummate a transaction involving our immunotherapy business, which would then require that we either fund increased operations internally or curtail operations.

***We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.***

Our commercial success will depend, in part, on obtaining and maintaining patent protection on our products and successfully defending our products against third-party challenges. Our technology will be protected from unauthorized use only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to:

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, a United States patent issued to a third-party covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe our work predates the invention disclosed in that patent. We are continuing to review that patent and will make a determination as to whether any action is necessary. In addition, others hold patents, and have pending patent applications, concerning *Listeria*-based immunotherapies. Those patents and new patents that may be issued upon the pending applications, if valid, would restrict us from bringing to market particular embodiments of *Listeria*-based immunotherapy products. While we believe that such restrictions do not preclude us from developing and commercializing our *Listeria*-based immunotherapy products, they may preclude us from pursuing certain product approaches that might otherwise be promising. Our patents expire at various dates between 2009 and 2018. Recent patent applications, principally related to our immunotherapy programs, will, if granted, result in patents with later expiration dates. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products.

We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings before the United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights.

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees and certain contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know-how and inventions.

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*As our international operations grow, we may be subject to adverse fluctuations in exchange rates between the United States dollar and foreign currencies. Consequently, we may suffer losses.*

Our international operations are subject to risks typical of an international business, including, among other factors: differing political, economic, and regulatory climates, different tax structures, and foreign exchange volatility. We do not currently enter into any hedging contracts to normalize the impact of foreign exchange fluctuations. As a result, our future results could be materially affected by changes in these or other factors.

Product sales of our blood safety products are typically made in Europe and generally are invoiced to customers in Euros. In addition, we incur operating expenses in foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support of our international operations. Foreign exchange rate fluctuations are recorded as a component of Interest (Expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. dollar may materially affect our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

*The market price of our stock may be highly volatile.*

The market prices for our securities and those of other emerging medical device and biotechnology companies have been, and may continue to be, volatile. For example, during the period from January 1, 2004 to March 31, 2007, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of \$1.60 to a high of \$14.76. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

biological or medical discoveries;

technological innovations or new commercial services by us or our competitors;

developments concerning proprietary rights, including patents and litigation matters;

regulatory developments in both the United States and foreign countries;

status of development partnerships;

dilution from future issuances of common stock;

public concern as to the safety of new technologies;

general market conditions;

comments made by analysts, including changes in analysts' estimates of our financial performance; and

quarterly fluctuations in our revenue and financial results.

## Edgar Filing: CERUS CORP - Form 10-Q

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.

*We may fail to comply fully with elements of the Sarbanes-Oxley Act of 2002. Our failure to maintain effective internal controls in accordance with Section 404 of this Act could have a material adverse effect on our stock price.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accountants attesting to and reporting on these assessments. These requirements extend to the operations of our subsidiary in Europe. If we fail to maintain the adequacy of our internal controls over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude in future periods that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on our assessment of, the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

- 3.1.1(1) Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
- 3.2(2) Amended and Restated Bylaws of Cerus.
- 4.2(3) Specimen Stock Certificate.
- 10.1(4) Cerus Corporation Change of Control Severance Benefit Plan.
- 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.

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- (1) Incorporated by reference to Cerus Current Report on Form 8-K, dated November 3, 1999.
  - (2) Incorporated by reference to Cerus Current Report on Form 8-K, dated April 26, 2007
  - (3) Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
  - (4) Management contract or compensatory arrangement.
  - (\*) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of Cerus Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q),irrespective of any general incorporation language contained in such filing.

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**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.

Date: May 1, 2007

CERUS CORPORATION

/s/ William J. Dawson  
William J. Dawson  
Chief Financial Officer

(Principal Financial and Accounting Officer)



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