CERUS CORP

FORM 10-Q
(Quarterly Report)

Filed 10/31/06 for the Period Ending 09/30/06

Address	2550 STANWELL DRIVE CONCORD, CA 94520
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10 - Q

(Mark One)

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

For the quarterly period ended September 30, 2006

or

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

For the transition period from _____to _____

Commission File Number 0-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ 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" as defined in Rule 12b-2 of the Exchange Act.

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 Act). YES ☐ NO ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

As of October 23, 2006, there were 27,817,586 shares of the registrant's common stock outstanding.

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CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q
NINE MONTHS ENDED SEPTEMBER 30, 2006

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED
(in thousands)

	September 30, 2006 (Unaudited)	December 31, 2005 (see Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 42,566	$ 5,780
Short-term investments	27,025	40,025
Accounts receivable and other current assets	9,624	5,200
Inventories	1,836	—
Total current assets	81,051	51,005
Non-current assets:		
Furniture and equipment, net of depreciation and amortization	1,517	1,235
Long-term investments	6,175	6,175
Other assets	267	245
Total assets	$ 89,010	$ 58,660
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,067	$ 2,092
Current loan and interest payable	—	4,826
Accrued liabilities	8,062	5,197
Deferred revenue	2,054	11,135
Deferred gain	3,520	—
Current portion of capital lease obligation	100	67
Total current liabilities	15,803	23,317
Capital lease obligation	41	68
Total liabilities	15,844	23,385
Commitments and contingencies		
Stockholders' equity		
Preferred stock	9,496	9,496
Common stock	28	23
Additional paid-in capital	378,088	332,694
Accumulated other comprehensive loss	(14)	(295)
Accumulated deficit	(314,432)	(306,643)
Total stockholders' equity	73,166	35,275
Total liabilities and stockholders' equity	$ 89,010	$ 58,660

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenue:				
Milestone and development funding	$ 2,597	$ 3,292	$ 10,618	$ 8,819
Government grants and cooperative agreements	4,583	3,519	8,764	9,547
Product revenue	794	69	2,049	395
Total revenue	7,974	6,880	21,431	18,761
Operating expenses:				
Cost of product revenue	373	—	836	—
Research and development	7,030	6,626	22,069	17,556
Selling, general and administrative	3,273	2,161	10,151	7,198
Total operating expenses	10,676	8,787	33,056	24,754
Loss from operations	(2,702)	(1,907)	(11,625)	(5,993)
Gain on loan settlement	—	—	—	22,089
Interest income and other, net	915	241	3,836	862
Net income (loss)	$ (1,787)	$ (1,666)	$ (7,789)	$16,958
Net income (loss) per common share:				
Basic	$ (0.06)	$ (0.07)	$ (0.30)	$ 0.76
Diluted	$ (0.06)	$ (0.07)	$ (0.30)	$ 0.72
Weighted average common shares outstanding used for basic and diluted net income (loss) per share:				
Basic	27,800	22,373	26,250	22,317
Diluted	27,800	22,373	26,250	23,694

See notes to condensed consolidated financial statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
UNAUDITED
(in thousands)

	Nine Months Ended September 30,	
	2006	2005
Operating activities:		
Net income (loss)	$ (7,789)	$ 16,958
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	527	504
Gain on loan settlement	—	(22,089)
Stock-based compensation to employees	2,023	100
Gain on sale of equipment	—	(4)
Changes in operating assets and liabilities:		
Accounts receivable	(3,768)	(701)
Inventories	(1,836)	—
Other assets	(678)	1
Deferred gain	3,520	—
Accounts payable and accrued expenses	3,030	295
Accrued interest	(326)	236
Deferred revenue	(9,081)	(6,587)
Net cash used in operating activities	(14,378)	(11,287)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(809)	(617)
Purchases of short-term investments	(21,902)	(5,000)
Sales of short-term investments	—	8,000
Maturities of short-term investments	35,183	8,911
Net cash provided by investing activities	12,472	11,294
Financing activities:		
Net proceeds from common stock public offering	42,372	—
Net proceeds from issuance of common stock from ESPP, stock options and restricted stock units	914	405
Repayment of loan	(4,500)	(34,500)
Payments on capital lease obligations	(94)	—
Net cash provided by (used in) financing activities	38,692	(34,095)
Increase (decrease) in cash and cash equivalents	36,786	(34,088)
Cash and cash equivalents, beginning of period	5,780	39,493
Cash and cash equivalents, end of period	$ 42,566	$ 5,405

See notes to condensed consolidated financial statements.

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CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
UNAUDITED

Note 1 – Basis of Presentation

Our accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and our subsidiary, Cerus Europe B.V., 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 only of normal recurring adjustments) considered necessary for a fair presentation have been included. The results of operations for the three and nine month periods ended September 30, 2006, are not necessarily indicative of the results that may be expected for the year ending December 31, 2006, 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, 2005, included in our Annual Report on Form 10-K for the year ended December 31, 2005. The accompanying balance sheet as of December 31, 2005, has been derived from our audited financial statements as of that date.

Revenue Recognition

In December 2003, the Securities and Exchange Commission published Staff Accounting Bulletin No. 104, “Revenue Recognition” (“SAB 104”). SAB 104 rescinds Staff Accounting Bulletin No. 101, “Revenue Recognition in Financial Statements” and provides guidance on the recognition, presentation and disclosure of revenue in financial statements. The Company recognizes revenue in accordance with SAB 104 and Emerging Issues Task Force (“EITF”) 00-21, “Accounting for Revenue Arrangements with Multiple Deliverables,” as applicable.

Our main sources of revenues through September 30, 2006, have been our research and development activities and agreements. Historically, development funding has consisted of payments made (i) by Baxter Healthcare Corporation (“Baxter”), a subsidiary of Baxter International Inc. (“Baxter International”), to us as reimbursement for development spending in excess of the levels determined by Baxter and us and (ii) by MedImmune, Inc. (“MedImmune”) to us as reimbursement for certain fee-for-service development activities. Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to 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. We evaluate licenses and research and development agreements that contain multiple elements in accordance with EITF 00-21 and accordingly allocate revenue to each element of the agreement based on their relative fair values.

We receive milestone and upfront consideration from collaborative partners, including MedImmune and BioOne Corporation (“BioOne”). This milestone and upfront consideration is earned through our research and development activities surrounding the collaborative agreements. Upfront consideration is generally deferred upon receipt and recognized ratably over the periods to which the payments relate.

We receive certain United States government grants that support our efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In accordance with Statement of Financial Accounting Standards No. 2, “Accounting for Research and Development Expenses,” research and development costs are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

Our use of estimates in recording accrued liabilities for research and development activities affects the amounts of research and development expenses recorded and as a direct result of estimates, revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

Effective February 1, 2006, we entered into an agreement with Baxter, which gave us 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, we now record product sales of the platelet system, rather than our negotiated share of gross profits from such sales under the prior agreement with Baxter. Also as a result of the February 2006 agreement, we record cost of revenues, which, for the three and nine month periods ended September 30, 2006, consisted solely of the value of platelet system inventory sold. Inventories consist of finished goods components of the platelet system and are recorded at the lower of cost or market value, determined on a first-in, first-out basis.

Stock based compensation

Beginning January 1, 2006, we adopted the provisions of, and account for stock-based compensation in accordance with, the Financial Accounting Standards Board’s (“FASB”) 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. We elected the modified-prospective method, under

which stock compensation costs related to options granted in periods prior to adoption are recognized based on their original valuation assumptions. The valuation provisions of FAS 123R apply to new grants and to grants that were outstanding as of the effective date and are subsequently modified. Estimated compensation for grants that were outstanding as of the effective date will be recognized over the remaining service period.

See Note 2 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.

On November 10, 2005, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards." We have elected to adopt the alternative transition method provided in the FASB Staff Position for calculating the tax effects (if any) of stock-based compensation expense pursuant to SFAS 123R. The alterative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123R.

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 counter party 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.

Recent 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 company has not yet issued financial statements, including for interim periods, for that fiscal year. We are currently evaluating the impact of SFAS 157, but do not expect the adoption of SFAS 157 to have a material impact on our consolidated financial position, results of operations or cash flows.

In July 2006, the FASB issued Financial Interpretation No. 48, "Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109" ("FIN 48"), which is a change in accounting for income taxes. FIN 48 specifies how tax benefits for uncertain tax positions are to be recognized, measured, and derecognized in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact of FIN 48 on our consolidated financial position, results of operations, and cash flows.

Other Significant Accounting Policies.

For all other significant accounting policies, refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

Note 2 – 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 1998 Non-Officer Stock Option Plan (the "1998 Plan"), and the 1999 Equity Incentive Plan (the "1999 Plan").

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. As of September 30, 2006, all restricted stock units pertaining to the March 2004 grants had vested and all related compensation expense had been recognized based on the valuation of $3.38 per share.

During the nine months ended September 30, 2006, we granted restricted stock units to our Chief Executive Officer and Vice Presidents in accordance with the 2005 bonus plan. 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. The restricted stock units granted during the nine months ended September 30, 2006, totaled 37,098 valued at $10.32 per share. None of the restricted stock units issued during the nine months ended September 30, 2006, were vested as of that date.

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. For those homogeneous groups where 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 Staff Accounting Bulletin No. 107 ("SAB 107") "Share Based Payment." The expected term of 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.

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.

Prior to the adoption of FAS 123R, we recognized the estimated compensation cost of restricted stock units over the vesting term. The estimated compensation cost is based on the fair value of our common stock on the date of grant. We will continue to recognize the compensation cost, net of estimated forfeitures, over the vesting term.

The assumptions used to value option grants for the three and nine months ended September 30, 2006, and 2005 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Expected term (in years)	4.01-6.28	5.00	3.77-6.28	5.00

Volatility	65.4%	60.7%	65.1%	55.9%
Risk-free interest rate	4.81%	4.22%	4.64%	4.22%

The assumptions used to value employee stock purchase rights for the three and nine months ended September 30, 2006, and 2005 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Expected term (in years)	0.50	0.50	0.50	0.50
Volatility	56.6%	60.7%	58.8%	55.9%
Risk-free interest rate	5.02%	4.22%	4.73%	4.22%

Total stock-based compensation recognized on our consolidated statement of income for the three and nine months ended September 30, 2006, was as follows:

	Option Grants and Stock Purchase Rights	
	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Income Statement Classifications		
Research and development	$ 247	$ 908
Selling, general and administrative	347	1,115
Total	$ 594	$ 2,023

The following table sets forth the pro forma amounts of net income (loss) and net income (loss) per share, for the three and nine months ended September 30, 2005, that would have resulted if we had accounted for our employee stock plans under the fair value recognition provisions of FAS 123:

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net income (loss):		
As reported	$ (1,666)	$ 16,958
Add: Stock-based compensation expense included in reported net income (loss), net of tax	49	148
Less: Total stock-based compensation expense determined under the fair value based method, net of tax	(595)	(1,789)
Pro forma net income (loss)	$ (2,212)	$ 15,317
Basic net income (loss) per share:		
As reported	$ (0.07)	$ 0.76
Pro forma	$ (0.10)	$ 0.69
Diluted net income (loss) per share:		
As reported	$ (0.07)	$ 0.73
Pro forma	$ (0.09)	$ 0.66

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, 2005	4,598	$ 13.03
Granted	405	$ 8.86
Cancelled	(133)	$ 19.59
Exercised	(124)	$ 3.32
Balances at September 30, 2006	4,746	$ 12.74

The following table depicts the population of stock options at range of exercise prices outstanding at September 30, 2006:

(Shares in thousands)	Options Outstanding			Options Vested	
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$1.950—2.050	152	7.85	$ 2.0486	78	$ 2.0499
$2.100—2.280	658	7.75	$ 2.2739	322	$ 2.2724
$2.360—2.890	523	7.86	$ 2.5025	244	$ 2.5134
$2.950—3.250	543	7.62	$ 3.2344	323	$ 3.2325
$3.430—4.740	483	7.80	$ 4.2728	273	$ 4.2272
$5.000—8.750	471	8.21	$ 7.4063	202	$ 7.1832
$8.860—8.860	576	9.01	$ 8.8600	132	$ 8.8600
$9.010—21.060	482	5.87	$ 14.5296	358	$ 15.8901
$21.061—50.050	498	4.30	$ 36.0181	498	$ 36.0181
$50.180—75.250	360	5.21	$ 55.4470	360	$ 55.4470
$1.9500 —75.2500	4,746	7.21	$ 12.7373	2,790	$ 17.8868

Note 3 – 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.

Senior management does not view segment results below operating income (loss) and, therefore, interest income, expense and other non-operating expenses are not allocated to reportable segments. For the periods presented, revenue from product sales, 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 grants administered by the National Institutes of Health and the Armed Forces are included in immunotherapies. Segment information for the three and nine months ended September 30, 2006, and 2005, is presented below (in thousands):

	Three Months Ended September 30, 2006		Three Months Ended September 30, 2005	
	Revenue	Operating Loss	Revenue	Operating Loss
Blood safety programs	$ 7,268	$ 813	$ 3,541	$ (431)
Immunotherapies	706	(3,515)	3,339	(1,476)
Totals	$ 7,974	$ (2,702)	$ 6,880	$ (1,907)

	Nine Months Ended September 30, 2006		Nine Months Ended September 30, 2005	
	Revenue	Operating Loss	Revenue	Operating Loss
Blood safety programs	$ 16,654	$ (2,042)	$ 10,075	$ (155)
Immunotherapies	4,777	(9,583)	8,686	(5,838)
Totals	$ 21,431	$ (11,625)	$ 18,761	$ (5,993)

Note 4 – Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net income (loss):				
As reported	$(1,787)	$(1,666)	$(7,789)	$16,958
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities	73	—	281	(95)
Comprehensive income (loss)	$(1,714)	$(1,666)	$(7,508)	$16,863

Note 5 – Basic and Diluted Net Income (Loss) Per Share

For all periods presented, basic net income (loss) per share is computed based on the weighted average number of shares of common stock outstanding during each period. Stock options and Series B preferred stock outstanding during the three and nine months ended September 30, 2006 and the three months ended September 30, 2005, were not included in the computation of diluted net loss per share because their effect was antidilutive. For the nine months ended September 30, 2005, diluted net income per share included the effect of 1,045,000 shares of common stock calculated on options outstanding using the treasury stock method and the Series B preferred stock, which was convertible into 332,700 shares of common stock.

Note 6 – Restructured Agreements with Baxter

Effective February 1, 2006, we entered into a restructuring of our agreements with Baxter related to the INTERCEPT Blood System. Under the terms of the February 2006 agreement, we 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. As a result of the agreement, we record all of the platelet and plasma system revenues.

Prior to entering the February 2006 agreement, we received 33.5 percent of the adjusted gross margins from sales of the platelet system, which are shown as product revenue on our statements of operations. Baxter has 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. Also as a result of this agreement, we repaid a $4.5 million promissory note and the related accrued interest during the three months ended March 31, 2006. This promissory note had been payable to Baxter since February 2005 and had an original maturity date of December 2006 with interest of 8%. At September 30, 2006, we had approximately $3.5 million in remaining deferred gains recorded on our condensed consolidated balance sheet which may be used to offset qualifying expenses we incur associated with the commercialization of the platelet and plasma systems. The nature of these qualifying expenses may be for cost of product revenue, selling, general and administrative, or research and development. For the nine months ended September 30, 2006, we have recognized gains of approximately $2.3 million associated with these qualifying expenses.

Baxter has agreed to manufacture systems and components, on a cost-plus basis, through 2008. Since these manufacturing agreements do not require Baxter to manufacture in an FDA-approved facility, we 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.

Note 7 – Transactions with BioOne

In April 2004, we made an investment in the common stock of BioOne, a privately-held Japanese corporation. BioOne was formed in 2004 to develop technologies to improve the safety of blood products in Asia, and is funded by equity investments from Japanese venture capital firms, other corporations and individual investors. Because our initial investment represented greater than 20% of BioOne's voting equity securities, we accounted for this investment under the equity method for the three months ended June 30, 2004, and reported our share of BioOne's net losses as a loss from equity affiliate and as a reduction of our investment.

In June 2004, Baxter and we 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, Baxter and we each received up-front payments of $10.0 million from BioOne. Our portion of the up-front payments is being deferred and recognized ratably as development funding over the development period. The agreement also provides for contingent milestone payments and royalties on future product sales, which would be shared equally by Baxter and us.

In December 2004, Baxter and we 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, we received a payment of $3.0 million from BioOne, which was recorded as deferred revenue as of December 31, 2004. A definitive agreement with BioOne for the plasma system was signed

by Baxter and us in June 2005. In December 2005 we received additional up-front payments of $2.0 million in cash and $5.0 million in BioOne's equity, both of which were recorded upon receipt as deferred revenue to be amortized over the remaining development period.

We made an additional $1.1 million investment in BioOne equity securities in July 2004. As a result of dilution from additional concurrent third party investments in BioOne, we then held less than 20% of the outstanding voting securities of BioOne and began accounting for our investment in BioOne under the cost method. As partial payment for rights to the plasma system in BioOne's territories, in December 2005 we received shares and a warrant, exercisable at a nominal price, for additional shares valued at $5.0 million based on a concurrent financing with new and existing investors completed by BioOne. We continue to hold less than a 20% interest in the voting securities of BioOne and thus continue to account for our investment under the cost method. As of September 30, 2006, our investment in BioOne was $6.2 million and was included in long-term investments on our balance sheets. We evaluate the carrying value of this investment periodically and have determined our carrying value is fairly stated.

Note 8 – 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. 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 approximately 1% of our outstanding common shares as of September 30, 2006. We have the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million.

Note 9 – Litigation

On August 31, 2006, we announced that we had reached agreement to settle the class action, 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 stockholders' 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, 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.

The settlement will become effective upon the satisfaction of a number of conditions, including, among others, the timely execution of a final stipulation, the approval of the settlement by the courts, and the final and non-appealable entry of a judgment by the courts dismissing the class action and derivative lawsuits with prejudice. Under terms of the settlement, we believe that this matter will not have a material effect on our results of operations or financial position; however, we cannot predict when, if ever, the settlement will become effective.

Note 10 – Public Stock Offering

In March 2006, we completed a public offering of 5,175,000 shares of common stock, which included the underwriters' exercise of their over-allotment option, resulting in net cash proceeds of approximately $42.4 million.

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

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and our 2005 audited financial statements and accompanying notes included in our 2005 Annual Report on Form 10-K. Operating results for the periods presented are not necessarily indicative of results for the year ending December 31, 2006, or any future period.

The following discussion includes forward-looking statements that involve risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "expect" and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including the risks and uncertainties of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development process, additional financing activities, manufacturing, reimbursement, market acceptance of any products, competitive conditions, our long term growth opportunity, legal proceedings, actions by Baxter and other factors discussed below in Part II, Item 1A—Risk Factors and in our other documents filed with the Securities and Exchange Commission, or SEC. We undertake no obligation to update any of the forward-looking statements contained herein to reflect any future events or developments.

Cerus, *INTERCEPT*, *INTERCEPT Blood System* and *Helinx* are United States registered trademarks of Cerus Corporation.

Baxter and *Intersol* are trademarks of Baxter International Inc.

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of blood safety systems and, more recently, immunotherapies for cancer and infectious disease. With the exception of a non-recurring gain recognized during the three months ended March 31, 2005, we have been generally unprofitable since inception and, as of September 30, 2006, had an accumulated deficit of approximately $314.4 million. Except for the platelet system, for which the European Union approved issuance of a CE mark, all of our product candidates are in the research and development stage. In late 2005, we filed a CE mark application for the plasma system and an investigational new drug application, or IND, with the United States Food and Drug Administration, or FDA, for CRS-100, a product candidate employing our attenuated *Listeria* technology platform, and we re-entered Phase I human clinical trials in the United States for the red blood cell system in the three months ended September 30, 2006. Our primary source of revenue is from milestone and development contracts and collaborative, U.S. government grants. More recently, we have been receiving European product revenues from the sale of our platelet system. We anticipate continued growth of our product sales as we penetrate European markets. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities on our product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after commercialization of additional products. Our ability to achieve a profitable level of operations in the future will depend on our ability to successfully commercialize and achieve market acceptance of our blood safety and immunotherapy product candidates. We may never achieve a profitable level of operations.

Through September 30, 2006, in addition to the product revenues from sales of our platelet system, 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 National Institutes of Health, or NIH. Under the agreements with MedImmune and BioOne, we are receiving development funding and may receive contingent milestone payments and royalties on future product sales.

As of September 30, 2006, we had cumulatively received $1.5 million of upfront and milestone payments from MedImmune under the terms of the agreement, consisting of a $1.0 million up-front payment and a $0.5 million milestone payment, and had received a total of $20.0 million in cash payments and equity securities from BioOne. Under the MedImmune agreement, we had also received development funding.

We also entered into cooperative agreements with the Armed Forces and received grants and contracts from the NIH to conduct certain research and development activities. We recognized $4.6 million and $3.5 million under funding awards received in connection with these agreements during the three months ending September 30, 2006, and 2005, respectively and classify these as government grants and cooperative agreements on our condensed consolidated statements of operations. During the three months ended September 30, 2006, we recognized $3.9 million of in connection with blood safety awards and $0.7 million related to our immunotherapy programs. We have been performing the research activities under a blood safety award since January and received final release of the award in September 2006. For the three months ended September 30, 2005, $1.1 million of these awards related to our blood safety programs and $2.4 million related to our immunotherapy programs. In late 2005, we mutually agreed to discontinue development efforts whereby, along with the Pharmaceutical Division of Kirin Brewery Co. Ltd., or "Kirin", we were developing and marketing products for stem cell transplantation.

Effective February 1, 2006, we entered into a new agreement with Baxter related to the INTERCEPT Blood System. Under terms of the February 2006 agreement, we gained worldwide rights to the INTERCEPT platelet and plasma systems previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. We previously acquired worldwide commercialization rights for the red blood cell system from Baxter. Beginning in 2007, we will pay Baxter royalties on product sales, with 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 gross profit from product sales. Under the terms of the February 2006 agreement, Baxter has 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 has agreed to manufacture systems and components for the platelet and plasma systems on a cost-plus basis through December 31, 2008, and

has agreed to supply only very limited types of components for the prototype of the red blood cell system. On October 3, 2006, Baxter announced that it had entered into a definitive agreement to sell its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to an investment group led by Texas Pacific Group. Subject to regulatory approvals and other customary closing conditions, Baxter and Texas Pacific Group expect to close the transaction by the first quarter of 2007. Our agreement with Baxter will remain in effect, although Baxter may assign its rights and obligations to an assignee capable of performing Baxter's obligations.

As a result of the February 2006 agreement with Baxter, we recorded net gains and deferred gains 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 September 30, 2006 we had approximately $3.5 million in deferred gains recorded on our condensed consolidated balance sheet which may be used to offset qualifying expenses we incur associated with the commercialization of the platelet and plasma systems. The nature of these qualifying expenses may be for cost of product revenue, selling, general and administrative, or research and development. For the nine months ended September 30, 2006, we have recognized gains of approximately $2.3 million associated with these qualifying expenses.

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

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 related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects are incurred. Revenue related to 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 as 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 to which the payments relate. 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 compensation expense—We issue stock-based awards to our employees, Board of Directors, Scientific Advisory Boards and certain contractors as strategic, long-term incentives. Beginning in the first quarter of 2006, we recorded stock-based compensation expense for these awards under 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 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 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. 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 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.

Results of Operations

Three and Nine Month Periods Ended September 30, 2006, and 2005

Revenue.

(in thousands, except percentage)	Three Months Ended September 30, 2006	2005	Change	
Milestone and development revenue	$ 2,597	$ 3,292	$ (695)	(21%)
Government grant and cooperative agreements	4,583	3,519	1,064	30%
Product revenue	794	69	725	1,051%
Total revenue	$ 7,974	$ 6,880	$1,094	16%

Milestone and development revenue from Baxter, BioOne and MedImmune decreased 21% to $2.6 million for the three months ended September 30, 2006, from $3.3 million for the comparable period in 2005. The comparative decrease was due primarily to the absence of revenue from MedImmune during the three months ended September 30, 2006, as a result of the completion of that agreement in early 2006. Milestone and development funding from BioOne, MedImmune, and Baxter was 26%, 0% and 7%, respectively, of total revenue for the three months ended September 30, 2006. Milestone and development revenue from, BioOne, MedImmune, and Baxter was 26%, 13%, 9%, respectively, of total revenue for the three months ended September 30, 2005. We expect to recognize the remaining of $2.1 million of deferred revenue from BioOne on our balance sheet at September 30, 2006, over the remainder of 2006.

Revenue from government grants and cooperative agreements increase 30% to $4.6 million for the three months ended September 30, 2006, from $3.5 million for the comparable period in 2005. The increase was due primarily to the recognition of revenue for research activities performed under an agreement with the Armed Forces, awarded in September 2006, relating to research activities that commenced in January 2006. At September 30, 2006, in excess of $1.9 million in government grant awards were pending. We anticipate the release of these awards in the remainder of 2006 and in 2007.

During the three months ended September 30, 2006, we recognized $0.8 million of product sales revenue from sales of the INTERCEPT Blood System for platelets in Europe. Prior to the February 2006 agreements with Baxter, product revenue represented our share of adjusted gross margins on platelet system sales; subsequent to February 1, 2006, product revenue represents all of the platelet system revenues. These quarterly results may not be indicative of platelet system revenue in the future.

During the three months ended September 30, 2005, we recognized $0.1 million of product sales revenue from our share of gross margins from sales of the INTERCEPT Blood System for platelets in Europe.

We do not expect sales of the platelet system in Europe to be significant at least until the system is approved for sale and reimbursement rates are established in the larger-market European countries. The INTERCEPT Blood System for platelets is currently undergoing validation studies and regulatory reimbursement review in many European countries.

(in thousands, except percentage)	Nine Months Ended September 30, 2006	2005	Change	
Milestone and development revenue	$10,618	$ 8,819	$1,799	20%
Government grant and cooperative agreements	8,764	9,547	(783)	(8%)
Product revenue	2,049	395	1,654	419%
Total revenue	$21,431	$18,761	$2,670	14%

During the nine months ended September 30, 2006, compared to the same period in 2005, total revenues increased $2.7 million, or 14%, to $21.4 million. The increase in revenues was attributable to milestone and development funding from BioOne received during the second half of 2005 and recognized ratably over the estimated remaining development period of the plasma system. At September 30, 2006, we estimated the remaining development period of the plasma system to be three months. In addition, our product sales contributed to the relative increase in 2006, reflecting revenue from the total sales of the platelet system as opposed to the results in 2005, which reflected our 33.5% of gross margins from total platelet system sales. Partially offsetting the 2006 increases in milestone and development and product revenue are reductions in the revenue received from government grants. At September 30, 2006, in excess of $1.9 million in government grant awards are pending. We anticipate the release of these awards in the remainder of 2006 and in 2007.

Cost of Product Revenue.

Prior to the February 2006 agreement with Baxter, we did not record cost of product revenue or gross margins from product sales. Subsequent to the February 1, 2006, effective date of the agreement, our cost of product revenue consisted solely of platelet system inventory sold. Inventory is accounted for on a first-in, first-out basis. These results may not be indicative of future costs of product sales or gross margins.

Research and Development.

(in thousands, except percentage)	Three Months Ended September 30, 2006	2005	Change	
Research and development	$ 7,030	$ 6,626	$404	6%

Research and development expenses include salaries and related expenses for scientific personnel, third-party consultants, licensed technologies, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, pre-clinical safety studies, manufacturing development and other laboratory studies. Beginning on January 1, 2006, our research and development expenses also include non-cash stock-based compensation expense as a result of adopting FAS 123R.

Research and development expenses increased 6% to $7.0 million for the three months ended September 30, 2006, from $6.6 million for the comparable period in 2005. Of the $7.0 million of research and development expense recognized during the three months ended September 30, 2006, $0.3 million was due to non-cash stock-based compensation recognized under FAS 123R. Overall, the increase from the three months ended September 30, 2005 was due primarily to increased development spending related to the red blood cell program and costs resulting from initiation of Phase I clinical trials for the red blood cell system and CRS-100.

Our total research and development costs included $4.0 million for our blood safety programs and $3.0 million for our immunotherapy programs for the three months ended September 30, 2006, and $3.2 million for our blood safety programs and $3.4 million for our immunotherapy programs for the comparable period in 2005.

(in thousands, except percentage)	Nine Months Ended September 30, 2006	2005	Change	
Research and development	$22,069	$17,556	$4,513	26%

Research and development expenses for the nine-month period ended September 30, 2006, increased $4.5 million to $22.1 million from the corresponding period in 2005. Of the $22.1 million in research and development expenses recognized during the nine months ended September 30, 2006, $0.9 million was due to non-cash stock-based compensation recognized under FAS 123R. The increase in research and development expenses was due to increased research and development efforts relating to our red blood cell system and our CRS-100 and CRS-207 cancer immunotherapy programs as well as costs incurred to initiate Phase I clinical trials for the red blood cell system and CRS-100. Our total research and development costs included $12.2 million for our blood safety programs and $9.9 million for our immunotherapy programs for the nine months ended September 30, 2006, and $7.4 million for our blood safety programs and $10.2 million for our immunotherapy programs for the comparable period in 2005.

We anticipate our research and development expenses will continue to increase as we continue clinical development of the red blood cell system and CRS-100 and preclinical development of CRS-207.

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 trial 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.

Selling, General and Administrative.

(in thousands, except percentage)	Three Months Ended September 30, 2006	2005	Change	
Selling, general and administrative	$ 3,273	$ 2,161	$1,112	51%

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

Selling, general and administrative expenses increased 51% to $3.3 million for the three months ended September 30, 2006, from $2.2 million for the comparable 2005 period. Of the $3.3 million of selling, general and administrative expense recognized during the three months ended September 30, 2006, $0.3 million was due to non-cash stock-based compensation recognized under FAS 123R. Overall, the increase from the second quarter of 2005 was principally attributable to costs associated with establishing and building our commercial operations in Europe, as well as increased legal and accounting fees.

(in thousands, except percentage)	Nine Months Ended September 30, 2006	2005	Change	
Selling, general and administrative	$ 10,151	$ 7,198	$2,953	41%

Selling, general and administrative expenses increased to $10.1 million during the nine months ended September 30, 2006, compared to $7.2 million during the corresponding period in 2005. The increase in selling, general and administrative expenses was attributable to expenses associated with establishing and building our commercial operations in Europe, as well as increased legal and accounting fees. Of the $10.1 million in selling, general and administrative expenses incurred during the nine months ended September 30, 2006, $1.1 million related to non-cash stock-based compensation recognized under FAS123R. Our European operations are not yet fully developed and staffed. As such, we anticipate continuing to increase spending in support of commercializing our INTERCEPT Blood Systems in Europe. Baxter is providing us with transition services in Europe under the February 2006 agreements through the end of 2006 on a cost plus basis as we complete building our European commercial capabilities. As we assume those transition activities currently provided by Baxter, we may experience increased costs in the performance of those activities.

Gain on Loan Settlement.

Under an agreement entered into with Baxter in 2005, we repaid $34.5 million and concurrently entered into a promissory note for $4.5 million payable with 8% interest as full satisfaction of a loan obligation during the nine months ending September 30, 2005. As a result of the 2005 agreement, during the nine months ended September 30, 2005, we recorded a non-operating gain of $22.1 million and accrued expenses of $0.8 million. In February 2006, we repaid the $4.5 million promissory note plus the accrued interest. As of September 30, 2006, we have no further loan obligations.

Net Interest Income (Expense) and Other, Net

Net interest income (expense) and other, net was $0.9 million and $3.8 million for the three and nine months ended September 30, 2006, respectively, compared to $0.3 million and $0.9 million during the respective comparable periods in 2005. Net interest income was $1.0 million and $2.1 million for the three and nine months ending September 30, 2006, respectively, and $0.2 million and $0.9 million for the respective comparable periods in 2005. We recognized a non-operating gain of $1.8 million during the nine months ended September 30, 2006, from cash consideration received from Baxter as a result of the February 2006 commercialization transition agreement. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. In March 2006 we completed a public offering of our common stock, which resulted in increased cash balances. We have invested these proceeds in marketable securities pursuant to our investment policy until such time as we have 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, payments received under our agreements with Baxter, BioOne, MedImmune and others, United States government grants and cooperative agreements and interest income. To date, we have not derived a significant amount of capital from product sales, and we will not derive significant capital from product sales unless and until one or more of our products receive regulatory approval and achieve market acceptance.

At September 30, 2006, we had cash, cash equivalents and short-term investments of $69.6 million. Net cash used in operating activities was $14.4 million for the nine months ended September 30, 2006, compared to $11.3 million for the same period in 2005. The increase in net cash used in operating activities was primarily due to changes in our operating assets and liabilities, notably increases in our receivables

and inventory balances offset by declines in our deferred revenue and other assets and increases in our accounts payable and accrued liabilities. The deferred revenues recorded on our balance sheet at September 30, 2006, are being amortized and recognized as revenue over the remaining estimated development periods to which they relate. All of the estimated development periods are expected to be completed by the end of 2006. Net cash provided by investing activities during the nine months ended September 30, 2006, was $12.5 million, primarily due to maturities of short-term investments. Net cash provided by financing activities during the nine months ended September 30, 2006, was $38.7 million, compared to cash used in financing activities of $34.1 million for the same period in 2005. The increase in 2006 compared to 2005 is largely due to the issuance of 5,175,000 shares of common stock in a public offering in March 2006, providing net proceeds of $42.4 million, offset by the repayment of a loan from Baxter Capital of $4.5 million plus accrued interest. During the same period in 2005, we repaid $34.5 million on the note due to Baxter. Working capital increased to $65.2 million at September 30, 2006, from $27.7 million at December 31, 2005, primarily due to the receipt of proceeds from our stock offering and, to a lesser degree, from the gain from the February 2006 commercialization transition agreement with Baxter recognized during the period.

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

Financial Instruments

We maintain an investment portfolio of various issuers, types and maturities. These securities are classified as available-for-sale and, consequently, are recorded on our 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 for the nine months ended September 30, 2006, totaled $0.3 million. Our investments primarily consist of short-term money market mutual funds, United States government obligations and commercial paper. Of our cash, cash equivalents and short-term investments balance of $69.6 million at September 30, 2006, approximately 61% have maturity dates less than 90 days from September 30, 2006, and approximately 8% have maturities of greater than 90 days and less than one year, and approximately 31% have maturities in excess of one year from September 30, 2006. We do not believe our exposure to interest rate risk to be material given the short-term nature of our investment portfolio. Given the investment mix of our portfolio at September 30, 2006, and our anticipated liquidity needs, we currently believe we have the ability and intent to hold our securities to their maturities without recognizing any gains or losses from sales prior to maturity. We do not believe our unrealized losses reflect more than a temporary decline in value of our marketable securities held. The following table illustrates our cash, cash equivalent and short-term investment with maturities relative to September 30, 2006:

(in thousands)

Remaining maturity from September 30, 2006	Market Value
Less than 90 Days	$ 42,566
Greater than 90 days and less than 1 year	$ 5,780
Greater than 1 year	$ 21,245
Total	$ 69,591

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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 September 30, 2006, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2006.

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

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

The settlement will become effective upon the satisfaction of a number of conditions, including, among others, the approval of the settlement by the courts, and the final and non-appealable entry of a judgment by the courts dismissing the class action and derivative lawsuits with prejudice. Under terms of the settlement, we believe that this matter will not have a material effect on our results of operations or financial position; however, we cannot predict when, if ever, the settlement will become effective.

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.

The INTERCEPT Blood System may not achieve broad market acceptance.

Under our previous agreements, Baxter's sales and marketing organization had made only modest progress in commercializing the platelet system in European countries where it has been fully approved for sale. Despite CE mark approval, Baxter 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. Our products may require significant changes to our potential customers' blood component collection methods, space and staffing requirements and require significant capital investment. 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. We have no experience negotiating reimbursement of medical products. In many cases, due to the structure of the blood products industry, we will have little control over reimbursement discussions, which generally occur between blood centers and national or regional ministries of health and private payors. For example, while the platelet system has been approved in France for use by blood centers in treating platelets, commercial adoption has been delayed pending determination of reimbursement rates for pathogen inactivated platelets. We may be required to seek explicit reimbursement in European countries for our plasma system, if and when approved by regulatory authorities, 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. The widespread adoption of managed care in the United States has also placed pressure on the pricing of medical products. These pressures can be expected to continue and may limit the prices we can obtain for our products.

We may be required to reduce the sales price for our products in order to make them economically attractive to our customers and to governmental and private payors, which would reduce and may eliminate our gross profit on sales. At our present low unit sales levels of the platelet system, our costs to manufacture and sell the platelet system are in excess of revenue. We may be unable to increase sales to a level sufficient to generate profit contribution. We believe that future product sales in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even if our products receive regulatory approval and reimbursement is available, failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenue in those geographies. The market for our pathogen inactivation systems in the United States is highly concentrated, dominated by a small number of blood collection organizations. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nation's blood and blood components supply. In Europe, the largest markets for our products are in England, Germany and France. Decisions on product adoption in England are centralized with the National Blood Service, where general cost containment pressures have delayed consideration of the INTERCEPT Blood System to date. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a blood center-by-blood center basis, but depend on both local and centralized regulatory approvals. While the platelet system has received in-country regulatory approval in France, adoption has been delayed in the absence of national reimbursement rates for pathogen inactivated platelets. 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, an advisory committee convened by and reporting to the FDA. 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 of the National Institutes of Health, 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. The failure to comply with these requirements could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result in enforcement action, which could harm our business. Gaining FDA approval for our platelet and plasma products would require additional investment and time, because the current manufacturing sites we rely upon for producing the platelet and plasma system products for European distribution are not FDA-qualified facilities. Regulatory authorities may also require post-marketing testing, which can involve significant expense. Governments or regulatory authorities may impose new regulations or other changes that could further delay or preclude regulatory approval of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

Distribution of our products outside the United States also is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. We will be required to obtain a CE mark extension from European Union regulators for our platelet system, originally obtained by Baxter in 2002, by May 2007. In addition to European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries, including France, Germany and England, to market our products. In addition, our customers in many countries must obtain regulatory approval to sell blood components treated with the INTERCEPT Blood System. The level of additional product testing varies by country, but could take a long time to complete. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in lost product sales and profitability.

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

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

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

Preclinical testing and clinical trials involving our immunotherapy product candidates are long, expensive and uncertain processes. We have only recently begun Phase I human clinical testing of our *Listeria* platform technology and we have not yet begun testing of our KBMA

platform technology in humans. Preclinical results in animals and *in vitro* testing we have conducted to date with our two

immunotherapy platform technologies may not translate to demonstration of safety and efficacy in human clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advancing stages of clinical trials, even after promising results in earlier preclinical and clinical trials. In addition, regulators and investigators may impose more stringent, time consuming and expensive clinical trial requirements than we might otherwise choose to pursue as a precondition to proceeding with clinical testing. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process.

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

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

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

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

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

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

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

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 Phase III clinical trial to evaluate the hemostatic efficacy and safety of the platelet system, using the Company's final commercial product design, as compared to conventional platelets. We also understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the apparent differences observed in that trial between the treatment groups in the category of pulmonary adverse events, and that data on such events would need to be gathered in the additional Phase III trial. The additional Phase III clinical trial would need to be completed and data from the trial submitted to the FDA before we could complete our regulatory submission. The FDA may not find the data from any additional clinical trials to be acceptable for approval. Before we begin an additional clinical trial, we will need to gain concurrence with the FDA on our trial design. We may not be able to reach concurrence on the size, scope or design of the study.

We have completed Phase IIIa, Phase IIIb and Phase IIIc clinical trials of the plasma system, in the United States, reports for which were filed with the FDA during 2005. A CE mark application for regulatory approval in Europe of the plasma system was submitted in December 2005. 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 antibodies in two patients, we have been conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce the potential for antibody reactivity to treated red blood cells. Based upon an internal evaluation of the results to date from these additional research activities and after consulting with regulatory authorities, we initiated a new Phase I trial in 2006 in the United States using a modified red blood cell system before potentially progressing to later-stage clinical trials. We are utilizing a manual processing system in the Phase I trial, which system is not in a commercially feasible form. A number of trial design, process and product design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials and while those clinical trials are being conducted, including determining the appropriate design of subsequent Phase II clinical trials, if deemed necessary, and Phase III clinical trials, and developing a commercially feasible red blood cell system, including disposables, hardware and software for implementing the process in blood collection centers. These development initiatives may be costly and time consuming. Even if the project proceeds on course, we would not expect to initiate a Phase III trial for our red blood cell system prior to late 2008. A delay in completing such activities could result in a delay in the timely progression to later stage trials. If we are unsuccessful in advancing a modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system program.

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. 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.

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

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

Upon reaching agreements with Baxter in February 2006, we became fully responsible for sales, marketing and distribution support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. As a consequence, we will no longer be able to rely upon Baxter for sales, marketing and distribution support of the INTERCEPT Blood System. Further, the February 2006 agreements require that Baxter will provide regulatory support for the INTERCEPT Blood System only through the end of 2006, after which time we can no longer rely on such support from Baxter. We have been particularly dependent on Baxter in Europe, where the platelet system has been approved for sale in certain countries. While the most recent agreements with Baxter call for a transition period through the remainder of 2006, during which time Baxter will make available, generally at our expense, certain human and organizational resources on an as needed basis, we will need to develop internal competencies in sales, marketing, distribution and regulatory support or arrange for third parties to provide certain of these necessary services by the end of 2006. If we fail to develop such internal competencies or establish acceptable relationships with third parties on a timely basis, our efforts to commercialize the INTERCEPT Blood System may be irreparably harmed.

- *We must develop marketing, sales, distribution, customer service and back office functions necessary to support commercialization of the INTERCEPT Blood System in Europe* . Historically, we have had a small scientific affairs group that has helped support Baxter's European sales and marketing organization; however, we did not maintain our own independent

sales and marketing organization. We may be unable to maintain existing customer relationships established by Baxter as we take on responsibility for sales, marketing and customer service. Beginning in early 2006, we began to recruit a small European organization dedicated primarily to selling and marketing the platelet system and, if approved, the plasma system, in Europe. We may be unable to recruit suitable sales, marketing, regulatory, quality and back office personnel on a timely basis, if at all. As we reduce our operational reliance on Baxter, we will also need to develop 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 affordable basis. In addition to adding sales and marketing capabilities, we will need 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 must 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 the subsidiary is fully staffed. Developing sales, marketing and operational capabilities ourselves will increase our costs and may delay commercialization of our pathogen inactivation systems.

- *We must develop regulatory capabilities for clinical-stage and Phase IV trials involving the INTERCEPT Blood System globally.* Under 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 remains as the registrant or applicant under European registrations and applications for a transition period in 2006. We do not currently have the appropriate resources or in-depth experience to support regulatory activities and post-approval trials relating to these products. We do not have adequate internal resources and capabilities to manage Phase IV and post-approval trials and to respond appropriately to possible customer complaints or required regulatory reporting of adverse events arising from the use of the platelet system. We will need to increase our regulatory and trial management resources or contract with independent regulatory consultants, which we may be unable to do on a timely basis. Adding regulatory and trial management resources will result in increased costs and may potentially delay regulatory filings. Delays or inabilities to complete regulatory filings and obtain approvals will also delay or prevent us from earning milestone payments from BioOne, and from being able to recognize sales of our products and attaining profitability. Our agreements with Baxter require that Baxter transfer to us European regulatory registrations for the platelet system and European regulatory applications for the plasma system once we have obtained necessary regulatory certification of our company-wide quality systems. An audit of our quality systems by European regulators and a corresponding audit of Baxter's quality systems, in its capacity as a contract manufacturer of the INTERCEPT Blood System, are prerequisites to such regulatory certification. Any delay in obtaining such certification would result in a delay in transferring regulatory registrations for the platelet system and obtaining regulatory approval of the plasma system in Europe and may have other adverse consequences. There may be unforeseen adverse consequences in making this transition if regulatory agencies view the change negatively, which in turn may lead to potential delays in approvals.

We will continue to rely on Baxter for manufacturing and supplying components of our platelet and plasma systems for a limited period of time. We are also relying on Baxter to complete certain development activities relating to the plasma system. Over a longer period, we will need to identify, select and qualify third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system.

- *We rely on third parties for manufacturing and supplying components of our platelet and plasma systems.* Under the terms of our agreements, Baxter is currently responsible for manufacturing and supplying illuminators and disposable kits associated with the platelet and plasma systems for commercial use through 2008 and certain components of the platelet and plasma systems through 2009. We will also be dependent on Baxter to transfer know-how relevant to the INTERCEPT Blood System; however, certain of Baxter's materials, manufacturing processes and methods are proprietary to Baxter. We may be unable to establish alternate sources of supply to Baxter without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review, which would delay our ability to commercialize the platelet and plasma systems. If Baxter fails to manufacture an adequate supply of components or devices within quality specifications, we will be required to seek alternate sources of supply from other component manufacturers. Under the terms of our agreements, Baxter has committed to conduct certain development activities for the plasma system that are necessary for CE mark approval of the disposable set and CE mark self-declaration for the UVA illuminator. If such activities are not completed in a timely manner, our CE mark submission and self-declaration for the plasma system will be delayed. However, Baxter is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System beyond 2006. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Any delay in the availability of devices or components from Baxter could delay further regulatory approvals, market introduction and subsequent sales of the systems. Moreover, the inclusion of components manufactured by others could require us to seek new approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. Baxter manufactures our platelet and plasma systems and only limited components for our red blood cell system in facilities that are not FDA-approved. Our agreements do not require Baxter to validate these manufacturing facilities with the FDA. In order to be sold in the United States, our systems would be required to be manufactured in an FDA-approved facility. FDA validation of a manufacturing facility, whether owned by Baxter or by another party, will be costly and time-consuming.

- *Baxter has entered into a definitive agreement to sell its Transfusion Therapies business unit and, under that agreement, will assign portions of its obligations within the agreements with us to third parties* . On October 3, 2006, Baxter announced that it had entered into a definitive agreement to sell its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to an investment group led by Texas Pacific Group. Subject to regulatory approvals and other customary closing conditions, Baxter and Texas Pacific Group expect to close the transaction by the first quarter of 2007. While the assignment provision of our February 2006 agreement with Baxter provides that Baxter may assign its obligations under our agreement to an assignee that is capable of performing Baxter's obligations, the Transfusion Therapies business unit under new ownership may fail to manufacture an adequate supply of components or devices of the INTERCEPT Blood System, which would subject us to the risks described above. Certain components of the INTERCEPT Blood System are currently manufactured or assembled at facilities not within the Transfusion Therapies business unit. Baxter will continue to be obligated to supply illuminators and disposable kits associated with the platelet and plasma systems to us generally through 2008 and for certain components through 2009. Baxter may fail to manufacture or supply an adequate supply of components or devices of the INTERCEPT Blood System, which would subject us to the risks described above. In addition, because the components of the INTERCEPT Blood System are manufactured and assembled at multiple facilities owned by both Baxter and the Transfusion Therapies business unit leading up to final assembly, Baxter and the Transfusion Therapies business unit under new ownership will remain interdependent with respect to the INTERCEPT Blood System supply chain. Baxter and the Transfusion Therapies business unit under new ownership may fail to coordinate or meet interdependent supply chain obligations, leading to a shared 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. All references to "Baxter" in these Risk Factors should be read, as to future contingencies, to include any assignee of Baxter's obligations under our agreements.
- *We will be required to identify and enter into agreements with third parties to manufacture the INTERCEPT Blood System products and related blood component storage solutions.* Baxter's manufacturing responsibilities for illuminators and disposable kits associated with the platelet and plasma systems in general extend through 2008 and for certain components of the platelet and plasma systems through 2009, after which we will assume manufacturing responsibilities. Except for very limited manufacturing of disposable components, Baxter is no longer obligated to provide manufacturing services related to the red blood cell system. We will need to identify parties to provide those manufacturing services related to our red blood cell system at all. It may be difficult to enter into these types of agreements on reasonable terms. In particular, it will be time-consuming for other manufacturers to develop the capability to manufacture the INTERCEPT Blood System products and blood component storage solutions economically and to gain regulatory approval to do so for commercial use. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to commercialize our products.
- *Our potential remedies against Baxter may be inadequate in assuring that Baxter meets its contractual obligations.* In the event of a failure by Baxter to perform its obligations to supply components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Our supply agreement with Baxter contains limitations on incidental and consequential damages that we may recover. Baxter's potential liability in the event of non-performance may not be sufficient to compel Baxter to continue to act in conformity with our agreements.

The platelet system is not compatible with platelet collection methods and platforms and platelet storage solutions manufactured by others.

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

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

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

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

efforts for its apheresis collection system in Japan. Under an agreement with Haemonetics Corporation, or Haemonetics, Baxter has agreed to provide Haemonetics with Intersol, with the objective that platelets collected on certain Haemonetics apheresis collection equipment may be directly treated using our platelet system. Making the Haemonetics apheresis collection system readily compatible with our platelet system will require certain changes in the Haemonetics device, and there can be no assurance that Haemonetics will undertake this effort on a timely basis or be commercially successful. Gambro, Inc., or Gambro, another major supplier of automated platelet collection systems, is conducting clinical trials of its own system for pathogen inactivation of platelets. For competitive reasons, Gambro may have little or no incentive to make its apheresis collection system compatible with our platelet system. Attaining compatibility with collection platforms and platelet storage solutions 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 in the United States and other countries 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 only been manufactured on a commercial scale on a limited basis. Baxter is responsible for manufacturing and assembling our platelet and plasma systems and Intersol products through 2008 and certain components of the platelet and plasma systems through 2009. Baxter relies on third parties to manufacture and assemble some of the system components, many of which are customized and have not been manufactured on a commercial scale. Baxter has produced some pathogen inactivation systems in modest commercial quantities, but may not be able to manufacture and assemble other systems or in larger quantities, or do so economically. Because of low sales volumes and other reasons, Baxter's costs to manufacture commercial components for the platelet system have been greater than we previously anticipated and may continue to rise. This may reduce our potential gross profit margin from European platelet and potential plasma system sales. We may be unable to contract with third parties to manufacture the INTERCEPT Blood System 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 Baxter or third-party manufacturers fail to produce our products or Intersol products satisfactorily, at acceptable costs and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations. In the United States, studies related to the platelet system disposable and compound manufacturing need to be completed and included in FDA submissions before the FDA would consider the applications for approval.

Baxter purchases certain key components of the INTERCEPT Blood System from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. It would be expensive and time-consuming to establish additional or replacement suppliers for these components. Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require Baxter or us to identify and qualify replacement components and may require that we conduct additional studies, which could include clinical trials, to validate required design or component changes. If we were required to redesign the products, our development costs would increase, and our programs 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 additional commercial manufacturer will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that its commercial scale manufacturing processes comply with government regulations. It may be difficult or impossible to economically manufacture our products on a commercial scale.

We will continue to rely on Baxter for transition services. Over a longer period, 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 is required to provide certain transition services relating to European activities, at our expense. These services include specified regulatory and clinical support activities, installation, maintenance and calibration services, and order entry, billing and collections from customers, monitoring and responding to customer complaints, and clinical education and training until December 31, 2006, and manufacturing technical information and advice until December 31, 2008. During the transition period to date, we have not received adequate information regarding Baxter's collection of accounts receivable from customers on our behalf. If Baxter fails to collect receivables from customers prior to the end of 2006, we may have difficulty collecting those receivables thereafter. Baxter is also obligated to supply supplemental transition services upon our request, also at our expense. If Baxter fails to provide these 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 in the United States and have not completed the components' commercial design.

The system disposables and instruments we used in many of 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 Blood System on schedule, our potential revenue would be delayed or diminished and our competitors may be able to bring products to market before we do.

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

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

Baxter and we have licensed rights to commercialization of the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore to BioOne. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in those countries. We understand that Baxter is not intending to maintain its CE mark registration for the platelet system after which time regulatory responsibility will have passed to us. In addition, we have applied for CE mark approval of the plasma system independently from Baxter, and Baxter is not intending to apply for a CE mark for the plasma system. However, BioOne is dependent on Baxter for the manufacture and supply of the platelet and plasma systems well beyond the time when Baxter intends to let its CE mark registration for the platelet system lapse. BioOne is also dependent on Baxter for providing certain regulatory support and the timely transition of regulatory files and dossiers. BioOne may be unable to qualify the platelet and plasma systems for sale in certain countries in its territory in the absence of CE marks being held by Baxter. 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 it is considered for approval in Japan, which would delay or prevent BioOne from achieving significant product sales. 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 is contractually obligated to pay us a milestone payment of cash and equity upon our receipt of CE mark approval for the plasma system in Europe. If BioOne does not pay us the milestone on a timely basis, rights to the plasma system in BioOne's territories would revert to us. A return of our rights to the plasma system in the BioOne territories would likely depress the value of BioOne's equity 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. 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. We have filed an IND for our first vaccine candidate, CRS-100, and have obtained clearance from FDA to proceed with a Phase I, dose-escalation clinical trial. We have received approval from the institutional review boards, or IRB's, at participating clinical sites, which is a predicate to enrolling subjects in the Phase I trial, and clinical investigators are in the process of enrolling eligible patients in the clinical trial. These investigators may encounter difficulties in enrolling suitable patients in our trials, which may contribute to delays and increased costs in completing the 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 effect our ability to develop and test these other product candidates in human clinical trials. Our Phase I clinical trial for CRS-100 involves testing in a patient population with advanced disease. We may be unable to test CRS-100 and our other product candidates in subsequent trials in patient populations that we believe may be better suited clinically or commercially to our vaccines.

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

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

The development and commercialization of product candidates employing our *Listeria* and KBMA platform technologies will be expensive, lengthy and uncertain. To date, we have relied not only upon internal scientific, development and financial resources, but also upon third parties. We have licensed our *Listeria* platform to MedImmune for use in developing a product candidate potentially applicable to cancers expressing EphA2, a proprietary antigen owned by MedImmune. We are collaborating with investigators at Johns Hopkins University on other cancer and infectious disease programs. We also rely on advice and insights from our scientific advisory board, a group of independent clinicians, professors and investigators, regarding our research and development activities. These relationships provide us with external perspectives and independent validation that may be critical to our future success. Loss of these relationships or failure to attract others may result in additional expense, delays in development and regulatory approval and failure to commercialize products. We have received significant funding from United States government agencies for research and development in both cancer and infectious disease, as well as funding from MedImmune under our license agreement relating to development of MEDI-543 (EphA2). 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. 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. Loss of funding from government sources and third parties would require us to reduce the scope of our research and development efforts in immunotherapeutics, narrowing the number of programs to those we could support through internal resources.

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

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

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

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

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

The significant majority of our operations are at a single site that is subject to lengthy business interruption in the event of a severe earthquake.

The significant majority of our facilities are in Concord, California and 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 activities in support of our 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 general and administrative expenses have resulted in substantial losses each year since our inception, including net losses of $58.3 million in 2003, $31.2 million in 2004. However, in 2005, we realized a $22.1 million nonrecurring gain associated with the restructuring of a loan payable. As a result of this gain, we recorded net income of $13.1 million in 2005. At September 30, 2006, we had an accumulated deficit of approximately $314.4 million. Except for the platelet system, which has received European CE mark approval, all of our products are in the research and development stage, and we have not received significant revenue from product sales. We have received substantially all of our revenue from our agreements with our development partners and from federal research grants and cooperative agreements. We will be required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. We expect our losses to continue at least until more of our product candidates are commercialized and achieve significant market acceptance.

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

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

As of September 30, 2006, we had been awarded $36.5 million in funding under cooperative agreements with the Department of Defense, and 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 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.

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, 2003 to September 30, 2006, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of $1.60 to a high of $21.75. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

- biological or medical discoveries;
- technological innovations or new commercial services by us or our competitors;
- developments concerning proprietary rights, including patents and litigation matters;
- regulatory developments in both the United States and foreign countries;
- status of development partnerships;

- dilution from future issuances of common stock;

- public concern as to the safety of new technologies;
- general market conditions;
- comments made by analysts, including changes in analysts' estimates of our financial performance; and
- quarterly fluctuations in our revenue and financial results.

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

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

We and certain of our current and former officers and directors are named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Northern District of California. The lawsuit is brought on behalf of a purported class of purchasers of our securities, and seeks unspecified damages. In addition, our directors and certain of our current and former officers have been named as defendants in a derivative lawsuit in the Superior Court for the County of Contra Costa, California, which names Cerus as a nominal defendant. The plaintiff in this action is a Cerus stockholder who seeks to bring derivative claims on behalf of Cerus against the defendants. The lawsuit alleges breaches of fiduciary duty and related claims. On August 31, 2006, we announced that we had reached agreements to settle the outstanding class action and derivative lawsuits. Pursuant to the terms of the settlement agreements, the plaintiffs agreed to provide the defendants with a release of all claims related to such class action and derivative lawsuits without any admission of wrongdoing or liability by any party. Under these settlement agreements, the total cash settlements will be funded entirely by insurance carriers under our directors' and officers' liability insurance policy and will have no financial impact on Cerus.

The settlement shall become effective upon the satisfaction of a number of conditions, including, among others, the approval of the settlement by the courts, and the final and non-appealable entry of a judgment by the courts dismissing the class action and derivative lawsuits with prejudice. We cannot predict when, if ever, the settlement will become effective. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation or likelihood that the proposed settlement will become effective. If the settlements do not become effective, we may have to incur substantial expenses in connection with these lawsuits and in the event of an adverse outcome, our business could be harmed.

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

(a) Exhibits

3.1.1(1)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2(2)	Bylaws of Cerus.
4.2(2)	Specimen Stock Certificate.
10.19+	Supply Agreement, dated July 18, 1994.
10.20 +	Custom Synthesis Agreement, dated March 14, 1996.
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.

+ Confidential treatment requested for certain portions of this exhibit.

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be 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.

(1) Incorporated by reference to Cerus' Current Report on Form 8-K, dated November 3, 1999.

(2) Incorporated by reference to Cerus' Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.

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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.

CERUS CORPORATION

Date: October 31, 2006

/s/ William J. Dawson
William J. Dawson
Chief Financial Officer
(Principal Financial and Accounting Officer)

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Exhibit Index

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SUPPLY AGREEMENT FOR STERITECH COMPOUND [*]

Agreement, effective as of July 18, 1994, by and between **[*]**, and **STERITECH, INC.**, a California corporation with offices at 2525 Stanwell Drive, Concord, California 94520 (**"Steritech"**).

WITNESSETH:

WHEREAS, Steritech is the owner of certain intellectual property rights respecting, and engages in certain research regarding the uses of, the compound designated **[*] (** the **"** Compound **"**); and

WHEREAS, [*] is able to synthesize and supply the Compound, manufactured in accordance with current U.S. Good Manufacturing Practices (**"** GMP **"**) standards and meeting Food and Drug Administration (**"** FDA **"**) quality standards;

NOW, THEREFORE, in consideration of the mutual covenants herein contained, the parties hereby agree as follows:

1. Promptly upon mutual agreement regarding amount of Compound to be manufactured as set forth in a requisition (sample shown in Exhibit A), **[*]** shall commence, and thereafter, as expeditiously as possible, shall proceed with the synthesis of Compound and shall deliver the completed Compound, meeting the analytical specifications defined in Exhibit B, to Steritech within a maximum time of ninety (90) days from date of requisition. **[*]** also agrees to deliver to Steritech all batch records and analytical data confirming conformance to specifications for each raw material, isolated intermediate and final product. The first requisition shall be for a minimum of ten (10) kilograms of Compound and future requisitioned amounts shall be within the limits of **[*]** present manufacturing capacity.

2. In consideration of the supply by **[*]** of the Compound as provided in this Agreement, Steritech agrees that it shall pay to **[*]** the amount agreed upon in writing at the time of the request to manufacture. Such payment shall be made by Steritech upon final delivery by **[*]** of the Compound conforming to agreed upon specifications and all test and batch records relating to its preparation. Steritech agrees to pay **[*]** sixty thousand dollars ($60,000) for the first requisitioned material and future costs shall be commensurate allowing for mutually agreed upon changes in process parameters.

3. In connection with the performance of this Agreement, **[*]** shall:

a. Purchase, test and release raw materials and intermediates as defined in specifications agreed upon by both parties. Raw materials shall conform to American Chemical Society (ACS), United States Pharmacopoeia / National Formulary (USP/NF) or European Pharmacopoeia (EP) specifications. Any exceptions to these specifications are shown in Exhibit C of this contract. All isolated intermediates as well as the Compound shall be analyzed at each step by **[*]** to adequately identify, characterize and assess purity of materials per attributes,

limits and test methods specified by Steritech. Such test methods may include spectral and/or chromatographic characterization and elemental analysis in conformance with stringent elemental analyses established by the Journal of Medicinal Chemistry or equivalent when requested by Steritech.

b. Prepare data sheets, spectral/chromatographic sheets, and description of preparative methods for all materials. **[*]** shall utilize a data sheet format that conforms to the requirements for a Batch Production Record as described in Part 211 of Title 21 of the Code of Federal Regulations. Further, Steritech reserves the right to review and approve all such records prior to their use in the production of intermediates or bulk drug substances. The preparative methods shall be sufficiently detailed for filing with the FDA as bulk manufacturing processes. This includes details of sources, purities and lot numbers of all raw materials and solvents used, their quantities, and detailed methodology of isolation and/or purification procedures.

c. Retain samples of Compound for one year after manufacture. Samples of this material will be made available to Steritech upon request.

d. Analyze Compound by test methods agreed upon by both parties that conform to USP or EP methods. Upon Steritech's request and approval, samples of Compound shall be made available to a third party for analytical testing.

e. Provide Steritech with a copy of each data sheet or Batch Production Record and all pertinent analytical data for its review and approval prior to delivery of each batch of Compound.

f. Provide evidence of the use of validated cleaning methods for equipment as per present manufacturing standards.

4. [*] shall also provide Steritech with samples of specified intermediates defined in the requisition (Exhibit A) for monitoring purposes only. Results obtained by such studies will have no effect on the acceptance and approval by Steritech of the final Compound.

5. [*] shall comply with all Government health and safety regulations:

a. FDA: **[*]** shall be registered with the FDA as a manufacturer of bulk drug substances. **[*]** shall inform Steritech of any facilities inspection or any other FDA action relative to the continued approval of its facilities by FDA for the manufacture of bulk drug substances and shall supply a copy of any FDA Form 483 or any other regulatory compliance letter or notice issued by the FDA to **[*]** during the term of this contract. Facilities shall meet FDA standards in accordance with the current Good Manufacturing Practices (cGMP). If during the course of the contract FDA inspections cite deficiencies which, in the opinion of Steritech, are judged to compromise the purity and/or quality of materials to be delivered, Steritech will have the right, by written notice to **[*]** and without incurring liability, to terminate the contract, without limitation of any other rights or remedies. An FDA facilities Drug Master File is available and on file with the FDA and is updated annually as required by FDA regulations.

b. Occupational Safety and Health Administration (OSHA): **[*]** shall comply with OSHA regulations.

c. Environmental Protection Agency (EPA): **[*]** shall comply with EPA regulations regarding the discharge of water and air pollutants and for assuring that disposal of all chemicals residues meet current EPA regulations.

d. Good laboratory safety controls and procedures shall be followed by **[*]** in carrying out the activities for this project.

6. In connection with the performance of the Agreement, Steritech shall:

a. Furnish reference samples needed for the required analyses.

b. Retain samples of the Compound for internal use and to support a Compound Drug Master File and Steritech's Investigational New Drug (IND) application.

c. Approve all specifications and production records prior to manufacture of the Compound.

7. Upon approval by Steritech, materials prepared shall be shipped as directed by Steritech. Containers shall be previously approved by Steritech. Batch records and required test samples must be received and approved prior to acceptance of the bulk shipment. Compound that does not meet the agreed upon specifications shall not be accepted under this agreement.

8. Steritech reserves the right to inspect **[*]** facilities, equipment, and controls for the manufacture of Steritech's compounds at dates and times that are mutually acceptable. Steritech also reserves the right to delegate such inspections to qualified third party auditors of its choosing as long as such auditors are bound by the same confidentiality agreement currently in effect between the two parties.

9. [*] further consents to the review by Steritech of **[*]** Master File for the Compound and the facility's Drug Master File. If requested by Steritech, **[*]** will provide such additional form of consent or authorization as the FDA may require in connection with such review. Steritech may include this Agreement and/or such additional form in Steritech's IND application.

10. This agreement shall apply to all requisitions of the Compound within three (3) years of the signing of this agreement unless superseded by a mutually agreed upon in subsequent agreement. This agreement does not obligate Steritech to request or pay for a specified number of batches or quantity of the Compound. Recognizing that a timely supply of Compound is critical to the ability of Steritech to proceed in its business, **[*]** shall give ninety (90) days notice in writing if it does not intend to accept one or several future requests for Compound under the terms of this agreement.

11. The Nondisclosure Agreement dated April 13, 1993 between the parties shall be deemed incorporated herein by reference and apply to all information disclosed by Steritech to **[*]**

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and all information generated hereunder. The chemicals prepared or handled under this contract shall be regarded as proprietary in nature. Under no circumstances shall chemicals or any information associated with these chemicals be released or divulged without prior approval of Steritech.

12. [*] will make prompt written disclosure to Steritech, will hold in trust for the sole right and benefit of Steritech, and hereby assigns to Steritech all right, title and interest in and to any inventions, developments, improvements or trade secrets, including without limitation optimized procedures, which **[*]** its employees or agents may solely or jointly conceive or reduce to practice, in the course of or as a result of the work hereunder concerning the Compound (including without limitation processes associated with its manufacture). **[*]** will assist Steritech in every proper way to obtain and enforce United States and foreign proprietary rights relating to any and all inventions, development, improvements or trade secrets of Steritech in any and all countries. To that end **[*]** will execute, verify and deliver such documents and perform such other acts (including appearing as a witness) Steritech may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such proprietary rights and the assignment thereof. In addition, **[*]** will execute, verify and deliver assignments of such proprietary rights to Steritech or its designee. Steritech shall compensate **[*]** at a reasonable rate for the time actually spent by **[*]** at Steritech's request on such assistance. In the event Steritech is unable for any reason, after reasonable effort, to secure **[*]** signature on any document needed in connection with the actions specified in the preceding paragraph, **[*]** hereby irrevocably designates and appoints Steritech and its duly authorized officers and agents as its agent and attorney-in-fact, to act for and in its behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by **[*]**

13. If any provision or clause of this Agreement, or portion thereof, shall for any reason be held to be invalid, illegal or unenforceable, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such provision or clause, or portion thereof, had never been contained in this Agreement, and there shall be deemed substituted therefor such other provision or clause, or portion thereof, as will most nearly accomplish the intent of the parties as expressed in this Agreement to the fullest extent permitted by law.

14. This Agreement shall be governed by and construed and enforced under the internal laws of the State of California (and not its principles of conflicts of law). The parties consent and submit to the jurisdiction of the courts of the State of California and of the United States for a judicial district within the territorial limits of the State of California for all purposes with respect to any action or proceeding in connection with this Agreement.

I N W ITNESS W HEREOF , the parties have caused this Agreement to be duly executed and delivered by their respective authorized representatives as of the effective date first above written.

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S TERITECH , I NC .	**[*]**
By: /s/ Stephen Isaacs	By: **[*]**
Name (Print): Stephen Isaacs	Name (Print): **[*]**
Title (Print): President/CEO	Title (Print): President
Date: July 22, 1994	Date: July 21, 1994

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EXHIBIT A

PAGE NO.	P.O. No.	ORDER DATE	VEND.
1	1695	7/15/94	

STERITECH, INC.
2525 Stanwell Dr., Suite 300
Concord, CA 94520
510-603-9071 FAX 510-603-9099

PURCHASE ORDER

V E N D O R **[*]**

S H I P T O **[*]**

ORDER DATE	CANCELLATION DATE	SHIP VIA	F.O.B.	TERMS
7/15/94		to be determined		Net 30 days

RESALE NO. / ITEM NO. / MFG. NO.	RESPONSIBILITY DESCRIPTION	REG. DATE / LOCATION	QUANTITY ORDERED	BRANCH QUANTITY BACK ORD.	QTY REC.	UNIT PRICE	EXTENSION
[*]	**[*] * [*]**		10 Kg			$60,000	

To be delivered to Steritech by Sept. 16, 1994.

Shipping requirements: Send 10g to Steritech plus one gram (1g) from each additional container. Upon approval, send rest of order to **[*]** unless specified otherwise.

Intermediates requested: Send to Steritech samples 1g of **[*] [*] [*]** and **[*]** prepared and used for the manufacture of this lot of **[*]**

* As per agreement signed July 18, 1994. “Supply Agreement for Steritech Compound **[*]**

SUBTOTAL	**$60,000**
PURCHASE ORDER NO.	**1695**
TOTAL ORDER VALUE	

AUTHORIZED SIGNATURE

ORDER TERMS AND CONDITIONS

1. **INVOICES must bear exact same prices and terms or authorization for changes must be received from our company in writing prior to shipping.**
2. **Goods not in accordance with specifications will be rejected and held at vendor’s risk awaiting disposal. Vendor must pay freight on all rejected material.**
3. **The right is reserved, to cancel all or part of this order if not delivered within the time specified.**
4. **Packing slips must accompany all shipments.**
5. **By acceptance of this order, vendor warrants that all merchandise shipped under this order does comply with all laws and regulations of Federal and State governments.**
6. **Back orders must be prepaid when less than a minimum freight shipment.**
7. **In the event of interruption of our business in whole or in part by reason of fire, flood, windstorm, earthquake, war, strike, embargo, acts of God, governmental action, or any causes beyond our control, we shall have the option of canceling undelivered orders in whole or part.**
8. **Acceptance of the purchase order, or shipment of any part of it will constitute an agreement to all of its specifications as to terms, delivery and prices.**

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EXHIBIT B

Specifications for [*]
[*] [*]

I.	**Identity**		
	A.	**IR spectrum**	spectrum compares with reference
	B.	**NMR**	spectrum compares with reference
			[*]
II.	**Purity**		
	A.	**HPLC**	**[*]** of reference standard by peak area
			[*]
	B.	**Loss on Drying**	**[*]** by weight

For documentation purposes only, the following other analyses of purity shall also be completed:

Elemental Analysis	Analysis shall be **[*]**
NMR	Analysis shall be **[*]**
HPLC	Analysis shall be **[*]**

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EXHIBIT C

Raw materials to be used in the manufacture of Steritech's **[*] [*] [*]** that do not conform to ACS, USP/NF or EP specifications for these reagents, or such specifications are not available:

[*] Part Number and Effective date	**Description and Vendor Information**
[*] 22 Feb 93	**[*]** Vendor: **[*]**
[*] 28 Mar 94	**[*]** Vendor: **[*]** (cat. no. **[*]**)
[*] 8 Feb 94	**[*]** Vendor: **[*]** (cat. no. **[*]** or equivalent)
[*] 8 Feb 94	**[*]** Vendor: **[*]** (cat. no. **[*]** or equivalent)
[*] 18 Feb 94	**[*]** Vendor: **[*]** (cat. no. **[*]** or equivalent)
[*] 7 Mar 94	**[*]** Vendor: **[*]** (cat. no. N/A), **[*]** (cat. no. **[*]** or equivalent)
[*] 8 Feb 94	**[*]** Vendor: **[*]** (cat. no. N/A)

All other raw materials used in this manufacturing process are of ACS, USP/NF or EP Grade.

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[*] **[*]**

CUSTOM SYNTHESIS AGREEMENT

CUSTOMER	Steritech, Concord, USA.
PROCESS	Production of S-59.

The following are the general terms and conditions covering the above conversion:

1. All work is undertaken under Confidentiality Agreement.

2. All work will be carried out in accordance with GMP.

3. Except as expressly stated process details will be supplied by Steritech and **[*]** do not guarantee yields or quality of product produced save to the extent that yields or quality are substantially affected by the negligence or willful misconduct or **[*]** personnel.

4. The project supervisors who are authorised to contract the work and to whom all reports should be furnished are:

Steritech : Dr. Susan Wollowitz
[*] : **[*]**

5. Written reports will be furnished to Steritech in a manner and timescale agreed between the project supervisors.

6. **[*]** will undertake to:

a. convert two batches of a minimum of 15 kgs each of **[*]** to S-59 in a campaign using a combination of our multi-purpose glass lined plant and out **[*]** pilot plant,

b. provide analytical support for the production campaign at **[*]**

c. isolate and handle the final product in a controlled environment,

d. clean down the plant after the second batch of S-59 and after each recrystallisation.

7. Steritech are responsible for supplying 30 kgs or **[*]** of the required quality to **[*]** before 1 April 1996. The minimum batch size which can be processed by **[*]** is 15kgs of **[*]** per batch. Should the campaign not take place due to non availability or non suitability of starting material at the reserved time and **[*]** is unable to fill the production slot, Steritech will be responsible for the charges under this proposal.

8. Steritech, by virtue of contracting this work, will own all intellectual property generated directly from the work and **[*]** will co-operate in any reasonable manner in transferring the intellectual property to Steritech. **[*]** will charge Steritech at standard rates for all time expended on this work.

[*] **[*]**

9. **[*]** will carry out the testing of the final product in accordance with TS295 (copy appended)

10. The costs for the work to be undertaken under this project will be as follows:

10.1 Conversion Cost IR£98,500

10.2 Chemist Time

Any development work requested will be charged at the following rates:

Senior Chemist	**[*]** per week
Development Chemist	**[*]** per week

10.3 Materials and Other

Materials and outside analytical services, which will only be contracted from **[*]** approved vendors, will be charged at cost to **[*]** plus 10% to cover administration. Any other out of pocket expenses will be charged at cost

10.4 Invoicing

Work will only be undertaken on receipt of a written purchase order from Steritech. Invoices will be raised at the end of the production campaign and will be due for payment within 30 days from date of invoice by way of transfer of funds to a bank account nominated on the invoice. Charges will be supported by appropriate documentation which will be available on request for inspection at **[*]** premises.

/s/ **[*]**
[*]
Finance Director

Accepted for and on behalf of Steritech Inc.:

/s/ Stephen Isaacs	Stephen Isaacs	3/14/96
Signature	Print Name	Date

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Exhibit 31.1

CERTIFICATION

I, Claes Glassell, Chief Executive Officer of Cerus Corporation, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2006

/s/ Claes Glassell
Claes Glassell
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, William J. Dawson, Chief Financial Officer of Cerus Corporation, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2006

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

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Claes Glassell, the Chief Executive Officer of Cerus Corporation (the "Company") and William J. Dawson, the Chief Financial Officer of the Company, each hereby certifies that, to the best of their knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2006, and to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of section 13(a) or section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 31st day of October, 2006.

/s/ Claes Glassell
Claes Glassell
Chief Executive Officer

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