CERUS CORP Form 10-Q May 12, 2010 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 March 31, 2010

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 (State or other jurisdiction of

68-0262011 (I.R.S. Employer

incorporation or organization)

Identification No.)

2411 Stanwell Drive

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 "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES "NO"

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

Large accelerated filer " Accelerated filer

Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company x Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES " NO x

As of April 28, 2010, there were 38.9 million shares of the registrant s common stock outstanding.

CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE MONTHS ENDED MARCH 31, 2010

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

		arch 31, 2010 naudited)		31, 2009 ee Note 1)
Assets				
Current assets:				
Cash and cash equivalents	\$	16,813	\$	17,287
Short-term investments		2,173		2,644
Accounts receivable, net of allowance of \$62 and \$66 at March 31, 2010 and December 31, 2009,				
respectively		3,639		3,625
Inventories		6,842		7,707
Prepaid and other current assets		1,049		1,096
Total current assets		30,516		32,359
Non-current assets:				
Property and equipment, net		1,116		1,217
Restricted cash		326		332
Other assets		539		583
Total assets	\$	32,497		34,491
T11792 1 2 11 11 2				
Liabilities and stockholders equity Current liabilities:				
	¢	2.000	ď	4 422
Accounts payable Accrued liabilities	\$	2,898 3,564	\$	4,423 5,286
		3,364		- ,
Accrued restructuring		375		113 345
Deferred revenue Current portion of long-term debt		367		343
Current portion of capital lease obligations		9		9
· · · · · · · · · · · · · · · · · · ·		-		-
Warrant liability		3,699		2,737
Total current liabilities		10,936		12,913
Non-current Liabilities		10,700		12,710
Long-term debt		4,511		
Other non-current liabilities		62		130
Total liabilities		15,509		13,043
Stockholders equity				
Preferred stock		9,496		9,496
Common stock		39		39
Additional paid-in capital		422,412		421,897

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Accumulated other comprehensive income		58
Accumulated deficit	(415,064)	(410,042)
Total stockholders equity	\$ 16,988	\$ 21,448
Total liabilities and stockholders equity	\$ 32,497	\$ 34,491

See notes to condensed consolidated financial statements.

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

		Three Months Ended March 31, 2010 2009	
Revenue:			
Product revenue	\$ 5,500	\$ 3,085	
Government grants and cooperative agreement	222	403	
Total revenue	5,722	3,488	
Cost of product revenue	3,158	2,094	
Cost of product revenue	3,130	2,094	
Gross profit	2,564	1,394	
Operating expenses:			
Research and development	1,250	2,012	
Selling, general and administrative	5,270	6,101	
Restructuring		712	
Total operating expenses	6,520	8,825	
Loss from anarotions	(2.056)	(7.421)	
Loss from operations	(3,956)	(7,431)	
Other income (expense), net	(1,066)	34	
Net loss	\$ (5,022)	\$ (7,397)	
Net loss per common share:			
Net loss per share basic	\$ (0.13)	\$ (0.23)	
Net loss per share diluted	\$ (0.13)	\$ (0.23)	
Weighted average common shares outstanding used for basic and diluted net loss per share:			
Basic	38,830	32,590	
Diluted	38,830	32,590	

See notes to condensed consolidated financial statements.

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Three Months Ended March 31, 2010 2009	
Operating activities:		
Net loss	\$ (5,022)	\$ (7,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	188	189
Stock-based compensation to employees	325	575
Unrealized (gain) loss on available for sale securities	47	(137)
Loss from revaluation of warrant liability	962	
Changes in operating assets and liabilities:		
Accounts receivable	(14)	806
Inventories	883	4
Other assets	54	74
Accounts payable and accrued expenses	(3,204)	(1,876)
Accrued restructuring	(89)	652
Deferred revenue	30	(35)
Net cash used in operating activities	(5,840)	(7,145)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(62)	(57)
Maturities of short-term investments	471	3,839
Net cash provided by investing activities Financing activities:	409	3,782
Net proceeds from issuance of common stock, ESPP, stock options and restricted stock units	190	43
Payments on capital lease obligations	(44)	
Proceeds from issuance of notes payable	4,811	
Net cash provided by financing activities	4,957	43
Net decrease in cash and cash equivalents	(474)	(3,320)
Cash and cash equivalents, beginning of period	17,287	10,303
Cash and cash equivalents, end of period	\$ 16,813	\$ 6,983

See notes to condensed consolidated financial statements.

CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

UNAUDITED

1. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (collectively referred to hereinafter as Cerus or the Company) after elimination of all intercompany accounts and transactions. These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, considered necessary for a fair presentation have been included. Operating results for the three-month period ended March 31, 2010, are not necessarily indicative of the results that may be expected for the year ending December 31, 2010, 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, 2009, included in our 2009 Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2009, has been derived from our audited financial statements as of that date.

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

The Company recognizes revenue in accordance with the FASB ASC Topic 605-25, Revenue Recognition - Arrangements with Multiple Deliverables, as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

The Company s main sources of revenues through March 31, 2010 were product revenue from sales of the INTERCEPT Blood System, research and development activities and agreements, United States government grants and awards, and commercialization agreements.

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all INTERCEPT Blood System sales, the Company uses a binding purchase order and signed sales contract as evidence of written agreement. The Company sells INTERCEPT Blood System directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective product. Deliverables and the units of accounting vary according to the provisions of the purchase order or sales contract. For revenue arrangements with multiple elements, the Company evaluates whether the delivered elements have standalone value to the customer, whether the fair value of the undelivered elements is reliably determinable, and whether the delivery of the remaining elements is probable and within the Company's control. When all of these conditions are met, the Company recognizes the revenue on the delivered elements. If these conditions are not met, the Company defers revenue until such time as all of the conditions have been met or all of the elements have been delivered. Consideration received is allocated to elements that are identified as discrete units of accounting based on the relative fair value method. At March 31, 2010 and December 31, 2009, the Company had \$0.4 million and \$0.3 million of short-term deferred revenue on its condensed consolidated balance sheets, respectively. Freight costs charged to customers are recorded as a component of revenue under FASB ASC Topic 605, Accounting for Shipping and Handling Fees and Costs. Value-added-taxes, or VAT, that the Company invoices to its customers and remits to governments, are recorded on a net basis, and are excluded from product revenue.

Research and Development Expenses

The Company receives certain United States government grants that support the Company's efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In accordance with FASB ASC Topic 730, Accounting for Research and Development Expenses, research and development expenses are charged to expense when incurred. Research and development expenses

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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.

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

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments.

In accordance with FASB ASC Topic 320, Accounting for Certain Investments in Debt and Equity Securities, the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at estimated fair value based on quoted market prices. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of other income (expense), net. The Company s available-for-sale securities consist primarily of United States government agency securities and corporate debt securities.

Unrealized gains and losses at March 31, 2010 and December 31, 2009, are reported in accumulated other comprehensive income (loss) on the Company s condensed consolidated balance sheets. The Company reviews all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. During the three months ended March 31, 2010 and 2009, the Company did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair value. The cost of securities sold is based on the specific identification method.

As of March 31, 2010, the Company also maintained a certificate of deposit for approximately \$0.2 million with a domestic bank. The Company holds this certificate of deposit for any potential decommissioning resulting from the Company s possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded as restricted cash on its condensed consolidated balance sheets at March 31, 2010 and December 31, 2009.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, short-term investments and accounts receivable.

Substantially all of the Company s cash, cash equivalents and short-term investments are maintained pursuant to the Company s investment policy at a major financial institution of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and type of investments that exist within its investment portfolio. All of the Company s investments carry high credit quality ratings, in accordance with its investment policy. At March 31, 2010, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company s cash equivalents and short-term investments.

Concentrations of credit risk with respect to trade receivables exist to the full extent of amounts presented in the condensed consolidated financial statements. On a regular basis, including the point of sale, the Company performs credit evaluations of its customers. Generally, the Company does not require collateral from its customers to secure accounts receivable. To the extent that the Company determines specific invoices or customer accounts may be uncollectible, the Company reserves against the accounts receivable on its balance sheet and records a charge on its statement of operations. The Company had recorded allowances for potentially uncollectible accounts receivable of approximately \$0.1 million at both March 31, 2010 and December 31, 2009. Actual collection losses may differ from management s estimate, and such differences could be material to the Company s financial position and results of operations.

The Company had three and four customers each accounting for more than 10% of the Company soutstanding trade receivables and aggregating approximately 55% and 73% of outstanding trade receivables at March 31, 2010 and December 31, 2009, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At March 31, 2010, and December 31, 2009, inventory consists of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the illumination devices. The Company s supply chain for certain of these components, held as work-in-process on its condensed consolidated balance sheet, can take in excess of one year for production to be

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complete before the work-in-process is utilized in finished disposable kits. Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Platelet and plasma system disposable kits generally have two-year lives from date of manufacture. The Company frequently reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise unsalable items. To the extent unsalable items are observed and there is no alternative use, the Company will record a write-down to net realizable value in the period that the impairment is first recognized.

Property and Equipment, net

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

The Company evaluates its long-lived assets for impairment in accordance with ASC Topic 360, Accounting for the Impairment or Disposal of Long-Lived Assets . The Company continually monitors events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the future undiscounted cash flows are less than the carrying amount of these assets, the Company recognizes an impairment loss based on the excess of the carrying amount over the fair value of the assets. The Company did not recognize impairment charges related to its long-lived assets during the three months ended March 31, 2010 or 2009.

Long-Term Investment in Related Party

At March 31, 2010 and December 31, 2009, the Company held an approximate 13% interest in the voting securities of BioOne Corporation, or BioOne, and accounted for its investment in BioOne under the cost method. At December 31, 2009, the Company evaluated several criteria to determine whether facts and circumstances supported the carrying value of its investment in BioOne. These criteria included, but were not limited to: third-party investor interest and participation in recent equity offerings at current pricing, business outlook of BioOne and available financial information. As a result of its evaluation of the criteria used to support its position in BioOne, the Company determined that there were no factors to support any carrying value of its investment in BioOne. As a result, at December 31, 2009, the Company completely impaired its investment in BioOne and as such recorded its investment at zero at March 31, 2010 and December 31, 2009.

Foreign Currency Remeasurement

The functional currency of the Company s foreign subsidiary is the United States Dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in United States Dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in United States Dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company s consolidated statements of operations as a component of interest income and other, net. The Company recorded foreign currency losses of \$0.1 million and gains of \$0.6 million during the three months ended March 31, 2010, and 2009, respectively.

Stock-Based Compensation

The Company maintains an equity incentive plan to provide long-term incentives for employees, contractors, members of the Board of Directors, and Scientific Advisory Board. The plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. The Company also maintains an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code.

The Company accounts for stock-based compensation in accordance with ASC Topic 505-50, Equity Based Payment to Non-Employees. Under the fair value recognition provisions, 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. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being met.

For its non-employee stock-based awards the Company considers 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. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee awards in its consolidated statements of operations.

See Note 10 for further information regarding our stock-based compensation assumptions and expenses.

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Warrant Liability

In August 2009, the Company issued warrants to purchase an aggregate of 2.4 million shares of common stock of the Company in connection with a registered direct offering. The outstanding warrants are classified as a liability, and as such the fair value of the warrants is recorded on the condensed consolidated balance sheet at inception of such classification and adjusted to fair value at each financial reporting date. The changes in fair value of the warrants are recorded in the condensed consolidated statements of operations as a component of other income (expense), net. The fair value of the warrants is estimated using the binomial-lattice option-pricing model. During the three months ended March 31, 2010, the Company recorded non-cash charges of \$1.0 million associated with changes in the fair value of the warrants from December 31, 2009. The warrants will continue to be reported as a liability until such time as the instruments are exercised or are otherwise modified to remove the provisions which require this treatment, at which time the warrants are adjusted to fair value and reclassified from liabilities to stockholders equity. If the warrants are reclassified as permanent equity, the fair value of the warrants would be recorded in stockholders equity and no further adjustment would be made in subsequent periods.

See Note 9 for further information regarding our warrant liability valuation.

Other Comprehensive Income (Loss)

The components of comprehensive income (loss) include net income (loss) and other comprehensive income (loss). The Company s only component of other comprehensive income (loss) for the three months ended March 31, 2010 and 2009 consisted of unrealized gains or losses from the Company s available-for-sales short-term investments. Other comprehensive income (loss) is reported as a separate component of stockholders equity.

Income Taxes

The Company accounts for income taxes in accordance with Accounting for Income Taxes, ASC Topic 740. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC Topic 740 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in ASC 740 is not an appropriate substitute for the derecognition of a tax position. The Company did not have any recorded liabilities for unrecognized tax benefits at March 31, 2010 or December 31, 2009. The Company recognizes interest accrued and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in is statements of operations, nor has its accrued for or made payments for interest and penalties. The Company continues to carry a full valuation allowance on all of its deferred tax assets. The tax years 2005 through 2009 remain subject to examination by the taxing jurisdictions to which the Company is subject.