

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)**

Edgar Filing: CERUS CORP - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**68-0262011**  
(I.R.S. Employer

Identification No.)

**2411 Stanwell Drive**

**Concord, California 94520**

(Address of principal executive offices, including Zip Code)

**(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 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 ☒

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

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

---

**Table of Contents**

**CERUS CORPORATION**

**QUARTERLY REPORT ON FORM 10-Q**

**THREE MONTHS ENDED MARCH 31, 2010**

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

Item 1.	<u>Financial Statements</u>	3
	<u>Condensed Consolidated Balance Sheets - March 31, 2010, and December 31, 2009</u>	3
	<u>Condensed Consolidated Statements of Operations - Three months ended March 31, 2010, and 2009</u>	4
	<u>Condensed Consolidated Statements of Cash Flows - Three months ended March 31, 2010, and 2009</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
Item 4.	<u>Controls and Procedures</u>	26
Item 4T.	<u>Controls and Procedures</u>	26

**PART II OTHER INFORMATION**

Item 1.	<u>Legal Proceedings</u>	26
Item 1A.	<u>Risk Factors</u>	26
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
Item 3.	<u>Defaults upon Senior Securities</u>	37
Item 5.	<u>Other Information</u>	37
Item 6.	<u>Exhibits</u>	38

<b><u>SIGNATURES</u></b>	39
--------------------------	----

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

(in thousands)

	<b>March 31, 2010 (Unaudited)</b>	<b>December 31, 2009 (see Note 1)</b>
<b>Assets</b>		
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
<b>Total current assets</b>	<b>30,516</b>	<b>32,359</b>
Non-current assets:		
Property and equipment, net	1,116	1,217
Restricted cash	326	332
Other assets	539	583
<b>Total assets</b>	<b>\$ 32,497</b>	<b>34,491</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,898	\$ 4,423
Accrued liabilities	3,564	5,286
Accrued restructuring	24	113
Deferred revenue	375	345
Current portion of long-term debt	367	
Current portion of capital lease obligations	9	9
Warrant liability	3,699	2,737
<b>Total current liabilities</b>	<b>10,936</b>	<b>12,913</b>
Non-current Liabilities		
Long-term debt	4,511	
Other non-current liabilities	62	130
<b>Total liabilities</b>	<b>15,509</b>	<b>13,043</b>
Stockholders' equity		
Preferred stock	9,496	9,496
Common stock	39	39
Additional paid-in capital	422,412	421,897

# Edgar Filing: CERUS CORP - Form 10-Q

Accumulated other comprehensive income	105	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.

**Table of Contents**

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

**UNAUDITED**

(in thousands, except per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
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
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 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.

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

(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities:</b>		
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)
<b>Investing activities:</b>		
Purchases of furniture, equipment and leasehold improvements	(62)	(57)
Maturities of short-term investments	471	3,839
Net cash provided by investing activities	409	3,782
<b>Financing activities:</b>		
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.

---

**Table of Contents**

**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**



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

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

---

## **Table of Contents**

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's outstanding 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**

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

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

## **Table of Contents**

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.

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

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

**Table of Contents****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 its statements of operations, nor has it 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.

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

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

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

	<b>Three Months Ended March 31, 2010      2009</b>	
Denominator:		
Basic weighted average number of common shares outstanding	38,830	32,590
Effect of dilutive potential common shares resulting from convertible preferred stock, stock options, unvested restricted stock units and ESPP shares		
Diluted weighted average number of common shares outstanding	38,830	32,590



**Table of Contents**

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

	2010	2009
Antidilutive securities weighted average shares	6,502	6,833

**Guarantee and Indemnification Arrangements**

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company after December 31, 2002, if these arrangements are within the scope of FASB Pre-codification, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications, as required under previously existing generally accepted accounting principles, in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements of the Company contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company's technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company's products have caused personal injury or other damage or loss. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become probable and estimable. There have been very few warranty costs incurred through March 31, 2010. Accordingly, at March 31, 2010, the Company has not accrued for any potential future warranty costs.

***Fair Value of Financial Instruments***

The Company applies the provisions of ASC Topic 820-10-65-4, *Fair Value Measurements*, relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of long-term debt approximates their carrying values. The carrying amounts and fair value of the Company's short term investments and warrant liability are described in Note 2. Financial Instruments to these condensed consolidated financial statements.

**New Accounting Pronouncements*****Revenue Recognition***

In October 2009, the FASB issued updated revenue recognition guidance under ASC Topic 605 relating to revenue arrangements with multiple deliverables. Under the revised guidance, companies with revenue arrangements that have multiple deliverables must assess whether or not multiple deliverables exist under the revised guidance, how the deliverables should be separated and how the consideration should be allocated to the elements. In addition, the revised guidance requires an entity to allocate revenue in an arrangement using the best estimated selling price (BESP) of deliverables if a vendor does not have vendor specific objective evidence of selling price or third-party evidence (TPE) of selling price. Each unit must have standalone value to the customer, similar to previous guidance. The revised guidance is effective for the Company beginning January 1, 2011.

***Variable Interest Entities***

In June 2009, the FASB issued amended standards for determining whether to consolidate a variable interest entity. These new standards amend the evaluation criteria to identify the primary beneficiary of a variable interest entity and requires ongoing reassessment of whether an enterprise is the primary beneficiary of the variable interest entity. The provisions of the new standards are effective for annual reporting periods beginning after November 15, 2009 and interim periods within those fiscal years. These standards were effective for the Company beginning January 1, 2010. The adoption of the new standards did not have an impact on the Company's condensed consolidated financial statements.

**Note 2. Financial Instruments**



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

The Company measures and records certain financial assets at fair value on a recurring basis, including its available-for-sale short-term investments. The Company's available-for-sale short-term investments consist of fixed income corporate bonds and United States government agency securities. The Company classifies investments with original maturities of three months or less at the date of purchase as cash equivalents. Cash equivalents consist of corporate commercial paper and money market funds, for which the carrying amount is a reasonable estimate of fair value. Similarly, the Company measures and records certain financial liabilities at fair value.

**Table of Contents**

At March 31, 2010, the fair values of certain of the Company's financial assets and liabilities were determined using the following inputs (in thousands):

<b>Fixed income available-for-sale-securities</b>		<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
	<b>Total</b>			
Money market funds <sup>(1)</sup>	\$ 8,355	\$ 8,355	\$	\$
Corporate bonds <sup>(2)</sup>	487		487	
United States government agency securities <sup>(2)</sup>	1,686		1,686	
	\$ 10,528	\$ 8,355	\$ 2,173	\$
<b>Liabilities</b>				
Warrant Liability <sup>(3)</sup>	\$ 3,699	\$	\$	\$ 3,699

At December 31, 2009, the fair values of certain of the Company's financial assets were determined using the following inputs (in thousands):

<b>Fixed income available-for-sale-securities</b>		<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
	<b>Total</b>			
Money market funds <sup>(1)</sup>	\$ 11,059	\$ 11,059	\$	\$
Corporate bonds <sup>(2)</sup>	657		657	
United States government agency securities <sup>(2)</sup>	1,987		1,987	
	\$ 13,703	\$ 11,059	\$ 2,644	\$
<b>Liabilities</b>				
Warrant Liability <sup>(3)</sup>	\$ 2,737	\$	\$	\$ 2,737

(1) Included in cash and cash equivalents on the Company's condensed consolidated balance sheet.

(2) Included in short-term investments on the Company's condensed consolidated balance sheet.

(3) Included in current liabilities on the Company's condensed consolidated balance sheet.

The Company classifies investments within Level 1 if quote prices are available in active markets. The Company classifies items in Level 2 if the investments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. These investments include: United States government agencies and corporate bonds. Investments are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs to models which vary by asset class. The Company did not hold financial assets which were recorded at fair value in the Level 3 category, which defines that one or more significant inputs or significant value drivers are unobservable, as of March 31, 2010 and December 31, 2009. The Company's warrant liability is recorded at fair value and classified in the Level 3 category. For further discussion, see Note 9.



**Table of Contents****Note 3. Cash, Cash Equivalents and Short-Term Investments**

The following is a summary of cash, cash equivalents and short-term investments at March 31, 2010 and December 31, 2009 (in thousands):

	Carrying Value	March 31, 2010 Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	\$ 8,458	\$	\$ 8,458
Money Market funds	8,355		8,355
Total cash and cash equivalents	\$ 16,813	\$	\$ 16,813
Short-term investments			
Corporate debt securities	\$ 447	\$ 40	\$ 487
United States government agency securities	1,621	65	1,686
Total short-term investments	\$ 2,068	\$ 105	\$ 2,173
	\$ 18,881	\$ 105	\$ 18,986

	Carrying Value	December 31, 2009 Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	\$ 6,228	\$	\$ 6,228
Money Market funds	11,059		11,059
Total cash and cash equivalents	\$ 17,287	\$	\$ 17,287
Short-term investments			
Corporate debt securities	\$ 629	\$ 28	\$ 657
United States government agency securities	1,957	30	1,987
Total short-term investments	2,586	\$ 58	2,644
	\$ 19,873	\$ 58	\$ 19,931

Short-term investments and cash equivalents consisted of the following by original contractual maturity (in thousands):

	March 31, 2010	December 31, 2009
Due in one year or less	\$ 8,355	\$ 11,059
Due greater than one year and less than three years	2,173	2,644
Total	\$ 10,528	\$ 13,703

The Company did not have any sales of available-for-sale investments during the three months ended March 31, 2010 and 2009. The Company did not record any other-than temporary declines in market value during the three months ended March 31, 2010 or 2009.

**Note 4. Inventories**

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

Inventories consisted of the following (in thousands):

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Work in progress	\$ 3,661	\$ 3,638
Finished goods	3,181	4,069
	<b>\$ 6,842</b>	<b>\$ 7,707</b>

The Company's inventory at March 31, 2010, and December 31, 2009, consisted of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the illumination devices. The Company is responsible for supplying Fenwal, Inc. with certain components for assembly into finished INTERCEPT disposable kits. The Company accounts for

**Table of Contents**

these components as work-in-process until such time as the components are used in the production of finished INTERCEPT disposable sets. The Company's work-in-process components are manufactured over a protracted length of time before being incorporated into the finished disposable kits. As a result, work-in-process costs accumulate for a period of time which can exceed one year.

**Note 5. Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Accrued compensation and related	\$ 760	\$ 942
Accrued inventory	1,301	2,366
Accrued contract and other accrued expenses	1,503	1,978
	<b>\$ 3,564</b>	<b>\$ 5,286</b>

**Note 6. Restructuring**

During the three months ended March 31, 2009, pursuant to the Board of Directors' approval, the Company began implementing a plan to focus resources on commercializing the INTERCEPT Blood System in Europe, to consolidate facilities, and to reduce its cost structure. Through March 31, 2010, cumulative restructuring costs incurred by the Company totaled \$0.8 million. During the three months ended March 31, 2010, the Company paid costs for one-time termination benefits for employee positions that were eliminated under the restructuring plan. Affected employees receive severance consideration and continuation of benefits, as well as transition assistance. The Company expects to pay all remaining on-time termination benefits by June 30, 2010.

A summary of the Company's restructuring costs is as follows (in thousands):

	<b>Balance at December 31, 2009</b>	<b>Restructuring Charge</b>	<b>Cash Payments</b>	<b>Balance at March 31, 2010</b>
One-time termination benefits	\$ 113	\$	\$ 89	\$ 24

**Note 7. Commitments and Contingencies****Operating Leases**

The Company leases its office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. The Company's facility leases qualify as operating leases under ASC Topic 840, "Accounting for Leases" and as such, are not included on its condensed consolidated balance sheets.

**Royalties**

The Company is obligated to pay royalties on certain INTERCEPT product sales based on a percentage of net sales generated. The royalty rates vary by product, with a rate of 10% of net sales for the platelet system, 3% for the plasma system, 5% for the red blood cell system, and 6.5% for illuminators.

**Purchase Commitments**

The Company is party to agreements with certain providers of INTERCEPT blood safety system components which the Company purchases and provides to Fenwal at no cost. Certain of these agreements require minimum purchase commitments from the Company.



**Table of Contents****Note 8. Long-term Note Payable**

Long-term note payable at March 31, 2010 consisted of the following (in thousands):

	Principal	Unamortized Discount	Total
Current Portion of note payable	\$ 435	\$ 89	\$ 346
Long-term portion of note payable	4,565	100	4,465
Long-term note payable.	\$ 5,000	\$ 189	\$ 4,811

On March 31, 2010, the Company entered into a growth capital facility agreement and immediately issued a senior secured long-term note payable for \$5.0 million. The notes issued under the agreement are secured by all of the Company's assets, except intellectual property and 35% of the shares of the Company's wholly-owned subsidiary, Cerus Europe B.V. The note carries a fixed interest rate of 12.04%, with interest only payments for the first nine months and then equal principal and interest payments for an additional 30 months. In connection with issuing the note, the Company agreed to paid an upfront facility fee of \$0.1 million and incurred closing costs of \$0.1 million. The combined facility fee and closing costs have been recorded as a discount to the note payable and will be amortized as a component of interest expense using the effective interest method over the term of the note (discount is based on implied interest rate of 13.84%).

In addition, the Company agreed to pay a \$0.4 million closing fee upon maturity of the note. The closing fee will be accreted to interest expense using the effective interest method over the life of the note. Under the growth capital facility, subject to certain conditions including compliance with covenants, the Company may borrow an additional \$5.0 million under an additional note payable between September 30 and December 31, 2010. The terms of the additional \$5.0 million note would be identical to the first note issued under the growth capital facility except the Company would not incur any additional upfront facility fees.

The Company is required to maintain compliance with certain customary and routine financial covenants. Additionally, the note requires the Company to generate minimum revenues at certain pre-established levels. As of March 31, 2010 and through May 12, 2010, the Company was in compliance with financial covenants set forth in the growth capital facility.

**Note 9. Stockholders' Equity***Series B Preferred Stock*

Fenwal holds 3,327 shares of the Company's Series B preferred stock. The 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. Fenwal may convert each share of Series B preferred stock into 100 shares of the Company's common stock at any time. If all shares of Series B preferred stock were converted to common stock, 332,700 shares of common stock would be issued, which represents approximately 1% of the outstanding common stock of the Company at March 31, 2010. The Company has the right to redeem the Series B preferred stock prior to conversion for a payment of \$9.5 million.

*Common Stock and Warrant Liability*

In August 2009, the Company received net proceeds of approximately \$12.1 million after deducting placement agent's fees and stock issuance costs of approximately \$1.1 million in a registered direct offering of 6.0 million units. Each unit sold consisted of one share of common stock and a warrant to purchase 4/10 of a share of common stock. Each unit was sold for \$2.20, resulting in the issuance of 6.0 million shares of common stock and warrants to purchase 2.4 million shares of common stock, exercisable at an exercise price of \$2.90 per share. The warrants contain certain provisions that, under certain circumstances which may be out of the Company's control, could require the Company to pay cash to settle the exercise of the warrants or may require the Company to redeem the warrants.

The offering was made pursuant to the Company's shelf registration statement on Form S-3. These warrants became exercisable on February 25, 2010 and are exercisable for a period of five years thereafter. The warrants are classified as a liability pursuant to Accounting for Derivative Instruments and Hedging Activities and Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity Topics of FASB ASC. Therefore, the fair value of the warrants is recorded on the condensed consolidated balance sheet as a liability and will be



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

adjusted to fair value at each financial reporting date thereafter until the earlier of exercise or expiration. At December 31, 2009, the fair value of the warrants was determined to be approximately \$2.7 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 2.69%, (ii) an expected term of 4.65 years, (iii) no dividend yield and (iv) a volatility of 82%. At March 31, 2010, the fair value of the warrants was determined to be approximately \$3.7 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 2.55%, (ii) an expected term of 4.40 years, (iii) no dividend yield and (iv) a volatility of 70%. Because the fair value of the warrants had increased from the December, 31, 2009 valuation, during the three months ended March 31, 2010, the Company recorded a \$1.0 million charge to its condensed consolidated statements of operations in other income (expense), net.

**Table of Contents****Note 10. Stock-Based Compensation**

The Company maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors and Scientific Advisory Boards. The Company also maintains an Employee Stock Purchase Plan which 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, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings.

The Company has granted restricted stock units to the Chief Executive Officer, Senior Vice Presidents, and Vice Presidents in accordance with the Bonus Plan for Senior Management of Cerus Corporation. Subject to each grantee's continued employment shares underlying the grants vest in three annual installments and are issuable at the end of the three-year vesting term.

The Company currently uses 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 the Company's 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 the expected term of the grants, the Company's expected stock price volatility, actual and projected employee stock option exercise behaviors, including forfeitures, the risk-free interest rate and expected dividends.

The Company does not recognize stock-based compensation on stock options that contain performance conditions, until such time as the performance criteria are probable of being achieved. As such, the Company had not recorded any such stock based compensation for the 50,000 performance-based stock options granted.

Total stock-based compensation recognized on the Company's condensed consolidated statements of operations for the three months ended March 31, 2010, and 2009, was as follows (in thousands):

	2010	2009
Research and development	\$ 62	\$ 169
Selling, general and administrative	263	406
	\$ 325	\$ 575

Activity under the Company's equity incentive 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, 2009	6,565	\$ 7.38
Granted	89	1.80
Cancelled	(138)	23.94
Exercised	(128)	1.28
Balances at March 31, 2010	6,388	\$ 7.07

**Note 11 Comprehensive Loss**

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Net loss:		
As reported	\$ (5,022)	\$ (7,397)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on available-for-sale securities	47	(137)
Comprehensive loss	\$ (4,975)	\$ (7,534)

**Table of Contents****Note 12. Development, License and Related Agreements****Agreements with Baxter and Fenwal**

In connection with the transfer of commercialization rights to the Company in February 2006, Baxter agreed to supply, at the Company's expense, certain transition services, including regulatory, technical and related administrative support through December 31, 2006. During that 2006 transition period, the Company recorded receivables of \$2.8 million from Baxter and payables of \$4.7 million to Baxter, associated with those transition services. The Company and Baxter disputed the amounts owed and due since 2006. As such, since 2006, the Company recorded the transition service receivables and payables on its condensed consolidated balance sheets. In December 2009, the Company and Baxter entered into a settlement agreement with both parties waiving all rights and obligations associated with the 2006 transition services. In consideration for agreeing to the settlement, the Company agreed to pay Baxter \$0.5 million which was recorded as a payable on its December 31, 2009 consolidated balance sheet. The \$0.5 million payable was paid by the Company during the three months ended March 31, 2010.

As a result of Baxter's sale of its transfusion therapies division in 2007 to Fenwal, the Company has certain agreements with Fenwal which require the Company to pay royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system.

In December 2008, the Company extended its agreement with Fenwal to manufacture finished disposable kits for the platelet and plasma systems through December 31, 2013. Under the amended manufacturing agreement, the Company pays Fenwal a set price per kit, which is established annually plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead is to be paid or refunded if actual manufacturing volumes are lower or higher than the annually estimated production volumes.

**Agreements with BioOne**

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. At March 31, 2010, the Company held 13% of the voting rights in BioOne. See Note 1 for additional information regarding the Company's investment in BioOne.

*Platelet Agreement*

In September 2004, Baxter and the Company entered into an agreement with BioOne for commercialization of the INTERCEPT Blood System for platelets in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for platelets in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. The agreement provides for contingent milestone payments and royalties on future product sales, which generally would be shared equally by Fenwal (Baxter's assignee) and the Company. The Company did not recognize any revenue under this agreement during the either the three months ended March 31, 2010 or 2009.

*Plasma Agreement*

A definitive agreement with BioOne for the plasma system was signed by Baxter and the Company in September 2005 for the commercialization of the INTERCEPT Blood System for plasma 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 plasma in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. The agreement provides for contingent milestone payments and royalties on future product sales, which generally would be shared equally by Fenwal (Baxter's assignee) and the Company. The Company did not recognize any revenue under this agreement during the three months ended March 31, 2010 or 2009.

**Note 13. Segment Information and Geographic Information**

At March 31, 2010, and 2009, the Company operated only one segment, blood safety. The Company's chief executive officer is the chief operating decision maker who evaluates performance based on the net revenues and operating income (loss) of the blood safety segment.

During the three months ended March 31, 2010, and 2009, the Company had the following significant customers, listed as a percentage of product revenue:

<b>Customer</b>	<b>2010</b>	<b>2009</b>
Movaco, S.A. (Spain and other EU countries)	23%	29%
Etablissement Francais du Sang (France)	16%	26%
Service Francophone du Sang (Belgium)	13%	6%

**Table of Contents**

Each of the above customers with at least 10% of product revenue operates in a separate country outside of the United States. During the three months ended March 31, 2010 and 2009, the Company also recognized government grants and cooperative agreement revenue which represents 4% and 12% of total revenue, respectively.

## **Table of Contents**

### **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 unaudited condensed consolidated financial statements and the accompanying notes included in this report and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2009. Operating results for the three months ended March 31, 2010 are not necessarily indicative of results that may occur in future periods.*

*This report contains forward-looking statements that involve risks and uncertainties. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements regarding the sufficiency of our cash resources, our ability to commercialize and achieve market acceptance of the INTERCEPT Blood Systems, the successful completion of our research, development and clinical programs our ability to manage cost increases associated with pre-clinical and clinical development for the INTERCEPT Blood Systems, our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood Systems, and our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others. In some cases, you can identify forward-looking statements by terms such as anticipate, will, believe, estimate, expect, plan, and similar expressions intended to identify such forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. There can be no assurance that these statements will prove to be correct. We discuss many of these risks and uncertainties in greater detail in the section entitled Risk Factors under Part II, Item 1A below. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q and the documents that we incorporate by reference in and have filed as exhibits to this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.*

#### **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, from 2001 until late 2007, immunotherapies for cancer and infectious disease. Our INTERCEPT platelet system, or the platelet system, and our INTERCEPT plasma system, or the plasma system, have received CE marks and are being marketed in Europe, Russia, the Middle East and selected countries in other regions around the world. We are pursuing regulatory approvals for the platelet and plasma systems in the United States and other countries. The INTERCEPT red blood cell system, or the red blood cell system, is in clinical development.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting studies and clinical development of our platelet and red blood cell systems, timing and magnitude of payments under awards from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We believe that cash received from product sales and our currently available cash balances and amounts available from our growth capital credit facility will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect and may need to raise additional capital. The capital markets and the financial services industry have continued to experience turmoil. We do not know whether capital will be available if and when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital we will need to curtail planned development and commercialization activities.

We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over the development and commercialization of the red blood cell system, or pursuit of regulatory approval of the platelet or plasma systems in the United States.

We have borrowed and in the future may further borrow capital from institutional and commercial banking sources. Potential borrowings may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. All of our authorized common stock have been either issued or reserved for issuance in connection with convertible preferred stock, warrants, our employee stock purchase plan, and our equity incentive plan.

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

Accordingly, in order to have shares available for future sale, we have submitted to our stockholders a proposal to increase the number of shares that are issuable under our certificate of incorporation. We cannot guarantee that our



**Table of Contents**

stockholders will approve the increase. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us.

We recognize growing, but still relatively modest, product revenues from the sale of our platelet and plasma systems in Europe, Russia, the Middle East, and certain other countries around the world. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products that, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses at least until after our platelet and plasma systems gain widespread commercial acceptance in Europe, Russia, the Middle East, and selected countries in other regions around the world. 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 products. We may never achieve a profitable level of operations. Subject to the availability of adequate funding from partners, government grants, and/or capital markets, we also anticipate continuing our expenditures in support of preclinical and clinical trials and device development of our red blood cell system and pursuit of regulatory approval in the United States for our platelet system over the next several years.

We pay royalties to Fenwal on product sales, at rates of 10% of net sales for the platelet system, 3% for the plasma system, 5% for the red blood cell system, and 6.5% on sales of UVA illuminators. In December 2008, we amended and extended our supply agreement with Fenwal for the manufacture of INTERCEPT finished disposable kits for the platelet and plasma systems through December 31, 2013. Under the amended manufacturing agreement, we pay Fenwal a set price per kit, which is established annually, plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead will be paid or refunded if actual manufacturing volumes are lower or higher than the annually estimated production volumes. Under the amended manufacturing agreement, we are responsible for providing certain disposable kit components to Fenwal at no cost to Fenwal. This required us to enter into supply arrangements with certain other manufacturers for those components, some of which contain minimum purchase commitments. As a result, our supply chain for certain of these components, held as work-in-process on our condensed consolidated balance sheet, can take over one year to complete production before being utilized in finished disposable kits.

We have worldwide commercialization rights for the INTERCEPT blood systems, except in certain parts of Asia. BioOne is responsible for commercializing the platelet and plasma systems, including regulatory efforts, in those certain parts of Asia. At March 31, 2010, we owned approximately 13% of the equity interest in BioOne and evaluate the carrying value of our investment in BioOne using a variety of criteria. These criteria included, but are 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 BioOne's position relative to these criteria, at December 31, 2009, we had completely written-down our investment in BioOne and recorded the carrying value of our equity interest in BioOne at zero.

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc., or Anza, in exchange for preferred stock representing approximately 20% of Anza's preferred equity. We accounted for the immunotherapy business as a discontinued operation and restated our consolidated financial statements for 2007 and prior periods to reflect that accounting treatment. We were informed in February 2009 that Anza had ceased operations. In July 2009, we entered into a three-way license agreement with Anza and Aduro BioTech, or Aduro, and separate agreements with each of Anza and Aduro (collectively, the Assignment Agreements). In November 2009, Anza transferred all of its intellectual property to Aduro pursuant to the terms of the Assignment Agreements. In exchange for agreeing to the transfer and for relinquishing our shares in Anza and releasing any claims against Anza, we received \$0.8 million in cash, preferred stock representing 10% of Aduro's capital and a 1% royalty on any future sales resulting from the transferred technology. Because Aduro's technology and efforts are in the very early stage of research and development, we have no basis to assign value to the equity we received in Aduro or to believe that such equity will have monetary value at such time we are allowed to sell it or that we will receive any royalties from Aduro.

Through March 31, 2010, in addition to the product revenues from sales of our platelet and plasma systems, we recognized revenue from grants and cooperative agreements with the Armed Forces.

**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 revenue recognition, inventory valuation, accrued liabilities, non-cash stock compensation assumptions, and income taxes. 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.



## **Table of Contents**

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

**Revenue** 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.

Revenue related to product sales is generally recognized when we fulfill our obligations for each element of an agreement. For all sales of our INTERCEPT Blood System products, we use a binding purchase order and signed sales contract as evidence of a written agreement. We sell INTERCEPT Blood System for platelets and plasma directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, we evaluate 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 our control. When all of these conditions are met, we recognize the revenue on the delivered elements. If these conditions are not met, we defer 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 market value method. Freight costs charged to customers are recorded as a component of revenue and value-added-taxes, or VAT, that we invoice to our customers and remit to governments are recorded on a net basis, which excludes such VAT from product revenue.

Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects are incurred. We receive certain United States government grants and contracts that support research 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.

**Inventory** We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our condensed consolidated balance sheet, can take over one year to complete production before being utilized in finished disposable kits. Under our manufacturing agreement with Fenwal, our carrying value of INTERCEPT disposable kits is dependent on an annually set price. In addition, at the end of each year, volume driven manufacturing overhead is either paid or refunded by or to us if manufacturing volumes are higher or lower than the anticipated manufacturing volumes at the time the price is established. As a result, at each interim period, manufacturing overhead can fluctuate and requires us to use judgment in accruing the manufacturing overhead. In addition, we use judgment in determining whether the manufacturing overhead is a cost of our inventory and recoverable when product is sold. We use significant judgment and evaluate manufacturing variances incurred during periods of abnormally low production by considering a variety of factors including the reasons for low production volumes, anticipated future production levels that correlate to and offset volumes experienced during abnormally low production cycles, and contractual requirements. We record manufacturing variances incurred during periods of abnormally low production volumes as a component of cost of product revenue when production volumes are abnormally low.

Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Our platelet and plasma system disposable kits generally have a two-year shelf life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. Our limited history selling the INTERCEPT Blood System limits the amount of historical data we have to perform this analysis. Generally, we write-down specifically identified obsolete, slow-moving, or known unsalable inventory that has no alternative use, using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts.

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

**Stock-based compensation** We issue stock-based awards to our employees, members of our Board of Directors, our Scientific Advisory Board and certain contractors as strategic, long-term incentives. We recorded stock-based compensation expense for employee awards in accordance with ASC 505-50, Compensation - Stock Compensation. We use the Black-Scholes option pricing model to determine the grant-date fair value of a stock award. We continue to apply the provisions of Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunctions with Selling, Goods or Services, for our non-employee stock-based awards. Under the provisions, the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of (i) the date at which a commitment for

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

performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee'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 condensed consolidated statements of operations.

## **Table of Contents**

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 discrete 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. The expected term of employee stock purchase plan shares is the term of 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 historical volatility of our common stock. 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. If we determine that sufficient actively traded options on our common stock exist, we may consider a combination of historical and implied volatility, or solely implied volatility.

*Risk-Free Interest Rate.* We base the risk-free interest rate that we use in the option valuation model on United States 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 affect our operating results. There is significant risk that the Black-Scholes option pricing model and the judgment we have used in ascertaining the variables will yield results that differ materially from the actual values realized upon the exercise, expiration, termination or forfeitures of the awards in the future. Historical results were utilized in deriving our variables, which may not be indicative of the future.

**Income Taxes** Since our inception, we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carry forwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. We do not recognize tax positions that have a lower than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance is not an appropriate substitute for the derecognition of a tax position. We did not have any recorded liabilities for unrecognized tax benefits at March 31, 2010 or 2009. We recognize interest accrued and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our statements of operations, nor have we accrued for or made payments for interest and penalties. We continue to carry a full valuation allowance on all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed.

## **Results of Operations**

### ***Three-Month Periods Ended March 31, 2010, and 2009***

#### ***Revenue***

# Edgar Filing: CERUS CORP - Form 10-Q

(in thousands, except percentage)	Three months ended March 31,		Change	
	2010	2009		
Product revenue	\$ 5,499	\$ 3,085	\$ 2,414	78%
Government grant and cooperative agreements	222	403	(181)	(45)%
Total revenue	\$ 5,721	\$ 3,488	\$ 2,233	64%

**Table of Contents**

Product revenue increased \$2.4 million to \$5.5 million during the three months ended March 31, 2010, compared to \$3.1 million during the comparable period in the prior year. The increase in product revenue was primarily a result of an increase in disposable kit sales to customers, and also impacted by an increase in illuminator sales during the first quarter of 2010 compared to the first quarter of 2009. Sales of disposable platelet and plasma system kits directly to existing customers continued to grow due to increased market penetration and customer adoption of the INTERCEPT Blood System in Europe and the Middle East. We expect product revenues for both the platelet and plasma systems will continue to increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway. These quarterly results may not be indicative of INTERCEPT Blood System revenue in the future.

Revenue from government grants and cooperative agreements decreased \$0.2 million to \$0.2 million for the three months ended March 31, 2010, from \$0.4 million for the comparable period in 2009. The decrease was due primarily to a decrease in activities subject to reimbursement under current awards with the United States Department of Defense, or DoD, for research activities related to our INTERCEPT Blood System programs.

**Cost of Product Revenue**

Our cost of product sales consists of the cost of the INTERCEPT Blood System inventory sold, royalties payable to Fenwal for product sales, certain order fulfillment costs and reserves for obsolete, slow-moving and scrapped inventory. Inventory is accounted for on a first-in, first-out basis.

(in thousands, except percentage)	Three months ended March 31,		Change	
	2010	2009		
Cost of product revenue	\$ 3,158	\$ 2,094	\$ 1,064	51%

Cost of product revenue increased \$1.1 million, to \$3.2 million during the three months ended March 31, 2010, compared to \$2.1 million during the comparable period in the prior year. The increase in cost of revenue was primarily due to a higher number of platelet kits sold, and also impacted by the increase in illuminator sales during the three months ended March 31, 2010 compared to March 31, 2009. We anticipate our cost of product revenue to increase in the future as a result of increased product sales.

Our realized gross margins on product sales were 43% during the three months ended March 31, 2010, up from 32% during the three months ended March 31, 2009. Our gross margins are affected by various factors, including manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which product is sold. Generally, we offer our distributors tiered volume discounts of varying magnitudes, depending on their purchase commitments, which depending on sales volumes to those distributors receiving tiered volume discounts, may impact our gross margins.

**Research and Development Expenses**

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

(in thousands, except percentage)	Three months ended March 31,		Change	
	2010	2009		
Research and development expenses	\$ 1,250	\$ 2,012	\$ (762)	(38)%

Research and development expenses decreased \$0.8 million to \$1.3 million for the three months ended March 31, 2010, compared to \$2.0 million for the comparable period in 2009. Of the total research and development costs incurred, non-cash stock-based compensation represented \$0.1 million and \$0.2 million for the three months ended March 31, 2010 and 2009, respectively. The decrease in our research and development expenses during the three months ended March 31, 2010, compared to 2009 was a result of reduced research and development activities driven primarily by the full period affect of our March 2009 restructuring plan and the associated reduction in force.

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

We anticipate our research and development spending will remain relatively stable over the near term. However, research and development spending may increase to the extent that we are able to find sources of funding to further our red blood cell system development efforts or pursue regulatory approval of the platelet system in the United States. 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 for more information regarding these risks and uncertainties.



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

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

(in thousands, except percentage)	Three months ended March 31,		Change	
	2010	2009		
Selling, general, and administrative	\$ 5,270	\$ 6,101	\$ (831)	(14)%

Selling, general, and administrative expenses decreased \$0.8 million to \$5.3 million for the three months ended March 31, 2010, compared to \$6.1 million for the comparable period in 2009. Of the \$5.3 million and \$6.1 million of selling, general and administrative expenses recognized during the three months ended March 31, 2010 and 2009, \$0.3 million and \$0.4 million, respectively, was due to non-cash stock-based compensation recognized during the respective periods. Overall, the decrease in selling, general and administrative from the three months ended March 31, 2009, was primarily due to decreased personnel costs resulting from the full period affect of our March 2009 restructuring plan.

We anticipate that we will be focused on maintaining our selling, and general and administrative spending around the current levels over the coming year, as part of a larger effort to focus our resources, contain operating expenses and conserve cash.

***Restructuring***

Restructuring costs during the three months ended March 31, 2009 include one-time termination benefits which include severance, benefits and outplacement assistance for the workforce reduction in March 2009.

(in thousands, except percentage)	Three months ended March 31,		Change	
	2010	2009		
Restructuring	\$	\$ 712	\$ (712)	N/A

During the three months ended March 31, 2009, pursuant to the Board of Directors' approval, we began implementing a plan to focus resources on commercializing the INTERCEPT Blood System in Europe, to consolidate our facilities, and to reduce our cost structure. Through March 31, 2010, we have incurred cumulative restructuring costs of \$0.8 million. During the three months ended March 31, 2009, we incurred costs for one-time termination benefits for employee positions that were eliminated under the restructuring plan. We also consolidated facilities and incurred certain other costs associated with the restructuring plan. We continued to implement our restructuring plan and incurred associated costs through the year ended December 31, 2009. We expect all of the costs accrued as one-time termination benefits at March 31, 2010 will be paid by June 30, 2010.

***Other Income (Expense), net***

Other Income (Expense), net consists of interest earned from our short-term investment portfolio, foreign exchange gain (loss), mark to market adjustments related to the calculated fair value of our outstanding warrants, and other non-operating gains and losses.

(in thousands, except percentage)	Three months ended March 31,		Change	
	2010	2009		
Other income (expense), net	\$ (1,066)	\$ 34	\$ (1,100)	(3232)%

Other income (expense), net decreased \$1.1 million to \$(1.1) million for the three months ended March 31, 2010, compared to \$34,000 during the comparable period in 2009. The decrease was primarily due to a \$1.0 million non-cash charge to mark-to-market the value of outstanding warrants associated with our August 2009 registered direct offering. We estimate the value of the 2.4 million outstanding warrants using a binomial-lattice valuation model. Future changes in stock price will result in similar adjustments as needed. Interest income was \$36,000 and

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

\$0.1 million for the three months ending March 31, 2010 and 2009, respectively. The decrease in interest income was primarily due to lower cash and investment balances, and lower yields on those balances maintained during the three months ended March 31, 2010, compared to the comparable period in 2009.

We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. We generally hold such investments until such time as we liquidate them to meet an operating cash need.

**Table of Contents****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 and others, United States government grants and cooperative agreements, and, to a lesser degree and more recently, contribution from product sales net of expenses and interest income.

At March 31, 2009, we had cash, cash equivalents and short-term investments of \$19.0 million. Net cash used in operating activities was \$5.8 million for the three months ended March 31, 2010, compared to \$7.1 million during the comparable period in 2009. The decrease in net cash used in operating activities was primarily due to changes in our operating assets and liabilities, notably decreases in our inventory balances and increases in our warrant liability, offset by declines in our other accrued expenses and accounts payable. Net cash provided by investing activities during the three months ended March 31, 2010, was \$0.4 million compared to \$3.8 million during the comparable period in 2009. The decrease was primarily due to fewer maturities of short-term investments. Over the past year, as our investments matured we did not reinvest the proceeds into similar investments, but generally invested the proceeds in money market funds with original maturities less than 90 days. Net cash provided by financing activities during the three months ended March 31, 2010, was \$5.0 million. There were no financing cash flows during the three months ended March 31, 2009. The increase in cash provided from financing activities during the three months ended March 31, 2010 was primarily due to proceeds received from the issuance of a long-term note payable issued on March 31, 2010. Working capital increased to \$19.6 million at March 31, 2010, from \$19.4 million at December 31, 2009, primarily due to lower accounts payable and accrued liabilities balances, partially offset by decreases in cash, cash equivalents, short-term investments, inventory, and the increased balance on our warrant liability.

Our near-term capital requirements are dependent on various factors, including operating costs and capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting clinical trials of our red blood cell system, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world, over the pursuit of regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system. Due to the numerous risks and uncertainties associated with the commercialization of the platelet and plasma systems, the time and cost involved in obtaining regulatory approval and subsequent launch of our platelet and plasma systems in the United States, and the development of the red blood cell system and other development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that may ultimately be associated with our anticipated clinical trials and other research and development activities. However, we believe that cash received from product sales, our currently available cash balances, and amounts available under our growth capital credit facility will be sufficient to meet our capital requirements for the next twelve months.

We have borrowed and in the future may further borrow capital from institutional and commercial banking sources. Potential borrowings may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. All of our authorized common stock have been either issued or reserved for issuance in connection with convertible preferred stock, warrants, our employee stock purchase plan, and our equity incentive plan. Accordingly, in order to have shares available for future sale, we have submitted to our stockholders a proposal to increase the number of shares that are issuable under our certificate of incorporation. We cannot guarantee that our stockholders will approve the increase. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or product, or grant licenses on terms that are not favorable to us. We do not know whether additional capital will be available if and when needed, or that, if available, we will be able to obtain additional capital on terms reasonable to us or our stockholders.

Historically, we had received significant awards in funding under cooperative agreements with the DoD for the INTERCEPT Blood System. Further funding awarded under Federal grants and cooperative agreements for the INTERCEPT Blood Systems may decline when compared to historic levels. Any such funding is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. The general economic environment, coupled with tight Federal budgets, has led to a general decline in the amount of government funding available. If we are unable to obtain Federal grant and cooperative agreement funding for the continued development of the INTERCEPT system in the United States at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs.

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

In late October 2008 we filed a shelf registration statement on Form S-3 to offer and sell up to \$200.0 million of common stock, preferred stock, warrants, and/or debt securities. This shelf registration statement was declared effective by the SEC in December 2008. In August 2009, we completed a registered direct offering under our shelf registration, netting proceeds of approximately \$12.1 million. We will not be able to utilize the remainder of the shelf registration statement until the number of authorized shares that are issuable under our certificate of incorporation is increased.

**Table of Contents*****Commitments and Off-Balance Sheet Arrangements***

Our commitments are as follows (in thousands):

	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Minimum purchase requirements	\$ 2,133	\$ 664	\$ 1,469	\$	\$
Operating leases	3,011	861	1,391	759	
Other commitment	178	139	39		
Long-term note payable	6,692	840	4,652	1,200	
Total contractual obligations	\$ 12,014	\$ 2,504	7,551	1,959	

Our minimum purchase commitments include certain components of our INTERCEPT blood safety system that we purchase from third party manufacturers and supplied to Fenwal for use in manufacturing finished disposable kits.

***Operating Leases***

We generally lease our office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. On December 10, 2009 we exercised a ten year extension option to extend the term of our lease relating to 2550 Stanwell Drive in Concord, California. By exercising this extension option, our lease payments will be increased. Our facility leases qualify as operating leases under FASB ASC Topic 840, Leases and as such, are not included on our balance sheet.

***Other commitments***

Our other commitments consist of financing obligations for payment of certain insurance premiums which expire in 2010. In addition, we financed certain of our leasehold improvements relating to our Amersfoort office. Under the terms of the financing arrangement, we are obligated to pay for these leasehold improvements on a monthly basis through the remaining lease term.

***Long-term note payable***

On March 31, 2010, we entered into a growth capital facility agreement and immediately issued a senior secured long-term note payable for \$5.0 million. The notes issued under the agreement are secured by all of our assets, except intellectual property. The note carries a fixed interest rate of 12.04%, with interest only payments for the first nine months and then equal principal and interest payments for an additional 30 months. In connection with issuing the note, we paid an upfront facility fee of \$0.1 million and incurred closing costs of \$0.1 million. The combined facility fee and closing costs have been recorded as a discount to the note payable and will be amortized as a component of interest expense using the effective interest method over the term of the note (discount is based on implied interest rate of 13.84%).

In addition, we agreed to pay a \$0.4 million closing fee upon maturity of the note. The closing fee will be accreted to interest expense using the effective interest method over the life of the note. Under the growth capital facility, subject to certain conditions including compliance with covenants, we may borrow an additional \$5.0 million under an additional note payable between September 30 and December 31, 2010. The terms of the additional \$5.0 million note would be identical to the first note issued under the growth capital facility except that we would not incur any additional upfront facility fees.

We are required to maintain compliance with certain customary and routine financial covenants. Additionally, the note requires us to generate minimum revenues at certain pre-established levels. As of May 12, 2010, we were in compliance with financial covenants set forth in the growth capital facility.

## **Table of Contents**

### **Financial Instruments**

We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of stockholders equity. 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 operations. Unrealized gains at March 31, 2010 and 2009 totaled \$0.1 million and \$0.1 million, respectively.

We invest our cash, cash equivalents and short-term investments in a variety of financial instruments, consisting primarily of high credit, high liquidity United States government agency securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. Certain of the investments in our portfolio are subject to general market risk and more specifically, the United States mortgage industry and financial institutions. We did not recognize any other than temporary impairments during the three months ended March 31, 2010 or 2009. The continued global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. There can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

### **Off-Balance Sheet Arrangements**

As of March 31, 2010, we had no contractual arrangements that create potential material risk for us and are not recognized in our condensed consolidated balance sheets.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

During the three months ended March 31, 2010, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2009.

### **ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.* Our chief executive officer and chief accounting officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this report, our chief executive officer and our chief financial officer have concluded that our disclosure controls and procedures were effective as of March 31, 2010.

*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 controls 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. Accordingly, our disclosure controls and procedures are designed to provide reasonable assurance, not absolute assurance, that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief financial officer have concluded, that based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objective of our disclosure control system were met.

### **ITEM 4T. CONTROLS AND PROCEDURES**

*Changes in Internal Control Over Financial Reporting.* There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II: OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

**None.**

**ITEM 1A. RISK FACTORS**

**Risk Factors**

*In evaluating our business, you should carefully consider the following risks, as well as the other information contained in this Quarterly Report on Form 10-Q. These risk factors could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occurs, our business, financial condition and operating results could be harmed. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business.*

## **Table of Contents**

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

We may encounter governmental and transfusion medicine community resistance to commercial adoption for any or all of our products. To gain market acceptance of our products, we must address issues and concerns from broad constituencies involved in the healthcare system, including blood banks, our direct customers, patients, transfusing physicians, hospitals, private and public sector payors, regulatory bodies and public health authorities. We may be unable to adequately demonstrate to these constituencies that the INTERCEPT Blood System is safe, effective and economical.

For logistical and financial reasons, the transfusion medicine industry has not always integrated new technologies into its processes, even those with the potential to improve the safety of the blood supply, such as the INTERCEPT Blood System. Our products may require significant changes to our potential customers' blood component collection methods, and potential customers may not believe that the benefits of using the INTERCEPT Blood System justify its cost. There is some loss of platelets as a result of our pathogen inactivation process. If the loss of platelets leads to increased costs, or our process requires changes in blood center or clinical regimens, customers may not adopt our platelet system. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called corrected count increment) and may be more effective than transfusion of INTERCEPT-treated platelets. While studies demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, customers may choose not to adopt our platelet system due to concerns relating to corrected count increment or efficacy. Some potential customers may await further safety information or additional studies before choosing whether to adopt our products. For instance, we have been informed by the largest group of blood centers in Germany that it will need to complete a clinical trial before purchasing our products on a routine basis. We cannot predict the final trial design, number of transfusions, enrollment duration, estimated time it will take to complete such a trial, or trial outcome.

Our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may limit their acceptance. For example, due to the biology of certain non-lipid enveloped viruses, including the hepatitis A virus, our products have not been demonstrated to inactivate these viruses. In addition, for human parvovirus B-19, which is also a non-lipid-enveloped virus, our testing has not demonstrated a high level of inactivation. Although we have shown high levels of inactivation of a broad spectrum of lipid-enveloped viruses, some customers may choose not to adopt our products based on considerations concerning inability to inactivate, or limited inactivation, of certain non-lipid-enveloped viruses. In addition, since prions do not contain nucleic acid, our products do not inactivate prions. While transmission of prions has not been a major problem in blood transfusions, and we are not aware of any competing products that inactivate prions, the inability to inactivate prions may limit market acceptance of our products.

We have conducted pre-clinical and clinical studies of our products in both *in vivo* and *in vitro* environments using well-established tests that are accepted by regulatory bodies. When an *in vitro* test was not generally available or not well-established, we conducted *in vivo* studies in mammalian models to predict human responses. Although we have no reason to believe that the *in vitro* and *in vivo* studies are not predictive of actual results in humans, we cannot be certain that the results of these *in vitro* and *in vivo* studies accurately predict the actual results in humans in all cases. To the extent that actual results in human patients differs from the results of our *in vitro* or *in vivo* testing, market acceptance of our products may be negatively impacted.

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-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. In addition, there is a risk that further studies we or others may conduct will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products, and existing customers may cease use of our products.

Market acceptance of our products may also be affected by blood center budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, or other third parties. In many cases, due to the structure of the blood products industry, we will have little control over budget and reimbursement discussions, which generally occur between blood centers and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept, or may not have the budget to purchase, INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for pathogens prior to transfusion, even after implementing our products some blood centers may not be able to afford to purchase our products. Furthermore, it is difficult to predict the reimbursement status of newly approved, novel medical device products. In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical products companies. The widespread adoption of managed care in the United States has also placed downward pressure on the pricing of medical products. These pressures, as well as health care reform measures enacted in the United States, may limit the prices we can obtain for our products.



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

Product adoption in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products. In addition, failure to gain approval or achieve widespread product adoption in key European countries may limit adoption in other countries.

---

**Table of Contents**

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, promote, distribute, 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 nations' 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. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a regional or even blood center-by-blood center basis, but depend on both local and centralized regulatory approval from the Paul Ehrlich Institute, or PEI. Product characteristics relating to platelet dose of INTERCEPT-treated platelets that have received marketing authorization from the PEI may be incompatible with market requirements. While INTERCEPT-treated platelets and plasma have received in-country regulatory approval and reimbursement rates have been established in France, adoption throughout France has been limited to certain blood centers. The Japanese Red Cross controls a significant majority of blood transfusions in Japan and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen inactivation of blood over a number of years and has yet to make a formal determination to adopt the INTERCEPT Blood System or any other competitive approach. 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 impaired.

***Our products and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic and foreign authorities. 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 platelet and plasma systems are not approved in the United States. Our red blood cell system requires extensive additional testing and development.***

Our products, both those sold commercially and those under development 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.

We have received CE mark approval for the INTERCEPT platelet and plasma systems, which is sufficient to allow us to sell our platelet and plasma systems in the European Union and allows us to sell the INTERCEPT platelet and plasma systems under import licenses to many countries outside of the European Union. In some countries including Germany, France, Switzerland, and Austria, additional regulatory approval of the blood products treated by our products is required before those blood products can be transfused into a human patient.

INTERCEPT-treated blood products have received those additional regulatory approvals from the Paul Ehrlich Institute in Germany (as to the largest branch of the German Red Cross), the Agence Française de Sécurité Sanitaire Des Produits de Santé, or Afssaps, in France, and SwissMedic in Switzerland. We have also obtained in-country regulatory approvals for the sale of INTERCEPT platelet and plasma systems in Russia. We have not received regulatory approval for commercial sale of the INTERCEPT Blood System in the United States and many other countries around the world. Our products are in various stages of development and regulatory approval, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our products must satisfy rigorous standards of safety and efficacy 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 demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale.

Clinical trials in particular are expensive and have a high risk of failure. Any of our product candidates may fail in the testing phase or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we will begin and conduct planned clinical trials on schedule, if at all. Clinical trial design, including enrollment criteria, endpoints, and anticipated label claims are subject to change, even if original objectives are being met. 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.

Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. 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.

## **Table of Contents**

Distribution of our products in markets outside the United States also is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation.

In May 2007, we obtained a CE mark extension in our name from European Union regulators for our platelet system, originally obtained by Baxter in 2002, and will need to obtain an extension every five years. In addition to European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries to market our products. We or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals.

We completed our Phase III clinical trial of the platelet system in the United States in March 2001 and 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 discrepancies in safety results. 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 and had shown statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. We now understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the FDA's questions. In November 2009, we and the FDA presented a proposed clinical trial protocol for a second Phase III clinical trial to the FDA's Blood Product Advisory Committee, or BPAC. Although the BPAC agreed with the proposed trial design, safety endpoints and efficacy endpoints, we believe we will need to reach agreement with the FDA on the means necessary to satisfy the BPAC's request for more stringent safety margins than we had proposed. Satisfying that request will likely require assessing data from additional patients in the trial than what we had proposed. Until the final study size and design requirements are determined, we will not be able to assess the feasibility of a second Phase III trial. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. We have no plans to initiate such a trial unless adequate funding from partners or government agencies is secured. The additional Phase III clinical trial will need to be completed and data submitted to the FDA before we can complete our regulatory submission.

We have completed Phase IIIa, Phase IIIb and Phase IIIc clinical trials of the plasma system, in the United States, reports for which were filed with the FDA during 2005. We obtained a CE mark approval in Europe of the plasma system in November 2006 and final French approval in May 2007 based on data from those trials of the plasma system. 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 or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval.

A Phase III clinical trial of our red blood cell system was terminated due to the detection of antibody reactivity to red blood cells treated with the INTERCEPT red blood cell system in one patient in the chronic arm of the trials. 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 from these additional research activities as well as additional *in vitro* and *in vivo* studies and after consulting with regulatory authorities, we initiated a new Phase I clinical trial in the fourth quarter of 2008 to test modifications to the red blood cell system. That new Phase I clinical trial was completed in early 2010, successfully meeting its primary endpoint of red cell recovery measured twenty-four hours after transfusion. In addition to red cell recovery, we also measured red cell lifespan, measured as the half-life of red cells circulating in transfusion recipients. INTERCEPT-treated red blood cells fell within the established normal reference range for red blood cells. Non-treated red cells were above the established normal reference range. Differences in the lifespan between INTERCEPT-treated red blood cells and non-treated red blood cells may inhibit our ability to obtain the necessary regulatory approvals or may impair market acceptance if the red blood cell system is successfully developed. 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. While those clinical trials are being conducted and further clinical work is planned, we will need to develop a commercially feasible red blood cell system. In the aggregate, these activities will require significant funding beyond our current resources. We will not commence the next phase of clinical trial activities until we have secured adequate funds. We expect that we can continue some level of program advancement with minimal spending, by leveraging grant funding from the Department of Defense and existing and potential partners. A delay in completing such development activities could result in a delay in the timely progression to later stage trials. If we are unsuccessful in advancing a 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.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by BPAC. BPAC would then make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or

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

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, the FDA would have to take into consideration the points of concern raised by BPAC which could affect the approval of the products.

## **Table of Contents**

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. In addition, we may be required to obtain approval from the Food and Drug Branch of the California State Department of Health for any product manufactured by us in California, including for clinical trial use. 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. 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, or GMP, and ISO 13485, a quality management system standard applicable to the products we sell in Europe. The failure to comply with these requirements on an ongoing basis could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result in an enforcement action, which could harm our business. The current manufacturing sites we rely upon for producing the platelet and plasma system products for international distribution and sale are not FDA-qualified facilities.

The FDA will require, and other regulatory authorities may also require, post-marketing testing, which can involve significant expense. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

At any time, the FDA and other regulatory authorities may require further 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 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. The FDA will require us to demonstrate a very low level of potential side effects from the use of our products.

Regulatory delays can also materially impact our product development costs. If we experience delays in testing, conducting trials 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 retain third-party investigators and organizations in an attempt to facilitate regulatory review and approval. If the delays are significant, our financial results and the commercial prospects for our products 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 data to support such claims. After regulatory approval for the initial indications, further studies may be necessary to gain approval for the use of the product for additional indications.

In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the United States, Germany, Canada, and Australia, and other countries, applicable to our prospective customers of INTERCEPT Blood System products, the blood centers that process and distribute blood and blood products. In those countries, blood centers and other customers will be required to obtain approved license supplements from the appropriate regulatory authorities in each country before making available blood products processed with our pathogen inactivation systems to hospitals and transfusing physicians. For example, our customers in Germany must obtain separate regulatory approvals to manufacture and sell blood components treated with the INTERCEPT Blood System. Our customers may lack the resources or capability to obtain such regulatory approvals. These requirements or regulatory delays in approving license applications or supplements may deter some blood centers from using our products. Blood centers that do submit applications or supplements for manufacturing and sale 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.

## **Table of Contents**

***We have limited experience operating a commercial organization. We rely on third parties to manufacture, market, sell, and distribute our products and to maintain customer relationships in a certain countries.***

Since February 2006, we have been fully responsible for sales, marketing, distribution and regulatory support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties on a timely basis, our attempts to commercialize the INTERCEPT Blood System may be irreparably harmed.

We operate a small organization, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in geographies where the INTERCEPT platelet and plasma systems are approved or can be imported through the import license process. We will need to maintain and continue to increase our competence in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems. Many of these competencies require compliance with European Union and local standards and practices, with which we have limited experience.

We have entered into contracts, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our pathogen inactivation products directly. We have entered into geographical distribution agreements for distribution in Spain, Italy, Portugal, Chile, the Czech Republic, Slovakia, Russia and CIS, Poland, Greece, Kuwait, Qatar, Saudi Arabia, and the United Arab Emirates. We rely on these distributors to market and sell the INTERCEPT Blood System, obtain any necessary in-country regulatory approvals, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. They may fail to sell product inventory they have purchased from us to end customers. Initial purchases of UVA illuminators or disposable kits by these third parties may not lead to follow-on purchases of disposable platelet and plasma system kits. We have limited visibility into the identity and requirements of blood banking customers these distributors may have. These third parties may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. We may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations.

***Our product design and manufacturing supply chain is highly technical and exposes us to significant risks.***

In March 2007, Baxter sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to a new company, Fenwal, Inc. Fenwal has agreed, through an agreement signed with us in December 2008, to manufacture disposable kits for the platelet and plasma systems through the end of 2013. However, Fenwal may fail to manufacture an adequate supply of disposable kits or to do so on a cost effective basis, which would subject us to loss of revenue and reduced contribution margin. Fenwal may fail to coordinate or meet interdependent supply chain obligations, leading to a failure to manufacture an adequate supply of components or devices of the INTERCEPT Blood System, which would also subject us to the risks described below. We contract with independent suppliers, including NOVA Biomedical Corporation, or NOVA, for the manufacture of UVA illuminators and certain components of the INTERCEPT Blood System which are manufactured or assembled at facilities not owned by Fenwal or Baxter. NOVA has not manufactured UVA illuminators for a number of years. Should NOVA have difficulties manufacturing UVA illuminators, we may not be able to supply customer demand or provide replacement UVA illuminators to existing customers. Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons, causing at least temporary interruptions in supply. For our product components, including assembly, we do not have qualified suppliers beyond those on whom we currently rely, and we understand that Fenwal relies substantially on sole suppliers of certain materials for our products. If we need to or choose to identify and qualify alternate suppliers, the process will be time consuming and costly. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. If we conclude that supply of the INTERCEPT Blood System or components from Fenwal and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources and may cause our supply chain to be less efficient.

Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require us to identify and qualify replacement components and may require that we conduct additional studies, which could include clinical trials, to demonstrate equivalency or validate any required design or component changes. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. We will likely be required to redesign the illuminator used in the platelet and plasma systems to manage the risk of obsolete components. Such redesign may be expensive and lead to regulatory delays in obtaining approvals to market the redesigned device.

Fenwal manufactures our platelet and plasma systems in facilities that are not FDA-approved. In order to be sold in the United States, our systems would be required to be manufactured in FDA-approved facilities. FDA validation of manufacturing facilities, whether owned by Fenwal or by other parties, will be costly and time-consuming.

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

If we determine to establish alternate manufacturers, we will also be dependent on Fenwal to transfer know-how relevant to the manufacture of the INTERCEPT Blood System; however, certain of Fenwal's materials, manufacturing processes and methods are proprietary to Fenwal. We may be unable to establish alternate sources of supply to Fenwal, NOVA, or other suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review. Fenwal is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Raw material and component suppliers may not meet quality specifications we have set, which would cause a disruption in supply and may lead to lost sales and irreparable damage to our customer relationships. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals.



**Table of Contents**

In the event of a failure by Fenwal or other manufacturers to perform their obligations to supply components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Our supply agreements with Fenwal and NOVA, and supply agreements with others contain limitations on incidental and consequential damages that we may recover. A supplier's potential liability in the event of non-performance may not be sufficient to compel the supplier to continue to act in conformity with our agreements.

We are in the early stages of commercializing the INTERCEPT Blood System and may not accurately forecast demand for the INTERCEPT Blood System. In addition, we generally require our distributors to provide us with sales forecasts and binding purchase orders and as such, we may make inventory purchase decisions based on these forecasts. We have contracted with third parties to supply platelet and plasma systems and components to meet forecasted demand. However, such forecasts may prove to be either higher or lower than actual commercial demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. We have entered into certain public tenders, some which call for us to maintain certain minimum levels of inventory. If Fenwal or third-party manufacturers fail to produce components or our finished products satisfactorily, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non-compliance with certain public tenders which may in turn result in permanent harm to our customer relations or loss of customers. Our platelet and plasma system disposables have received regulatory approval for two-year shelf lives. We and our distributors may be unable to ship product to customers prior to the expiration of product shelf life, which would require that we destroy or consume the outdated inventory in product demonstration activities. Product expiration may in turn lead to elevated destruction costs or reduced gross margins.

***The platelet and plasma systems are not compatible with some commercial collection methods and practices.***

The equipment and materials used to collect platelets and plasma vary by manufacturer and by geographic region. Blood component collection and preparation practices also differ from country to country and blood center to blood center. Platelets and plasma may be collected from a single donor by apheresis, using an automated collection machine, or prepared from whole blood collections. Our system for platelets is designed for both apheresis platelets and pooled whole blood-derived platelets.

We estimate that most of platelet components used in the United States are collected by apheresis, and a portion of those components are collected in volumes outside the range of our current products. Accordingly, in addition to the clinical study for our platelet system currently under discussion with the FDA, we would need to develop and test additional configurations of the platelet system in order to address the entire apheresis market in the United States. Further, in order to address the market for whole blood-derived platelets, we would need to perform additional product development and testing, including additional clinical trials. Other countries, notably Japan, have collection and preparation practices that may require development and testing of additional product configurations. These development activities would increase our costs significantly, and may not be successful.

Our platelet system is suitable for platelets collected and stored in Intersol and SSP+ storage solutions and for platelets suspended in plasma. If we need to qualify our product with new storage solutions, additional development and testing will be required.

Our system for plasma is designed for single donor apheresis collections or for pooling of multiple units prepared from whole blood collections. Some blood centers, notably those in Belgium, do not currently permit pooling of whole blood-derived plasma components, which prevents use of our plasma system by those centers.

Certain manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System compatible with their platforms. Attaining compatibility with collection platforms manufactured by others may require adaptations to either the INTERCEPT Blood 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 INTERCEPT Blood System may be delayed until the system receives regulatory approval for use on such other equipment, if required.

***We have used prototypes of the INTERCEPT red blood cell system in our preclinical studies and clinical trials and have not completed the commercial system design. We will be required to identify and enter into agreements with third parties to develop and manufacture the commercial red blood cell system.***

The red blood cell system that we used in our preclinical studies and recently completed Phase I red blood cell trial is a prototype 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, which may increase our expenses and delay the commercialization of our products. We may determine

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

that although the modified red blood cell system may overcome technical issues encountered in the past, it may not be commercially feasible from potential customers' perspectives. If we fail to develop commercial versions of the INTERCEPT red blood cell system on schedule, our potential revenue would be delayed or diminished and our potential 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 will likely be 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 will need to identify and contract with parties to perform manufacturing related to our red blood cell system, including the chemical compounds used in the red blood cell system. It may be difficult to enter into these types of agreements on reasonable terms. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to

## **Table of Contents**

commercialize the red blood cell system, even if we successfully complete clinical development. Any new or additional commercial manufacturer will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that its commercial scale manufacturing processes comply with government regulations and that its compounds are equivalent to originally licensed compounds in order for us to maintain commercial licensure of our products. It may be difficult or impossible to economically manufacture our products on a commercial scale.

### ***BioOne may fail to take advantage of commercialization rights for our platelet and plasma systems in many Asian countries.***

Fenwal and we have licensed to BioOne rights to commercialize the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. BioOne is subject to similar risks in its territories regarding commercialization of the INTERCEPT Blood System as we are. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in countries where it holds licenses to commercialize the INTERCEPT platelet and plasma systems. BioOne is dependent on Fenwal and us for the manufacture and supply of the platelet and plasma systems. BioOne may be unable to qualify the platelet and plasma systems for sale in certain countries in its territory.

BioOne has made little 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 reliant on BioOne's performance to realize milestone and royalty revenue from commercialization of our platelet and plasma systems in those countries. In Japan, regulatory authorities may require our platelet and plasma systems to be widely adopted commercially in Europe or approved by the FDA before the platelet and plasma systems are considered for approval in Japan, which would delay or prevent BioOne from achieving significant product revenue. BioOne has been operating with limited capital and resources and at very diminished capacity. At these reduced operating levels, we expect that BioOne's ability to commercialize the platelet and plasma systems in its Asian territories is significantly compromised. We understand that BioOne will need to raise additional capital to continue its operations beyond the near term. BioOne may be unable to successfully commercialize those products licensed from Fenwal and us. Even if BioOne fails to commercialize the INTERCEPT Blood System in its territories, we may be unable to assert contractual rights to regain commercialization rights on satisfactory terms, if at all.

### ***If our competitors develop and market products that are more effective, convenient, or economical than our products and product candidates, our commercial opportunity will be reduced or eliminated.***

We expect our products to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use, and may compete 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 have, or 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. These alternative strategies may be more effective in inactivating certain types of pathogens from blood products, including non-lipid-enveloped pathogens, such as hepatitis A virus, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, for which our products have not demonstrated a high level of inactivation. While our products can effectively inactivate a broad spectrum of pathogens in blood components, including more robust inactivation of many pathogens than has been shown by other companies, market acceptance of our products may be reduced if customers determine that competitor's products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. In Europe, several companies, including Grifols S.A., Octapharma AG and MacoPharma International, are developing or selling commercial pathogen inactivation systems or services to treat fresh frozen plasma. CaridianBCT is developing a pathogen inactivation system for blood products and has been issued CE marks for a pathogen reduction system for both platelets and plasma. We understand that CaridianBCT has also commenced trials on a pathogen inactivation system for whole blood, which if successful, may offer competitive advantages over our INTERCEPT Blood System.

New methods of testing whole blood for specific pathogens have been approved by the FDA and in Europe, as have tests for bacteria in platelets. Other companies 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 limit the potential market for our products.

### ***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. Our insurance coverage may be inadequate to offset losses we may incur.***

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

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

## **Table of Contents**

observed in clinical and preclinical testing could be discovered after a marketing approval has been received. For example, in cases where we have obtained regulatory approval for our products, we have demonstrated pathogen inactivation to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. 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.

***If we fail to obtain the capital necessary to fund our future operations or if we are unable to generate positive cash flows from our operations, we will need to curtail planned development or sales and commercialization activities.***

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting studies and clinical development of our platelet and red blood cell systems, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We believe that our available cash balances and funds under our growth capital credit facility will be sufficient to meet our capital requirements for at least the next twelve months. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect.

We have borrowed and in the future may further borrow capital from institutional and commercial banking sources. Potential borrowings may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to product revenues, our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us.

Our ability to raise additional capital by selling common stock is limited. All of our authorized common stock have been either issued or reserved for issuance in connection with convertible preferred stock, warrants, our employee stock purchase plan, and our equity incentive plan. Accordingly, in order to have shares available for future sale, we have submitted our stockholders a proposal to increase the number of shares that are issuable under our certificate of incorporation. We cannot guarantee that our stockholders will approve the increase. Our ability to raise additional capital may also be adversely impacted by global, regional or national economic conditions. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms favorable to us or our stockholders. If we are unable to raise additional capital we may need to curtail planned development. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over development and commercialization of the red blood cell system and pursuit of regulatory approval of the platelet or plasma system in the United States.

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

Historically, we had received significant awards in funding under cooperative agreements with the DoD. Further funding awarded under Federal grants and cooperative agreements for the INTERCEPT Blood Systems may decline when compared to historic levels. Access to 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 United States Congress. If we are unable to obtain Federal grant and cooperative agreement funding for future research and development 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.

## **Table of Contents**

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

We may never achieve a profitable level of operations. Our development and selling, general, and administrative expenses have resulted in substantial losses each year since our inception with the exception of the year ended December 31, 2005. The platelet and plasma systems are not yet approved in the United States or in many other countries around the world. The red blood cell system is in early stage clinical development and may never emerge from the clinical development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which may reduce or altogether eliminate our gross profit on sales. At our present sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer the systems are in excess of revenue. Contribution from product sales is unlikely to exceed the costs we incur in research, development, and commercialization of the INTERCEPT Blood System for near-term. We expect our losses to continue at least until the INTERCEPT Blood System achieves more significant market acceptance. To the extent that we are able to secure funding from partners or government agencies for further development of the red blood cell system or an additional Phase III clinical trial of the platelet system in the United States, we will incur costs of such activities would extend the period during which we expect to operate at a loss.

***We have issued long-term notes payable containing certain covenants that we may be unable to comply with. Our operations may not provide sufficient cash to meet the repayment obligations of the note***

On March 31, 2010, we entered into a growth capital credit agreement (the "Growth Agreement") for \$10.0 million and immediately issued a note payable for \$5.0 million. The agreement and note are secured by all of our assets, except for intellectual property. The agreement and note require that we comply with certain customary and routine covenants, including the requirement to meet minimum revenue levels at certain pre-established levels. If we are unable to comply with these minimum revenue levels, the lender may call the note which would require us to repay the principal of the note sooner than we have anticipated. In the event that the note was called, we may be unable to pay back the principal, which would allow the lender to liquidate collateralized assets.

In addition, our operations may not reach the levels needed to meet the scheduled repayment obligations of the note. If we are unable to meet the scheduled repayment obligations of the note using our available cash, we may be forced to liquidate other assets, refinance the notes or issue equity securities to raise the necessary cash to meet our obligations. There is no assurance that we would be able to sufficiently or timely liquidate assets to meet the note's repayment obligations or that we would be able to refinance the notes or issue equity.

***Our investment portfolio may become impaired by further deterioration of the capital markets.***

Our cash equivalent and short-term investment portfolio as of December 31, 2009 consisted primarily of high credit, high liquidity United States government agency securities, asset backed securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We follow an established investment policy and set of guidelines to monitor, manage and limit our exposure to interest rate and credit risk.

As a result of adverse financial market conditions, investments in some financial instruments, such as structured investment vehicles, sub-prime mortgage-backed securities, auction rate securities and collateralized debt obligations, may pose risks arising from liquidity and credit concerns. We have limited holdings of these investments in our portfolio; however, the current disruptions in the credit and financial markets have negatively affected investments in many industries, including those in which we invest. We did not recognize any other-than-temporary impairments on our investment portfolio during the three months ended March 31, 2010. The recent global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

***Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from a single site that may be subject to lengthy business interruption in the event of a severe earthquake. We also may suffer loss of computerized information and may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems.***

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

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

scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us. We have also taken measures to limit damage that may occur from the loss of computerized data due to power outage, system or component failure, or corruption of data files. However, we may lose critical computerized data, which may be difficult or impossible to recreate, which may harm our business. We may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems, which may subject us to fines or adverse consequences, up to and including loss of our abilities to conduct business.

***We do not anticipate receiving significant economic benefit from the spin-off of our immunotherapy business.***

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc. for preferred stock representing an equity interest of approximately 20% of Anza's preferred equity. We were informed that Anza had ceased operations by March 31, 2009. In July 2009, we and Anza's remaining stockholders agreed that we would relinquish our ownership in Anza and that Anza would transfer all of its



## **Table of Contents**

intellectual property to Aduro BioTech Inc, or Aduro. In November 2009, in exchange for the transfer, we received \$0.8 million in cash, preferred shares representing 10% of Aduro's capital and a royalty on any future sales resulting from the transferred technology. There is no assurance that the equity we have received in Aduro will have monetary value at or that we will receive any royalties from Aduro.

***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 there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems, if and when those products are sold in the United States. Our key blood safety patents generally expire at various dates between 2012 and 2026. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fenwal to United States and foreign patents relating to the INTERCEPT Blood System, which expire from 2010 to 2023. 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.

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

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

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

Our product sales are generally invoiced to customers in Euros. In addition, we purchase finished disposable kits for our platelet and plasma systems and incur operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. For example, continued weakening of the Euro relative to the U.S. dollar would impact the amount of product revenue and portions of our cost of goods sold and operating expenses that we report. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

## **Table of Contents**

*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, 2007 to March 31, 2010, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of \$0.55 to a high of \$10.29. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

decisions regarding reimbursement and commercial adoption by customers, national blood services or governmental bodies;

biological or medical discoveries;

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

developments concerning proprietary rights, including patents and litigation matters;

regulatory developments;

status of development partnerships;

dilution from future issuances of common stock, including through the exercise of vested stock options;

debt financings, with terms that may not be viewed favorably by stockholders;

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.

Recently, the stock market has experienced extreme price and volume fluctuations due to the unprecedented turmoil and upheaval of the credit markets and the financial services industry, which have particularly affected the market prices for emerging biotechnology and medical device companies, and has adversely affected the market price of our common stock.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accountants attesting to the effectiveness of our internal controls. These

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

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 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.

*Provisions of our charter documents, our stockholder rights plan and Delaware law could make it more difficult for a third party to acquire us, even if the offer may be considered beneficial by our stockholders.*

Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti-takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. In addition, Section 203 of the Delaware General Corporation Law, unless its application has been waived, provides certain default anti-takeover protections in connection with transactions between the company and an interested stockholder of the company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent stockholders. Our board of directors has also adopted a stockholder rights plan, or poison pill, which would significantly dilute the ownership of a hostile acquirer. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine.

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

None.

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

None.

### **ITEM 5. OTHER INFORMATION**

None.

## **Table of Contents**

### **ITEM 6. EXHIBITS**

- 3.1.1(1) Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
- 3.2(2) Amended and Restated Bylaws of Cerus.
- 4.2(3) Specimen Stock Certificate.
- 4.3(4) Stockholder Rights Plan, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
- 4.4(5) Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
- 4.5(6) Form of Registered Direct Common Warrant.
- 10.43(7)(9) Employment Letter, by and between Cerus Corporation and Laurence M. Corash, M.D. dated March 2, 2010.
- 10.44(7)(9) Bonus Plan for Senior Management of Cerus Corporation, as amended on March 3, 2010.
- 10.45(8)( ) Loan and Security Agreement, by and between Cerus Corporation and Oxford Finance Corporation, dated March 31, 2010.
- 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 Accounting Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1(\*) Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 333-72185), filed with the SEC on November 12, 1999.
- (2) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on April 30, 2007
- (3) Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
- (4) Incorporated by reference to Cerus Quarterly Report on form 10-Q, for the quarter ended June 30, 2009.
- (5) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on October 30, 2009.
- (6) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on August 20, 2009.
- (7) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on March 8, 2010.
- (8) Filed herewith.
- (9) Management contract or compensatory arrangement.
- (\*) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of Cerus Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.  
Confidential treatment has been requested with respect to portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

**Table of Contents**

**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: May 12, 2010

/s/ Kevin D. Green  
Kevin D. Green  
Chief Accounting Officer

(on behalf of registrant and as Principal Financial Officer)

## **Table of Contents**

### **Exhibit Index**

- 3.1.1(1) Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
- 3.2(2) Amended and Restated Bylaws of Cerus.
- 4.2(3) Specimen Stock Certificate.
- 4.3(4) Stockholder Rights Plan, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
- 4.4(5) Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
- 4.5(6) Form of Registered Direct Common Warrant.
- 10.43(7)(9) Employment Letter, by and between Cerus Corporation and Laurence M. Corash, M.D. dated March 2, 2010.
- 10.44(7)(9) Bonus Plan for Senior Management of Cerus Corporation, as amended on March 3, 2010.
- 10.45(8)( ) Loan and Security Agreement, by and between Cerus Corporation and Oxford Finance Corporation, dated March 31, 2010.
- 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 Accounting Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1(\*) Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 333-72185), filed with the SEC on November 12, 1999.
- (2) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on April 30, 2007
- (3) Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
- (4) Incorporated by reference to Cerus Quarterly Report on form 10-Q, for the quarter ended June 30, 2009.
- (5) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on October 30, 2009.
- (6) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on August 20, 2009.
- (7) Incorporated by reference to Cerus Current Report on Form 8-K, filed with the SEC on March 8, 2010.
- (8) Filed herewith.
- (9) Management contract or compensatory arrangement.
- (\*) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of Cerus Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.  
Confidential treatment has been requested with respect to portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.