CERUS CORP
Form 10-Q
November 15, 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 September 30, 2010

or

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

For the transition period from: _____ to _____

Commission File Number 0-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2550 Stanwell Drive

Concord, California 94520

(Address of principal executive offices, including Zip Code)

(925) 288-6000

(Registrant s telephone number, including area code)

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

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of October 5, 2010, there were 40.0 million shares of the registrant s common stock outstanding.

Table of Contents

CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets - September 30, 2010, and December 31, 2009	3
	Condensed Consolidated Statements of Operations - Three and nine months ended September 30, 2010, and 2009	4
	Condensed Consolidated Statements of Cash Flows - Nine months ended September 30, 2010, and 2009	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	27
Item 4.	Controls and Procedures	27
Item 4T.	Controls and Procedures	28

PART II OTHER INFORMATION

Item 1.	Legal Proceedings	28
Item 1A.	Risk Factors	28
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	38
Item 3.	Defaults upon Senior Securities	38
Item 4.	Reserved	38
Item 5.	Other Information	38
Item 6.	Exhibits	39

Table of Contents

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2010 (Unaudited)	December 31, 2009 (see Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 11,884	$ 17,287
Short-term investments	1,325	2,644
Accounts receivable, net of allowance of $8 and $66 at September 30, 2010 and December 31, 2009, respectively	3,512	3,625
Inventories	7,334	7,707
Prepaid expenses and other current assets	1,245	1,096
Total current assets	25,300	32,359
Non-current assets:		
Property and equipment, net	2,552	1,217
Restricted cash	331	332
Intangible assets, net	3,483	
Other assets	494	583
Total assets	$ 32,160	$ 34,491
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 3,076	$ 4,423
Accrued liabilities	5,052	5,286
Accrued restructuring		113
Deferred revenue	233	345
Current portion of long-term debt	1,264	
Current portion of capital lease obligations	10	9
Warrant liability	5,073	2,737
Total current liabilities	14,708	12,913
Non-current liabilities		
Long-term debt	3,591	
Long-term portion of capital lease obligations	8	15
Other non-current liabilities	1,545	115
Total liabilities	19,852	13,043
Commitments and contingencies		

Stockholders equity		
Preferred stock	9,496	9,496
Common stock	40	39
Additional paid-in capital	426,975	421,897
Accumulated other comprehensive income	120	58
Accumulated deficit	(424,323)	(410,042)
Total stockholders equity	$ 12,308	$ 21,448
Total liabilities and stockholders equity	$ 32,160	$ 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenue:				
Product revenue	$ 4,521	$ 4,567	$ 15,712	$ 11,523
Government grants and cooperative agreement	470	247	936	985
Total revenue	4,991	4,814	16,648	12,508
Cost of product revenue	2,324	4,242	8,416	8,856
Gross profit	2,667	572	8,232	3,652
Operating expenses:				
Research and development	1,282	1,230	3,776	4,867
Selling, general and administrative	5,089	5,340	15,664	16,850
Restructuring		15		856
Total operating expenses	6,371	6,585	19,440	22,573
Loss from operations	(3,704)	(6,013)	(11,208)	(18,921)
Non-operating income (expense):				
Warrant liability revaluation	(721)		(2,336)	
Foreign exchange gain (loss)	827	320	(246)	(520)
Interest expense	(226)	(2)	(458)	(5)
Other income (expense), net	(8)	58	(33)	200
Total non-operating income (expense)	(128)	376	(3,073)	(325)
Net loss	$ (3,832)	$ (5,637)	$ (14,281)	$ (19,246)
Per share information:				
Net loss per share basic and diluted	$ (0.10)	$ (0.16)	$ (0.37)	$ (0.58)
Weighted average common shares outstanding basic and diluted	39,310	35,000	39,020	33,420

See notes to condensed consolidated financial statements.

Table of Contents

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Nine Months Ended September 30,	
	2010	**2009**
Operating activities:		
Net loss	$ (14,281)	$ (19,246)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	561	682
Stock-based compensation	1,300	1,549
Revaluation of warrant	2,336	
Non-cash interest expense	101	
Loss on sale of fixed assets	56	109
Changes in operating assets and liabilities:		
Accounts receivable	113	1,028
Inventories	643	2,720
Other assets	(149)	27
Accounts payable and accrued expenses	(201)	1,279
Accrued restructuring	(113)	209
Deferred revenue	(112)	(142)
Net cash used in operating activities	(9,746)	(11,785)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(1,603)	(140)
Increase in other assets	(589)	(32)
Sale of short-term investments	88	
Maturities of marketable securities	1,293	8,929
Net cash (used in) provided by investing activities	(811)	8,757
Financing activities:		
Net proceeds from issuance of common stock and exercise of stock options	356	12,193
Payments on capital lease obligations and notes	(57)	(2)
Proceeds from note payable, net of discount	4,855	
Net cash provided by financing activities	5,154	12,191
Net (decrease) increase in cash and cash equivalents	(5,403)	9,163
Cash and cash equivalents, beginning of period	17,287	10,303
Cash and cash equivalents, end of period	$ 11,884	$ 19,466
Supplemental disclosures:		
Non-cash asset acquisition	$ 2,931	$
Cash paid for interest	$ 379	$ 1

See notes to condensed consolidated financial statements.

Table of Contents

CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

UNAUDITED

Note 1. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and its 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 normal recurring adjustments and reclassifications, considered necessary for a fair presentation, have been made. Operating results for the nine-month period ended September 30, 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 Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or 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 September 30, 2010 were product revenue from sales of the INTERCEPT Blood System, and United States government grants and awards.

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 or non-conforming 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 stand-alone 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 September 30, 2010 and December 31, 2009, the Company had $0.2 million and $0.3 million, respectively, of short-term deferred revenue on its condensed consolidated balance sheets. Freight costs charged to customers are recorded as a component of revenue under 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.

Table of Contents

Research and Development Expenses

The Company receives certain United States government grants that support the Company s efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In accordance with ASC Topic 730, Accounting for Research and Development Expenses, research and development expenses are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

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 ASC Topic 320, Accounting for Certain Investments in Debt and Equity Securities, the Company classifies 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 September 30, 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 September 30, 2010, the Company did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair market value. During the nine months ended September 30, 2010, the Company recorded other-than-temporary impairment losses of $0.04 million. During three and nine months ended September 30, 2009, the Company did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair value. See Note 2 regarding the inputs used to determine the fair value of the Company s investments. The cost of securities sold is based on the specific identification method.

As of September 30, 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 September 30, 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. Generally, all of the Company s remaining investments carry high credit quality ratings, in accordance with its investment policy. At September 30, 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 at the time 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 $0.01 million and $0.1 million at September 30, 2010 and December 31, 2009, respectively. 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.

At September 30, 2010, the Company had two customers, each accounting for more than 10% of the Company s outstanding trade receivables and aggregating approximately 37% of outstanding trade receivables. At December 31, 2009, the Company had four customers each accounting for more than 10% of the Company s outstanding trade receivables and aggregating approximately 73% of outstanding trade receivables. To date, the Company has not experienced collection difficulties from these customers.

Table of Contents

Inventories

At September 30, 2010 and December 31, 2009, inventory consisted 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 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 unsaleable 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. At September 30, 2010 and December 31, 2009, the Company had $0.1 million and $0.3 million, respectively, reserved for potential obsolete or expiring product.

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 and nine months ended September 30, 2010 or 2009.

Long-Term Investment in Related Party

At 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. The Company completed an asset acquisition from BioOne during the three months ended September 30, 2010, and tendered its equity interest in BioOne.

Intangible Assets

As part of the asset acquisition during the three months ending September 30, 2010, the Company acquired a commercialization license for the INTERCEPT Blood System for both platelets and plasma in parts of Asia, demonstration illuminators, and inventory. As consideration for this purchase the Company issued 937,886 shares of the Company s common stock and tendered the 13% interest in the voting securities of BioOne. In addition, the Company is obligated to issue another 234,471 shares six months from the effective date of August 24, less any claims arising from the acquisition. Based on the guidance of ASC, Topic 850, *Business Combinations,* and ASC, Topic 350, *Intangibles Goodwill and Other,* the Company assigned the total consideration transferred, less inventory which is recorded at its fair value, to the remaining assets based on their relative fair values. See Note 5 for further information on intangible asset purchase.

The Company periodically reviews its amortizable intangibles for events or changes in circumstances indicating that the carrying amount of such assets may not be recoverable. If the carrying amounts of the assets exceed their respective fair values, additional impairment tests are performed to measure the amount of the impairment loss, if any.

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. The Company recorded foreign currency gains of $0.8 million and $0.3 million during the three months ended September 30, 2010, and 2009, respectively. The Company recorded foreign currency losses of $0.2 million and $0.5 million during the nine months ended September 30, 2010, and 2009, respectively.

Table of Contents

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 718, Compensation Stock Compensation. 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 follows ASC Topic 505-50, Equity Based Payment to Non-Employees and considers the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of 1) the date at which a commitment for performance by the counter party to earn the equity instrument is reached or 2) the date at which the counter party s performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee awards in its consolidated statements of operations.

See Note 11 for further information regarding our stock-based compensation assumptions and expenses.

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. The fair value of the warrants is estimated using the binomial-lattice option-pricing model. During the three and nine months ended September 30, 2010, the Company recorded non-cash charges of $0.7 million and $2.3 million, respectively, associated with changes in the fair value of the warrants. 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 10 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 and nine months ended September 30, 2010 and 2009 consisted of unrealized gains or losses from the Company s available-for-sale 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 ASC Topic 740, Accounting for Income Taxes, . 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 September 30, 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 condensed consolidated statements of operations, nor has its accrued for or made payments for interest and penalties. The Company continues to carry a full valuation allowance on all of its deferred tax assets. The tax years 2005 through 2009 remain subject to examination by the taxing jurisdictions to which the Company is subject.

9

Table of Contents

Net Loss Per Share Basic and Diluted

Basic and diluted loss per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period.

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

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Numerator:				
Net loss	$ (3,832)	$ (5,637)	$ (14,281)	$ (19,246)
Denominator:				
Basic and diluted weighted average number of common shares outstanding	39,310	35,000	39,020	33,420
Net loss per common share basic and diluted	$ (0.10)	$ (0.16)	$ (0.37)	$ (0.58)

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

	2010	2009
Antidilutive securities weighted average shares	9,866	8,968

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. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications, 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 September 30, 2010 and the Company is unaware of any probable and estimable claims. Accordingly, at September 30, 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 amounts. 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.

Table of Contents

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 stand-alone value to the customer, similar to previous guidance. The revised guidance is effective for the Company beginning January 1, 2011.

Variable Interest Entities

In September 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 require 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

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.

At September 30, 2010, the fair values of certain of the Company s financial assets and liabilities were determined using the following inputs (in thousands):

Available-for-sale-securities	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds[1]	$ 7,210	$ 7,210	$	$
Corporate bonds[2]	115		115	
United States government agency securities[2]	1,210		1,210	
	$ 8,535	$ 7,210	$ 1,325	$
Liabilities				
Warrant Liability[3]	$ 5,073	$	$	$ 5,073

Table of Contents

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

Available-for-sale-securities	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds[1]	$ 11,059	$ 11,059	$	$
Corporate bonds[2]	657		657	
United States government agency securities[2]	1,987		1,987	
	$ 13,703	$ 11,059	$ 2,644	$
Liabilities				
Warrant Liability[3]	$ 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 September 30, 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 10.

Note 3. Cash, Cash Equivalents and Short-Term Investments

The following is a summary of cash, cash equivalents and short-term investments (in thousands):

	Carrying Value	September 30, 2010 Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	$ 4,674	$	$ 4,674
Money Market funds	7,210		7,210
Total cash and cash equivalents	$ 11,884	$	$ 11,884
Short-term investments			
Corporate debt securities	$ 57	$ 58	$ 115
United States government agency securities	1,148	62	1,210
Total short-term investments	$ 1,205	$ 120	$ 1,325
	$ 13,089	$ 120	$ 13,209

	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

Table of Contents

	September 30, 2010	December 31, 2009
Due in one year or less	$ 7,210	$ 11,059
Due greater than one year and less than three years	1,325	2,644
Total	$ 8,535	$ 13,703

Realized gains and losses from the sale of available-for-sale investments and from other-than-temporary declines in market value are recorded in Other income (expense), net. Gross proceeds and the realized losses from the sale of available-for-sale investments totaled $0.07 million and $0.02 million, respectively during the three and nine months ended September 30, 2010. During the three and nine months ended September 30, 2009, the Company did not have any sales of available-for-sale investments. During the three months ended September 30, 2010 the Company did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair market value. During the nine months ended September 30, 2010, the Company recorded other-than-temporary impairment losses of $0.04 million. During the three and nine months ended September 30, 2009, the Company did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair market value.

Note 4. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2010	December 31, 2009
Work in progress	$ 2,945	$ 3,638
Finished goods	4,389	4,069
	$ 7,334	$ 7,707

The Company s inventories at September 30, 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 its manufacturer, Fenwal, Inc., with certain components for assembly into finished INTERCEPT disposable kits. The Company accounts for these components as work-in-process until such time as the components are used in the production of finished INTERCEPT disposable kits. 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. Acquired Intangible Assets

During the three months ended September 30, 2010, the Company completed an asset acquisition from BioOne, effective August 24, 2010. The assets acquired included a commercialization license for the INTERCEPT Blood System for both platelets and plasma in parts of Asia, demonstration illuminators, and inventory. As consideration for this purchase, the Company issued 937,886 shares of the Company s common stock and tendered its ownership in the equity of BioOne. In addition, the Company is obligated to issue another 234,471 shares six months from the effective date less any claims arising from the acquisition. Based on the guidance of ASC, Topic 850, *Business Combinations,* and ASC, Topic 350, *Intangibles Goodwill and Other,* the Company assigned the total consideration given, less inventory which is recorded at its fair value, to the remaining assets based on their relative fair values. The total value of the consideration provided, including transaction costs, was $4.0 million. The portion of consideration assigned to the license, shown on our balance sheet as an intangible asset, was $3.5 million. The intangible asset is subject to periodic amortization over the weighted-average estimated useful life of 10 years.

Table of Contents

The following is a summary of intangibles at September 30, 2010 (in thousands):

	Gross Carrying Amount	September 30, 2010 Accumulated Amortization	Net Carrying Amount
Intangibles subject to amortization:			
License Intercept Asia	$ 3,483	$	$ 3,483
Total	$ 3,483	$	$ 3,483

The Company did not recognize any amortization expense for the three and nine months ending September 30, 2010. Estimated amortization expense for each of the ensuing years through December 31, 2015 is, as follows (in thousands):

Year ending December 31,	Estimated Amortization Expense
2010	$ 116
2011	348
2012	348
2013	348
2014	348
2015	348

Note 6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2010	December 31, 2009
Accrued compensation and related	$ 1,649	$ 942
Accrued inventory	833	2,366
Accrued contract and other accrued expenses	2,570	1,978
	$ 5,052	$ 5,286

Note 7. Restructuring

In March 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. Effected employees received severance consideration and continuation of benefits, as well as transition assistance. All one-time termination benefits have been paid as of September 30, 2010. No additional costs are expected to be incurred by the Company under this restructuring plan.

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

	Balance at December 31, 2009	Restructuring Charge	Cash Payments	Balance at September 30, 2010

One-time termination benefits	$ 113	$	$ 113	$	

Table of Contents

Note 8. 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, Leases and as such, are not included on its condensed consolidated balance sheets.

In addition to the operating leases themselves, certain of the Company s leases provided for lease incentives and landlord-financed leasehold improvements, which are capitalized and amortized over the life of the lease. At September 30, 2010, the Company had financed $1.0 million of leasehold improvements. The Company pays for the financed leasehold improvements as a component of rent and is required to pay interest and reimburse its landlords over the remaining life of the respective leases.

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. These royalties are recorded as part of cost of product revenue.

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.

Note 9. Long-term Note Payable

Long-term note payable at September 30, 2010 consisted of the following (in thousands):

	Principal	Unamortized Discount	Total
Current portion of note payable	$ 1,346	$ 82	$ 1,264
Long-term portion of note payable	3,654	63	3,591
Long-term note payable.	$ 5,000	$ 145	$ 4,855

On March 31, 2010, the Company entered into a growth capital facility agreement, of which the Company immediately borrowed and issued a senior secured long-term note payable for $5.0 million. The note issued under the agreement is secured by all of the Company s 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, the Company 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 an 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, 2010 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. Non compliance with the covenants may result in the principal of the note becoming due and payable.

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. For 2010, our revenues, on a trailing six-month basis, are required to be at least 80% of our projected revenues. For 2011, our revenues are required to be at least 5,700,000 per quarter. As of September 30, 2010 and through November 15, 2010, the Company was in compliance with financial covenants set forth in the growth capital facility.

Note 10. 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

Table of Contents

stock, 332,700 shares of common stock would be issued, which represents approximately 1% of the outstanding common stock of the Company at September 30, 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, from 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 from the issuance date. 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 ASC. Therefore, the fair value of the warrants is recorded on the condensed consolidated balance sheet as a liability and will be 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 September 30, 2010, the fair value of the warrants was determined to be approximately $5.1 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 0.01%, (ii) an expected term of 3.90 years, (iii) no dividend yield and (iv) a volatility of 63%. Because the fair value of the warrants had increased from the December 31, 2009 valuation, during the nine months ended September 30, 2010, the Company recorded a $2.3 million charge to its condensed consolidated statements of operations.

Note 11. 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 and nine months ended September 30, 2010, and 2009, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$ 104	$ 121	$ 266	$ 395
Selling, general and administrative	398	382	1,034	1,154

	$ 502	$ 503	$ 1,300	$ 1,549

Table of Contents

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	976	2.89
Cancelled	(326)	16.08
Exercised	(196)	1.60
Balances at September 30, 2010	7,019	$ 6.52

Note 12. Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive loss. Other comprehensive loss for all periods presented comprises unrealized holding gains and losses 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss:				
As reported	$ (3,832)	$ (5,637)	$ (14,281)	$ (19,246)
Other comprehensive loss:				
Net unrealized gain/(loss) on available-for-sale securities	(24)	13	62	(152)
Comprehensive loss	$ (3,856)	$ (5,624)	$ (14,219)	$ (19,398)

Note 13. Development and License Agreements

Agreements with Baxter and Fenwal

In connection with the transfer of commercialization rights to the Company in February 2006, Baxter International Inc., or 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 first quarter of 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. During the three months ended September 30, 2010, the Company made royalty payments to Fenwal of $0.4 million and during the three months ended September 30, 2009 there were no royalty payments made. During the nine months ended September 30, 2010 and September 30, 2009, the Company made royalty payments of

$1.3 million and $0.6 million, respectively. At December 31, 2009 and September 30, 2010, the Company owed royalties to Fenwal of $0.8 million and $0.8 million, respectively.

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 paid or refunded if actual manufacturing volumes are lower or higher than the annually estimated production volumes. The Company made payments to Fenwal of $2.2 million and $1.6 million relating to the manufacturing of the Company products during the three months ended September 30, 2010 and September 30, 2009, respectively, and $6.7 million and $4.1 million during the nine months ended September 30, 2010 and September 30, 2009, respectively. At December 31, 2009 and September 30, 2010, the Company owed Fenwal of $3.7 million and $2.2 million, respectively, for INTERCEPT disposable kits manufactured.

Table of Contents

Note 14. Segment Information and Geographic Information

At September 30, 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 nine months ended September 30, 2010 and 2009, the Company had the following significant customers, listed as a percentage of product revenue:

Customer	2010	2009
Etablissement Francais du Sang	22%	23%
Movaco, S.A.	20%	27%
Delrus Inc	15%	*
Service Du Sang	12%	12%

* Represents amounts less than 10%

During the nine months ended September 30, 2010 and 2009, the Company also recognized government grants and cooperative agreement revenue which represented 6% and 8% of total revenue, respectively.

Note 15. Subsequent Event

On November 10, 2010, the Company announced that it had sold 7,368,422 units in an underwritten public offering made pursuant to the Company s shelf registration statement on Form S-3. Each unit was sold for $2.85 and consisted of one share of common stock and a warrant to purchase 0.5 of a share of common stock. The warrants have an exercise price of $3.20 per share, are exercisable beginning six months from the close date and are exercisable for a period of five years thereafter.

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 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 and nine months ended September 30, 2010 are not necessarily indicative of results that may occur in future periods.

This report contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are contained principally in the sections entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors. 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 about our estimates 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 costs 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 in this Quarterly Report on Form 10-Q in greater detail in the section entitled Risk Factors under Part II, Item 1A below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, 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.

Table of Contents

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 selected in-country approvals and are being marketed in a number of countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East and selected countries in other regions around the world. We are pursuing regulatory approvals for the platelet system in the United States and platelet and plasma systems in other countries. The INTERCEPT red blood cell system, or the red blood cell system, is currently 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 and our ability to meet the covenants and repayment obligations associated with our notes payable. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors and the timing and cost of our development programs. 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 available cash balances 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 continue to prioritize commercialization of the platelet and plasma systems in a number of countries in Europe, the CIS, the Middle East and in selected countries in other regions around the world over pursuit of development and commercialization of the red blood cell system, or regulatory approval of the platelet or plasma systems in the United States. Subject to the availability of adequate funding from partners, government grants and/or capital markets, we plan to continue to pursue regulatory approval of the INTERCEPT platelet system, and actively seek regulatory approval of the INTERCEPT plasma system, in the United States. In addition, subject to the availability of adequate funding, we plan to continue our expenditures in support of preclinical and clinical trials and device development with respect to our INTERCEPT red blood cell system with the intent of initially pursuing regulatory approval in Europe and then, subject to the availability of adequate funding, worldwide.

We have borrowed and in the future may 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 our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us. The credit markets and the financial services industry have continued to experience turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. 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 to us or our stockholders. If we are unable to raise additional capital we will need to curtail planned development and may need to curtail commercialization activities.

We recognize product revenues from the sale of our platelet and plasma systems in Europe, the CIS countries, the Middle East, and certain other countries around the world. We expect our operations will result in continued losses at least until after our platelet and plasma systems gain widespread commercial acceptance in Europe, the CIS, 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 over the next several years.

We have worldwide commercialization rights for the INTERCEPT blood systems. 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 requires 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.

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc., or Anza, for 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

Table of Contents

operations. In July 2009, we entered into a three-way license agreement with Aduro BioTech, or Aduro, and Anza 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 shares representing 10% of Aduro s capital stock 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 have received in Aduro or that such equity will have monetary value at such time as we are allowed to sell it or that we will receive any royalties from Aduro.

Through September 30, 2010, in addition to the product revenues from sales of our platelet and plasma systems, we have 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. We evaluate our estimates on an ongoing basis, including those related to revenue recognition, inventory valuation, intangibles, accrued liabilities, stock-based 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.

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 stand-alone 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.

20

Table of Contents

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.

Intangible assets On August 24, 2010, we entered into an Asset Purchase and Redemption Agreement with BioOne Corporation, or BioOne, providing for the acquisition of certain assets from BioOne. Pursuant to this purchase of certain assets of BioOne, we own commercialization rights in certain parts of Asia, which we have classified as an intangible asset on our condensed consolidated balance sheet. We allocated the consideration paid for the intangible assets based on the guidance of ASC, Topic 850, Business Combinations , and ASC Topic 350, Intangibles Goodwill and other . Under that guidance, we allocated the consideration paid based on the relative fair value of all assets acquired. The allocation of the consideration paid for the assets required that we use significant judgment in determining the fair value of each of the assets acquired. In addition, the resulting carrying value of the intangible asset will need to be reviewed regularly for impairment and more frequently if facts and circumstances indicate that we may not be able to recognize future value at the same level as our carrying value. This assessment will require that we use significant judgment about the facts and circumstances surrounding the asset, including the expected remaining life of the asset and the expected cash flows from the asset. Based on these key assumptions, judgments and estimates, we determine whether we need to record an impairment charge to reduce the value of the asset carried on our balance sheet to its estimated fair value. Assumptions, judgments and estimates about future values are complex and often subjective. They can be affected by a variety of factors, including external factors such as industry, regulatory and economic trends, and internal factors such as changes in our business strategy or our internal 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 718, Compensation-Stock Compensation . We use the Black-Scholes option pricing model to determine the grant-date fair value of a stock award. We apply the provisions of ASC 505-50, Equity Based Payments to Non-Employees 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 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.

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 pricing model on United States Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Table of Contents

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 pricing model.

If factors change and we utilize different assumptions in determining the grant-date fair value of stock-based 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 September 30, 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 and Nine -Month Periods Ended September 30, 2010 and 2009

Revenue

(in thousands, except percentage)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Product revenue	$ 4,521	$ 4,567	$ (46)	(1)%	$ 15,712	$ 11,523	$ 4,189	36%
Government grants and cooperative agreement	470	247	223	90%	936	985	(49)	(5)%
Total revenue	$ 4,991	$ 4,814	$ 177	4%	$ 16,648	$ 12,508	$ 4,140	33%

Product revenue decreased $0.05 million to $4.5 million during the three months ended September 30, 2010, compared to $4.6 million during the comparable period in the prior year. Product revenue was relatively consistent during the three months ended September 30, 2010. Product revenue increased $4.2 million to $15.7 million during the nine months ended September 30, 2010, compared to $11.5 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 was also driven by an increase in illuminator sales compared to 2009. The increase in sales of disposable platelet and plasma system kits was directly attributable to existing customer sales and increased market penetration and customer adoption of the INTERCEPT Blood System in Europe and the Middle East. We expect that 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 increased $0.2 million to $0.5 million for the three months ended September 30, 2010, from $0.2 million for the comparable period in 2009. The increase was due primarily to an increase in activities subject to reimbursement under a new grant award for $1.4 million with the United States Department of Defense, or DoD, for research activities for our INTERCEPT Blood System programs. Government grant revenue decreased slightly by $0.05 million to $0.9 million during the nine months ended September 30, 2010, compared to $1.0 million during the comparable period in the prior year. Government grant revenue was relatively

consistent as the DoD continued to provide grant awards in support of our red blood cell program.

Cost of Product Revenue

Our cost of product revenue 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.

Table of Contents

(in thousands, except percentage)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Cost of product revenue	$ 2,324	$ 4,242	$ (1,918)	(45)%	$ 8,416	$ 8,856	$ (440)	(5)%

Cost of product revenue decreased $1.9 million to $2.3 million during the three months ended September 30, 2010, from $4.2 million during the comparable period in the prior year. The decrease in cost of revenue was primarily due to lower per-unit carrying costs of the inventory sold as a result of higher 2010 production volumes and certain costs incurred in 2009 as a result of abnormally low manufacturing volumes during the three months ended September 30, 2009. The low manufacturing volumes during 2009 resulted from our decision to sell down existing inventory and optimize inventory levels. Cost of product revenue decreased $0.4 million to $8.4 million during the nine months ended September 30, 2010, from $8.9 million during the comparable period in the prior year. The decrease in cost of revenue was primarily due to certain costs incurred as a result of abnormally low manufacturing volumes during the nine months ended September 30, 2009. We anticipate our cost of product revenue will increase in the future as a result of increased product sales volume.

Our realized gross margins on product sales were 49% during the three months ended September 30, 2010, up from 7% during the three months ended September 30, 2009. For the nine months ending September 30, 2010, our realized gross margins on product sales were 46%, up from 23% for the nine months ended September 30, 2009. The changes in 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, 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 September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Research and development	$ 1,282	$ 1,230	$ 52	4%	$ 3,776	$ 4,867	$ (1,091)	(22)%

Research and development expenses increased $0.05 million to $1.3 million for the three months ended September 30, 2010, from $1.2 million for the comparable period in 2009. Of our total research and development costs incurred, stock-based compensation represented $0.1 million for each of the three months ended September 30, 2010 and 2009. The slight increase in our research and development expenses during the three months ended September 30, 2010, compared to 2009 was the result of the development activities for our red blood cell system.

Research and development expenses decreased $1.1 million to $3.8 million for the nine months ended September 30, 2010, from $4.9 million for the comparable period in 2009. Of our total research and development expenses incurred, stock-based compensation represented $0.3 million and $0.4 million for the nine months ended September 30, 2010 and September 30, 2009, respectively. The decrease in our research and development expenses during the nine months ended September 30, 2010, compared to 2009, was a result of the effect of our March 2009 restructuring and the associated reduction in force.

We anticipate our research and development spending will remain relatively stable over the near term. However, research and development spending may increase if we are able 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.

Selling, General, and Administrative Expenses

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

Table of Contents

(in thousands, except percentage)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Selling, general, and administrative	$ 5,089	$ 5,340	$ (251)	(5)%	$ 15,664	$ 16,850	$ (1,186)	(7)%

Selling, general, and administrative expenses decreased $0.3 million to $5.1 million for the three months ended September 30, 2010, from $5.3 million for the comparable period in 2009. Of these amounts, stock-based compensation represented $0.4 million for each of the three months ended September 30, 2010 and 2009. Overall, the decrease in selling, general and administrative expenses from the three months ended September 30, 2010, was primarily due to the decreased personnel costs driven primarily by our March 2009 restructuring plan and the associated reductions in force and also impacted by our continue emphasis on cost control.

Selling, general, and administrative expenses decreased $1.2 million to $15.7 million for the nine months ended September 30, 2010, from $16.9 million for the comparable period in 2009. Of the $15.7 million and $16.9 million of selling, general and administrative expenses recognized during the nine months ended September 30, 2010 and 2009, respectively, $1.0 million and $1.2 million, was due to non-cash stock-based compensation recognized during the respective periods. Overall, the decrease in selling, general, and administrative expenses for the nine months ended September 30, 2010, was primarily due to the decreased personnel costs driven primarily by our March 2009 restructuring plan and the associated reductions in force.

We anticipate that we will be focused on maintaining our selling, general, and administrative spending at or 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 three and nine months ended September 30, 2009, include one-time termination benefits, facility consolidation and related moving costs.

(in thousands, except percentage)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Restructuring	$	$ 15	$ (15)	(100)%	$	$ 856	$ (856)	(100)%

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 facilities, and to reduce our cost structure. During the three and nine months ended September 30, 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. All of the costs accrued as one-time termination benefits at March 31, 2009 were paid by September 30, 2010.

Non-Operating Income (Expense)

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

(in thousands, except percentage)	Three months ended September 30, 2010	2009	Change		Nine months ended September 30, 2010	2009	Change	
Warrant liability revaluation	$ (721)	$	$ (721)	(100)%	$ (2,336)	$	$ (2,336)	(100)%
Foreign exchange gain (loss)	827	320	507	158%	(246)	(520)	274	53%
Interest expense	(226)	(2)	(224)	(11200)%	(458)	(5)	(453)	(9060)%
Other income (expense), net	(8)	58	(66)	(114)%	(33)	200	(233)	(117)%

Total non-operating income (expense)	$ (128)	$ 376	$ (504)	(134)%	$ (3,073)	$ (325)	$ (2,748)	(846)%

In August 2009, we issued warrants to purchase an aggregate of 2.4 million shares of common stock in connection with a registered direct offering. The fair value of the warrants is estimated using the binomial-lattice option-pricing model. 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. At September 30, 2010, no warrants had been exercised. 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. A non-cash charge to mark-to-market the value of outstanding warrants of $0.7 million was recorded for the three months ended September 30, 2010, and $2.3 million for the nine months ended September 30, 2010. Future changes in stock price will result in similar adjustments as needed.

Table of Contents

We recorded foreign currency gains of $0.8 million and $0.3 million during the three months ended September 30, 2010, and 2009, respectively. The increase in foreign currency gains was primarily attributable to favorable foreign currency variances. We recorded foreign currency losses of $0.2 million and $0.5 million during the nine months ended September 30, 2010, and 2009, respectively. The decrease in foreign currency losses was also attributable to favorable foreign currency variations between the Euro and U.S. dollar, our functional currency.

Interest expense was $0.2 million of expense for the three months ended September 30, 2010, compared to $2,000 of expense during the comparable period in 2009. Interest expense was $0.5 million of expense for the nine months ended September 30, 2010, compared to $5,000 of expense during the comparable period in 2009. The increase in interest expense was due to interest incurred from borrowings on our credit facility.

Liquidity and Capital Resources

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, debt financing, United States government grants and cooperative agreements, and contribution from product sales, net of expenses, and interest income.

At September 30, 2010, we had cash, cash equivalents and short-term investments of $13.2 million. Net cash used in operating activities was $9.7 million for the nine months ended September 30, 2010, compared to $11.8 million during the comparable period in 2009. The decrease in net cash used in operating activities was primarily due to lower operating costs offset by changes in our operating assets and liabilities. Net cash used by investing activities during the nine months ended September 30, 2010, was $0.8 million compared to $8.8 million provided by investing activities during the comparable period in 2009. The decrease in cash provided was primarily due to fewer maturities of short-term investments. Over the past year, as our investments mature we have not reinvested the proceeds into similar investments, but have generally invested the proceeds in money market funds with original maturities of less than 90 days. Net cash provided by financing activities during the nine months ended September 30, 2010, was $5.2 million, compared to $12.2 million during the nine months ended September 30, 2009. The decrease in cash provided from financing activities year over year was primarily due to proceeds received from the public offering in August 2009. Working capital decreased to $10.6 million at September 30, 2010, from $19.4 million at December 31, 2009, primarily due to decreases in cash, cash equivalents, short-term investments, inventory, the increased balances on our warrant liability and the current portion of our note payable, which was partially offset by lower accounts payable and accrued liabilities balances.

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 preclinical 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 and our ability to meet the covenants and repayment obligations associated with our notes payable. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors and the timing and cost of our development programs. 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 available cash balances 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 continue to prioritize commercialization of the platelet and plasma systems in a number of countries in Europe, the CIS and the Middle East and in selected countries in other regions around the world. Subject to the availability of adequate funding from partners, government grants and/or capital markets, we plan to continue to pursue regulatory approval of the INTERCEPT platelet system, and actively seek regulatory approval of the INTERCEPT plasma system, in the United States. In addition, subject to the availability of adequate funding, we plan to continue our expenditures in support of preclinical and clinical trials and device development with respect to our INTERCEPT red blood cell system with the intent of initially pursuing regulatory approval in Europe and then, subject to the availability of adequate funding, worldwide. Because of 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.

We have borrowed and in the future may 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 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.

Table of Contents

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. 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.

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, with net proceeds of approximately $12.1 million, after deducting placement agent s fees and stock issuance of approximately $1.1 million.

Commitments and Off-Balance Sheet Arrangements

Commitments

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	2,480	718	1,227	535	
Other commitment	1,384	456	221	214	493
Long-term note payable	6,441	1,752	4,689		
Total contractual obligations	$ 12,438	$ 3,590	7,606	749	493

Our minimum purchase commitments include certain components of our INTERCEPT blood safety system that we purchase from third party manufacturers and supply 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 to the operating leases we have for office and laboratory space, certain of our leases provided for landlord-financed leasehold improvements. At September 30, 2010, we had financed $1.0 million of leasehold improvements. We pay for the financed leasehold improvements as a component of rent and are required to reimburse our landlords over the remaining life of the respective leases.

Table of Contents

Long-term note payable

On March 31, 2010, we entered into a growth capital facility agreement, of which we immediately borrowed and 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 agreed to pay 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 an 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, 2010 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. For 2010, our revenues, on a trailing six-month basis, are required to be at least 80% of our projected revenues. For 2011, our revenues are required to be at least 5,700,000 per quarter. As of September 30, 2010 and through November 15, 2010, we were in compliance with financial covenants set forth in the growth capital facility.

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 totaled $0.1 million at both September 30, 2010 and December 31, 2009.

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. During the three months ended September 30, 2010, we did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair value. During the nine months ended September 30, 2010, we recorded other-than-temporary impairment losses of $0.04 million. During three and nine months ended September 30, 2009, we did not recognize any losses associated with investments experiencing an other-than-temporary decline in fair value. See Note 2 of our Notes to Condensed Consolidated Financial Statements contained herein regarding the inputs used to determine the fair value of our investments. The current 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 September 30, 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 nine months ended September 30, 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 accounting officer have concluded that our disclosure controls and procedures were effective as of September 30, 2010.

Table of Contents

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 accounting 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 September 30, 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.

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. In addition to blood banks, our direct customers, we must also address issues and concerns from broad constituencies involved in the healthcare system, from patients, to transfusing physicians, hospitals, private and public sector payors, regulatory bodies and public health authorities. Any one of these constituencies may be able to delay or block adoption of the INTERCEPT Blood System. We may be unable to adequately demonstrate to these constituencies that the INTERCEPT Blood System is safe, effective and economical, or that the benefits of using the INTERCEPT Blood System products justify their cost.

Use of the platelet system results in some processing loss of platelets. If the loss of platelets leads to increased costs for our customers, or our process requires changes in blood center or clinical regimens, prospective 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 also demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, customers may choose not to adopt our platelet system due to considerations relating to corrected count increment or efficacy.

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.

Furthermore, due to limitations of those tests, we cannot exclude that a sufficient quantity of pathogen or pathogens may still be present in active form which could present a risk of infection to the transfused patient. Such uncertainty may limit the market acceptance of our products.

Table of Contents

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. Budgetary concerns may be further exacerbated by recently enacted economic austerity programs implemented in European countries. The economic austerity programs may limit the adoption of new technologies, including 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.

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

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 approvals and centralized regulatory approvals 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. 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 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. 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 any pathogen inactivation 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, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country s regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue in that country. 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.

Table of Contents

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

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

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.

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 Germany, France, Switzerland, and Austria, additional regulatory approval of the blood products treated by our products has been 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 the CIS. 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.

Distribution of our products in markets outside the United States is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In some countries, we may be required to register as a medical device manufacturer, even though we outsource manufacturing to third parties. In addition 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 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

Table of Contents

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. In order to meet the more stringent safety margins, we may need to enroll and collect data from more patients than what we had initially proposed to BPAC. 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 prohibitive due either to prospective cost, availability of patients in the target population, or logistics. 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.

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 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.

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, a post-marketing clinical study, 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.

We have conducted many toxicology studies to demonstrate the INTERCEPT platelet and plasma systems safety, and we have conducted and plan to conduct toxicology studies for the INTERCEPT red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products safety, which could delay commercialization. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate our having to redesign our product 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 in the proposed second Phase III trial of the platelet system. Trials of this type may be too large and expensive to be practical.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibody reactivity to red blood cells treated with the INTERCEPT red blood cell system in two patients 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 modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system program.

Table of Contents

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 regulators 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.

In August 2010, in connection with our acquisition of assets from BioOne, we regained the rights to commercialize the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. BioOne had made little progress in commercializing the platelet and plasma systems in Asian territories. Regulatory authorities in these countries 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.

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

We are responsible for sales, marketing, distribution, maintenance and regulatory support of the INTERCEPT Blood System worldwide. 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 have a wholly-owned subsidiary, 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, Poland, Greece, Kuwait, Qatar and Australia. 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. Agreements with our distributors typically require the distributor to maintain quality standards that are compliant with standards generally accepted for medical devices. We may be unable to ensure that our distributors are compliant with such standards. Distributors 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 and contractual provisions.

Our 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 for us 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. 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

Table of Contents

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 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.

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.

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. 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 product demonstration costs or reduced gross margins.

The platelet system is not compatible with some commercial platelet collection methods.

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

In order to address the entire market in the United States, we would need to develop and test additional configurations of the platelet system. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. In order to gain regulatory approvals for a pathogen inactivation system compatible with random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma systems. These development activities would increase our costs significantly, and may not be successful.

Table of Contents

Other 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 prototype components in our preclinical studies and clinical trials of the INTERCEPT red blood cell system and have not completed the components commercial design. We will be required to identify and enter into agreements with third parties to manufacture the red blood cell system and related blood component storage solutions.

Our red blood cell system that we used in our preclinical studies and recently completed Phase I red blood cell trial are prototypes of systems to be used in the final products. As a result, we expect regulatory authorities will require us to perform additional preclinical and clinical studies using the commercial versions of the systems to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial products, which may increase our expenses and delay the commercialization of our products. We may determine 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 contract with third-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 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.

If our competitors develop and market products that are more effective 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 conducted a clinical trial on a pathogen inactivation system for whole blood. Caridian s product candidate, 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 marketing rapid, point-of-care bacterial tests, and developing 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.

Table of Contents

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.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and pharmaceutical products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in clinical and preclinical testing could be discovered 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 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 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 may 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 a number of countries in Europe, the CIS, and 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.

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

Table of Contents

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.

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 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 and allocate funding 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 Credit Agreement) for $10.0 million of which we immediately borrowed and issued a note payable for $5.0 million. The agreement and loan are secured by all of our U.S. assets, except for intellectual property. The agreement and note require that we comply with certain customary and routine covenants, including the requirement to meet growing revenue levels set at pre-established levels. For 2010, our revenues, on a trailing six-month basis, are required to be at least 80% of our projected revenues. For 2011, our revenues are required to be at least 5,700,000 per quarter. If we are unable to increase our product revenues to comply with the covenants in the Credit Agreement, 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 due to non-compliance with the covenants, we may be unable to pay back the principal which would allow the lender to liquidate collateralized assets. This in turn, would harm our business.

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, in which case our business would be significantly harmed and may force the Company into bankruptcy.

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

Our cash equivalent and short-term investment portfolio as of September 30, 2010 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 recognized other-than-temporary impairments of $0.04 million on our investment portfolio during the nine months ended September 30, 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 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

Table of Contents

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 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 exists 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.

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

Product sales of our blood safety products are typically made in Europe and generally are invoiced to customers in Euros. In addition, we 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. Foreign exchange rate fluctuations are recorded as a component of interest (expense) and other, net on our condensed consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

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, 2008 to September 30, 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 $7.29. 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.

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 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 4. RESERVED

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

2.1(1)	Asset Purchase and Redemption Agreement, dated as of August 24, 2010, by and between Cerus Corporation and BioOne Corporation.
3.1.1(2)(8)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2(3)	Amended and Restated Bylaws of Cerus.
4.2(4)	Specimen Stock Certificate.
4.3(5)	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(6)	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(7)	Form of Registered Direct Common Warrant.
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. 333-21937), filed with the SEC on August 30, 2010.
(2) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 333-72185), filed with the SEC on November 12, 1999.
(3) Incorporated by reference to Cerus Current Report on Form 8-K (No. 000-21937), filed with the SEC on April 30, 2007.
(4) Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(5) Incorporated by reference to Cerus Quarterly Report on form 10-Q, for the quarter ended June 30, 2009.
(6) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 000-21937), filed with the SEC on October 30, 2009.
(7) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 000-21937), filed with the SEC on August 20, 2009.
(8) Incorporated by reference to Cerus Quarterly Report on form 10-Q, for the quarter ended June 30, 2010.
(*) 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.

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: November 15, 2010

/s/ Kevin D. Green
Kevin D. Green
Vice President, Finance, and Chief Accounting Officer

(on behalf of registrant and as Principal Financial Officer)

Table of Contents

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