CERUS CORP Form 10-Q October 31, 2006 Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10 - Q

(Mark One)

X 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

Commission File Number 0-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 68-0262011 (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 x NO "

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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 x Non-accelerated filer "

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES $\,^{\circ}\,$ NO $\,$ x

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.

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)

Assets	•	tember 30, 2006 naudited)	2005	
Current assets:				
	\$	12 566	¢	5,780
Cash and cash equivalents Short-term investments	Ф	42,566 27,025	\$	40,025
Accounts receivable and other current assets		9,624		5,200
Inventories		1,836		3,200
inventories		1,030		
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)

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Total stockholders equity	73,166	35,275
Total liabilities and stockholders equity	\$ 89,010	\$ 58,660

See notes to condensed consolidated financial statements.

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended		Nine Months Ended		
	Septem 2006	September 30, 2006 2005		September 30, 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.

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 Investing activities:	(14,378)	(11,287)
Purchases of furniture, equipment and leasehold improvements	(809)	(617)
Purchases of short-term investments	(21,902)	(5,000)
Sales of short-term investments	(21,902)	8,000
Maturities of short-term investments	25 192	8,911
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

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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

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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

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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.

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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.&#