CERUS CORP
Form 10-Q
August 08, 2011
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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 June 30, 2011

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

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

As of July 29, 2011, there were 47.7 million shares of the registrant s common stock outstanding.

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CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE AND SIX MONTHS ENDED JUNE 30, 2011

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2011 (Unaudited)	December 31, 2010 (see Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 17,167	$ 28,948
Short-term investments	613	1,061
Accounts receivable, net of allowance of $69 and $51 at June 30, 2011 and December 31, 2010, respectively	4,420	4,792
Inventories	9,968	5,957
Prepaid and other current assets	864	997
Total current assets	33,032	41,755
Non-current assets:		
Property and equipment, net	2,141	2,390
Goodwill	1,316	1,316
Intangible assets, net	1,849	1,950
Restricted cash	312	305
Other assets	450	451
Total assets	$ 39,100	$ 48,167
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,682	$ 3,230
Accrued liabilities	5,334	6,003
Deferred revenue	123	248
Current portion of long-term debt	1,876	1,747
Current portion of capital lease obligations	11	10
Warrant liability	10,082	8,465
Total current liabilities	22,108	19,703
Non-current liabilities:		
Long-term debt	2,159	3,131
Long-term portion of capital lease obligations	0	6
Other non-current liabilities	1,588	1,595
Total liabilities	25,855	24,435
Commitments and contingencies		
Stockholders equity:		
Preferred stock	9,496	9,496
Common stock	48	47
Additional paid-in capital	441,976	441,034

Accumulated other comprehensive income	1	108
Accumulated deficit	(438,276)	(426,953)
Total stockholders equity	$ 13,245	$ 23,732
Total liabilities and stockholders equity	$ 39,100	$ 48,167

See notes to condensed consolidated financial statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenue:				
Product revenue	$ 6,753	$ 5,690	$ 12,936	$ 11,190
Government grants and cooperative agreements	0	245	436	467
Total revenue	6,753	5,935	13,372	11,657
Cost of product revenue	3,978	2,934	7,423	6,092
Gross profit	2,775	3,001	5,949	5,565
Operating expenses:				
Research and development	1,994	1,244	3,802	2,494
Selling, general and administrative	6,207	5,304	11,735	10,574
Amortization of intangible assets	51	0	101	0
Acquisition related costs, net	0	132	0	383
Total operating expenses	8,252	6,680	15,638	13,451
Loss from operations	(5,477)	(3,679)	(9,689)	(7,886)
Non-operating income (expense):				
Loss from revaluation of warrant liability	(339)	(653)	(1,617)	(1,615)
Foreign exchange gain (loss)	(258)	(975)	439	(1,073)
Interest expense	(220)	(227)	(453)	(232)
Other expense, net	(19)	(25)	(3)	(26)
Total non-operating expense	(836)	(1,880)	(1,634)	(2,946)
Net loss	($ 6,313)	($ 5,559)	($ 11,323)	($ 10,832)
Net loss per common share:				
Basic	($ 0.13)	($ 0.14)	($ 0.24)	($ 0.28)
Diluted	($ 0.13)	($ 0.14)	($ 0.24)	($ 0.28)
Weighted average common shares outstanding used for calculating net loss per common share:				
Basic	47,620	38,940	47,530	38,880
Diluted	47,620	38,940	47,530	38,880

See notes to condensed consolidated financial statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Six Months Ended June 30,	
	2011	**2010**
Operating activities		
Net loss	($ 11,323)	($ 10,832)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	520	369
Stock-based compensation	923	798
Loss from revaluation of warrant liability	1,617	1,615
Gain (loss) on sale of fixed assets	(16)	39
Non-cash interest expense	93	51
Other-than-temporary loss on marketable securities	0	35
Changes in operating assets and liabilities, net of effects of acquired business:		
Accounts receivable	372	158
Inventories	(4,011)	1,440
Other assets	133	(208)
Accounts payable	1,452	(910)
Accrued restructuring	0	(113)
Accrued liabilities	(672)	(579)
Deferred revenue	(125)	(133)
Net cash used in operating activities	(11,037)	(8,270)
Investing activities		
Purchase of furniture, equipment and leasehold improvements	(70)	(797)
Purchase of certain other assets	(90)	(44)
Maturities of investments	341	970
Net cash provided by investing activities	181	129
Financing activities		
Net proceeds from issuance of common stock due to exercise of stock options and purchase from ESPP	20	196
Proceeds from note payable, net of discount	0	4,852
Payments on capital lease obligations and notes	(945)	(55)
Net cash provided by (used in) financing activities	(925)	4,993
Net decrease in cash and cash equivalents	(11,781)	(3,148)
Cash and cash equivalents, beginning of period	28,948	17,287
Cash and cash equivalents, end of period	$ 17,167	$ 14,139
Supplemental disclosures:		
Cash paid for interest	$ 401	$ 154

See notes to condensed consolidated financial statements.

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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 of America (GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission, (SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring entries, considered necessary for a fair presentation have been made for the three and six months ended June 30, 2011. As previously reported in the Company s 2010 Annual Report on Form 10-K in Note 18. Quarterly Financial Information in the Notes to Consolidated Financial Statements, adjustments relating to the acquisition of certain assets from BioOne Corporation (BioOne) were made to previously reported financial statements for the three and six months ended June 30, 2010. These adjustments reduced long-term assets and increased operating expenses by $0.1 million and $0.4 million for the three and six months ended June 30, 2010, respectively. Operating results for the three and six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011, or for any future periods.

These condensed consolidated financial statements and notes should be read in conjunction with the Company s audited financial statements and notes thereto for the year ended December 31, 2010, which were included in the Company s 2010 Annual Report on Form 10-K, filed with the SEC on March 16, 2011. The accompanying balance sheet as of December 31, 2010 has been derived from the Company s 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

In October 2009, the Financial Accounting Standards Board (FASB,) issued updated revenue recognition guidance under Accounting Standards Codification (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, or TPE, of selling price. Each unit must have stand-alone value to the customer, similar to previous guidance. Effective January 1, 2011, the Company adopted the revised guidance for revenue recognition in accordance with the FASB, ASC Topic 605-25, *Revenue Recognition - Arrangements with Multiple Deliverables,* on a prospective basis for applicable transactions originating or materially modified after December 31, 2010. This guidance does not change the units of accounting for the Company s revenue transactions. The adoption of this revised guidance did not have a material impact on the Company s results of operations for the three and six months ended June 30, 2011 nor is it currently anticipated to have a material impact on future periods.

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 June 30, 2011 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 products, the Company uses a binding purchase order and signed sales contract as evidence of written agreement. The Company sells INTERCEPT Blood System for platelets and plasma directly to blood banks, hospitals,

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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 each 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. Prior to adoption of ASU No. 2009-13, consideration received was allocated to elements that were identified as discrete units of accounting based on the relative fair value method. Beginning January 1, 2011, consideration received is allocated to elements that are identified as discrete units of accounting based on the BESP. The Company has determined that VSOE is not discernable due to the Company s limited history of selling its products and variability in its pricing. Since the Company s products are novel and unique and are not sold by others, third-party evidence of selling price is unavailable.

At June 30, 2011 and December 31, 2010, the Company had $0.1 million and $0.2 million, respectively, of short-term deferred revenue on its condensed consolidated balance sheets related to future performance obligations. 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 (VAT) that the Company invoices to its customers and remits to governments, are recorded on a net basis, which excludes such VAT from product revenue.

Research and Development Expenses

The Company receives certain United States government grants that support the Company s efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In addition, 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 original maturities of three months or less from the date of purchase to be classified as cash equivalents. Investments with original maturities of greater than three months but less than one year from the date of purchase are classified as short-term investments. These investments primarily consist of marketable debt securities, which including money market instruments, United States government agency securities and corporate debt securities, and are classified as available-for-sale.

In accordance with ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities,* the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at estimated fair value based on quoted market prices. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities are recorded in Accumulated other comprehensive income on the Company s condensed consolidated balance sheets. Realized gains and losses from the sale or maturity of available-for-sale investments are recorded in Other income (expense), net on the Company s condensed consolidated statements of operations. The cost of securities sold is based on the specific identification method. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest expense.

The Company also 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. Other-than-temporary declines in market value are recorded in Other expense, net on the Company s condensed consolidated statements of operations.

As of June 30, 2011, 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 June 30, 2011 and December 31, 2010.

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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, which is in accordance with its investment policy. At June 30, 2011, 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 balance sheets. 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 condensed consolidated statement of operations. The Company had recorded allowances for potentially uncollectible accounts receivable of approximately $0.1 million at both June 30, 2011 and December 31, 2010. Actual collection losses may differ from management s estimate, and such differences could have a material impact to the Company s financial position and results of operations.

The Company had three customers each accounting for more than 10% of the Company s outstanding trade receivables, which accounted for approximately 57% and 54% of outstanding trade receivables at June 30, 2011 and December 31, 2010, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

Inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, UVA illumination devices (illuminators), and certain replacement parts for the illuminators. Platelet and plasma system disposable kits generally have two-year life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured over a protracted length of time, which can exceed one year, before being incorporated and assembled by Fenwal, Inc. (Fenwal) into the finished INTERCEPT disposable kits.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or market value. The Company frequently reviews the composition of inventory to identify obsolete, slow-moving or otherwise unsalable items. To the extent unsalable items are observed and there is no alternative use, the Company writes-down its inventory to net realizable value in the period that it is first recognized. The write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of product revenue on the Company s condensed consolidated statements of operations. At June 30, 2011 and December 31, 2010, the Company had $0.2 million and $0.4 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.

Goodwill and Intangible Assets, net

Goodwill and intangible assets, net is derived at the time of a business acquisition, in which the Company assigns the total consideration transferred to the acquired assets based on each asset s fair value and any residual amount becomes goodwill, an indefinite life intangible asset. Intangible assets, net, which include the INTERCEPT Asia license, are subject to periodic amortization over the estimated useful life of ten years. The amortization of the Company s intangible assets, net, is recorded in Amortization of intangible assets on the Company s condensed consolidated statements of operations.

Goodwill is not amortized but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that they may be impaired. The Company evaluates goodwill on an annual basis as of the end of the third quarter of each fiscal year. The test for goodwill impairment is a two-step process. The first step compares the fair value of

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each reporting unit with its respective carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired and, therefore, the second step of the impairment test is unnecessary. The second step, which is used to measure the amount of impairment loss, compares the implied fair value of each reporting unit s goodwill with the respective carrying amount of that goodwill. If the carrying amount of the reporting unit s goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. Management has determined that it operates as a single reporting unit and therefore evaluates goodwill impairment at the enterprise level. There were no impairment charges during the three or six months ended June 30, 2011.

See Note 5 in the Notes to condensed consolidated financial statements for further information regarding the valuation of goodwill and intangible assets, net.

Long-lived Assets

The Company evaluates its long-lived assets for impairment by continually monitoring 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 expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the 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 six months ended June 30, 2011 and 2010.

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 condensed consolidated statements of operations. The Company recorded foreign currency losses of $0.3 million and $1.0 million during the three months ended June 30, 2011 and 2010, respectively, and $1.1 million during the six months ended June 30, 2010. The Company recorded foreign currency gains of $0.4 million during the six months ended June 30, 2011.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation Stock Compensation.* Stock-based compensation expense 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, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

For stock-based awards issued to non-employees, 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 to be the earlier of 1) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or 2) the date at which the grantee performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee stock-based awards in its condensed consolidated statements of operations.

See Note 10 in the Notes to condensed consolidated financial statements for further information regarding the Company s stock-based compensation assumptions and expenses.

Warrant Liability

In August 2009 and November 2010, the Company issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively. The material terms of the warrants were identical under each issuance except for the exercise price, date issued and expiration date. The fair value of these outstanding warrants, calculated using the binomial-lattice option-pricing model, is classified as a liability on the condensed consolidated balance sheets and is adjusted at each subsequent reporting period, until the warrants are exercised or are modified to remove the provisions which require this treatment. Gains and losses from warrant revaluation are recorded in Loss from revaluation of warrant liability on the condensed consolidated statements of operations. During the three and six months ended June 30, 2011, the Company recorded non-cash charges of $0.3 million and $1.6 million, respectively, associated with changes in the fair value of the warrants from December 31, 2010. During the three and six months

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ended June 30, 2010, the Company recorded non-cash charges of $0.7 million and $1.6 million, respectively, associated with changes in the fair value of the warrants from December 31, 2009. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders equity and no further adjustment to the fair value would be made in subsequent periods.

See Note 9 in the Notes to condensed consolidated financial statements for further information regarding the Company s valuation of warrant liability.

Other Comprehensive Income

The components of comprehensive loss include net loss and other comprehensive income. The Company s only component of other comprehensive income for the three and six months ended June 30, 2011 and 2010 consisted of unrealized gains from the Company s available-for-sales short-term investments. Other comprehensive income is reported as a separate component of stockholders equity.

Income Taxes

The Company accounts for income taxes using an asset and liability approach 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 Topic 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 June 30, 2011 or December 31, 2010. The Company recognizes accrued interest 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. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company s tax years 2006 through 2010 remain subject to examination by the taxing jurisdictions.

Net Loss Per Share

Basic loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted loss per share uses the same weighted average number of common shares outstanding for the period as calculated for the basic loss per share as the inclusion of any commons stock equivalents would be anti-dilutive. If the Company earned net income, diluted earnings per share would assume conversion of all potentially dilutive securities, such as stock options, convertible preferred stock, warrants and restricted stock units.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per common share for the three and six months ended June 30, 2011 and 2010 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Numerator:				
Net loss	($ 6,313)	($ 5,559)	($ 11,323)	($ 10,832)
Denominator:				
Basic weighted average number of common shares outstanding	47,620	38,940	47,530	38,880
Effect of dilutive potential common shares resulting from convertible preferred stock, stock options, restricted stock units, warrants and ESPP shares	0	0	0	0
Diluted weighted average number of common shares outstanding	47,620	38,940	47,530	38,880
Net loss per common share:				
Basic	($ 0.13)	($ 0.14)	($ 0.24)	($ 0.28)

Diluted	($ 0.13)	($ 0.14)	($ 0.24)	($ 0.28)

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 for the three and six months ended June 30, 2011 and 2010 (shares in thousands):

	Three Months Ended June, 30		Six Months Ended June, 30	
	2011	2010	2011	2010
Weighted average of anti-dilutive common shares	13,635	9,102	13,592	9,206

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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 that the Company is a party to, 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 known and are estimable. There have been very few warranty costs incurred through June 30, 2011, and the company is unaware of any future warranty claims. Accordingly, at June 30, 2011 and December 31, 2010, the Company did not accrue for any potential future warranty costs.

Fair Value of Financial Instruments

The Company applies the provisions of fair value 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 Company measures and records certain financial assets and liabilities at fair value on a recurring basis, including its available-for-sale securities and warrant liability. The Company classifies instruments within Level 1 if quote prices are available in active markets, which include its money market funds as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. The Company classifies instruments in Level 2 if the instruments 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 instruments include the Company s available-for-sale securities related to United States government agencies and corporate debt securities. The available-for-sale securities 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 classifies instruments in Level 3 if one or more significant inputs or significant value drivers are unobservable, which include its warrant liability.

See Note 2 in the Notes to condensed consolidated financial statements for further information regarding the Company s valuation on financial instruments.

New Accounting Pronouncements

In May 2011, the FASB issued updated fair value measurement guidance under ASU No. 2011-14 *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs,* surrounding changes in the valuation premise of highest and best use of an asset, the application of premiums and discounts, and enhanced disclosure requirements. Under ASU No. 2011-14, the measurement of fair value of financial instruments will primarily be measured at the level of the unit of account whereas it was historically able to utilize the valuation premise of highest and best use of an asset, which can be applied primarily to measuring the fair value of nonfinancial assets only going forward. In addition, the application of blockage factors and other premiums and discounts in a fair value measurement will be prohibited in the valuation of all fair value levels of the hierarchy. The new disclosure requirements include, but are not limited to, further qualitative and quantitative discussions regarding level 3 fair value measurements, specifically significant unobservable inputs used, description of the valuation processes and sensitivity analysis, the disclosure of any transfers and the reasons thereof between levels 1 and 2, and the determination of assets and liabilities that are not recorded at fair value to be categorized under the fair value hierarchy. The updated fair value measurement guidance is effective for interim and annual periods beginning after December 15, 2011, which will begin for the Company on January 1, 2012. The Company does not anticipate that the additional disclosure requirements will have a material impact on the condensed consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05 *Presentation of Comprehensive Income,* which eliminates the presentation of other comprehensive income from the consolidated statements of stockholders equity. Instead, companies would have the option to display net income and other comprehensive income in two separate, but consecutive statements or combine net income and other comprehensive income in one continuous statement, which would be referred to the consolidated statements of comprehensive income. The new presentation requirements under this guidance are effective for interim and annual periods beginning after December 15, 2011, which will begin for the Company on January 1, 2012, and retrospective application is required for all periods presented. The Company does not anticipate that the additional disclosure requirements will have a material impact on the condensed consolidated financial statements.

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Note 2. Fair Value on Financial Instruments

The fair values of certain of the Company s financial assets and liabilities were determined using the following inputs at June 30, 2011 (in thousands):

	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]	$ 6,599	$ 6,599	$ 0	$ 0
Corporate debt securities [2]	0	0	0	0
United States government agency securities [2]	613	0	613	0
Total financial assets	$ 7,212	$ 6,599	$ 613	$ 0
Warranty liability [3]	$ 10,082	$ 0	$ 0	$ 10,082
Total financial liabilities	$ 10,082	$ 0	$ 0	$ 10,082

The fair values of certain of the Company s financial assets were determined using the following inputs at December 31, 2010 (in thousands):

	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]	$ 6,178	$ 6,178	$ 0	$ 0
Corporate debt securities [2]	73	0	73	0
United States government agency securities [2]	988	0	988	0
Total financial assets	$ 7,239	$ 6,178	$ 1,061	$ 0
Warranty liability [3]	$ 8,465	$ 0	$ 0	$ 8,465
Total financial liabilities	$ 8,465	$ 0	$ 0	$ 8,465

(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.

A reconciliation of the beginning and ending balances for warrant liabilities using significant unobservable inputs (Level 3) from December 31, 2010 to June 30, 2011 was as follows (in thousands):

Balance at December 31, 2010	$ 8,465
Issuance of warrants	0
Change in revaluation	1,617
Balance at June 30, 2011	$ 10,082

The Company did not have any transfers amongst fair value measurement levels during the six months ended June 30, 2011.

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

The following is a summary of cash, cash equivalents and short-term investments at June 30, 2011 (in thousands):

	Carrying Value	Gross Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	$ 10,568	$ 0	$ 10,568
Money market funds	6,599	0	6,599
Total cash and cash equivalents	17,167	0	17,167
Short-term investments:			
Corporate debt securities	0	0	0
United States government agency securities	612	1	613
Total short-term investments	612	1	613
Total cash, cash equivalents and short-term investments	$ 17,779	$ 1	$ 17,780

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

	Carrying Value	Gross Unrealized Gain	Fair Value
Cash and cash equivalents:			
Cash	$ 22,770	$ 0	$ 22,770
Money market funds	6,178	0	6,178
Total cash and cash equivalents	28,948	0	28,948
Short-term investments:			
Corporate debt securities	14	59	73
United States government agency securities	939	49	988
Total short-term investments	953	108	1,061
Total cash, cash equivalents and short-term investments	$ 29,901	$ 108	$ 30,009

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

	June 30, 2011		December 31, 2010	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Due in one year or less	$ 6,599	$ 6,599	$ 6,178	$ 6,178
Due greater than three years and less than five years	612	613	953	1,061
Total cash equivalents and short-term investments	$ 7,211	$ 7,212	$ 7,131	$ 7,239

The maturities of certain short-term investments were estimated primarily based upon assumed prepayment features and credit enhancement characteristics.

Gross realized gains from the sale or maturity of available-for-sale investments were minimal during the three and six months ended June 30, 2011 and 2010. The Company did not record any gross realized losses from the sale or maturity of available-for-sale investments during the three and six months ended June 30, 2011 and 2010, nor did it record losses on investments experiencing an other-than-temporary decline in fair value during the three and six months ended June 30, 2011. The Company recorded minimal losses on investments experiencing an other-than-temporary decline in fair value for the three and six months ended June 30, 2010.

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Note 4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2011	December 31, 2010
Work-in-process	$ 3,866	$ 2,652
Finished goods	6,102	3,305
Total inventories	$ 9,968	$ 5,957

Note 5. Goodwill and Intangible Assets, net

Goodwill

During the three and six months ended June 30, 2011, there were no impairment charges recognized and the Company did not dispose of or recognize additional goodwill. As a result, at both June 30, 2011 and December 31, 2011, the carrying amount of goodwill was $1.3 million, which resulted from the August 2010 acquisition of certain assets from BioOne, a privately held Japanese company established to develop technologies to improve the safety of blood products in Asia.

Intangible Assets, net

The following is a summary of intangible assets, net at June 30, 2011 (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
License - INTERCEPT Asia	$ 2,017	($ 168)	$ 1,849
Total intangible assets	$ 2,017	($ 168)	$ 1,849

The following is a summary of intangible assets, net at December 31, 2010 (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
License - INTERCEPT Asia	$ 2,017	($ 67)	$ 1,950
Total intangible assets	$ 2,017	($ 67)	$ 1,950

The Company recognized $0.05 million and $0.1 million in amortization expense related to intangible assets for the three and six months ended June 30, 2011. During the three and six months ended June 30, 2011, there were no impairment charges recognized and the Company did not renew or extend the term of the acquired intangible assets.

The expected annual amortization expense of the intangible assets, net at June 30, 2011 are $0.1 million for the remaining six months of 2011, $0.2 million each subsequent year thereafter through December 31, 2019 and $0.1 million in 2020.

Note 6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2011	December 31, 2010
Accrued compensation and related	$ 1,299	$ 1,861
Accrued inventory	1,847	1,424
Accrued contract and other accrued expenses	2,188	2,718
Total accrued liabilities	$ 5,334	$ 6,003

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Note 7. Commitments and Contingencies

Operating Leases

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

Royalties

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

Purchase Commitments

The Company is party to agreements with certain providers for certain components of INTERCEPT blood safety system which the Company purchases from third party manufacturers and supplies to Fenwal at no cost for use in manufacturing finished disposable kits. Certain of these agreements require minimum purchase commitments from the Company.

Note 8. Long-term Note Payable

Long-term note payable at June 30, 2011 consisted of the following (in thousands):

	Principal	Unamortized Discount	Total
Current portion of long-term debt	$ 1,935	($ 59)	$ 1,876
Long-term debt	2,181	(22)	2,159
Total long-term note payable	$ 4,116	($ 81)	$ 4,035

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

	Principal	Unamortized Discount	Total
Current portion of long-term debt	$ 1,822	($ 75)	$ 1,747
Long-term debt	3,178	(47)	3,131
Total long-term note payable	$ 5,000	($ 122)	$ 4,878

On March 31, 2010, the Company entered into a growth capital facility agreement and immediately issued a senior secured long-term note payable for $5.0 million. The 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, which will be accreted to interest expense using the effective interest method over the life of the note. In March 2011, the Company entered into an amendment to its growth capital facility. Under the terms of the amendment, the Company may borrow an additional $5.0 million through September 30, 2011. 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. In addition, the amendment modifies the covenants under which the Company must comply. Under the amended agreement, 2011 revenues, on a trailing six-month basis, are required to be at least 80% of projected revenues. Revenues for 2012 and beyond are required to be at least 5.7 million per quarter. Non-compliance with the covenants could result in the principal of the note becoming due and payable. As of June 30, 2011, the Company was in compliance with financial covenants set forth in the amended growth capital facility.

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Principal and interest payments on the long-term note payable at June 30, 2011 for each of the following five years are as follows (in thousands):

Year ended December 31,	
2011	1,163
2012	2,326
2013	1,782
2014	0
2015	0

Note 9. Stockholders Equity

Series B Preferred Stock

Fenwal holds 3,327 shares of the Company s Series B preferred stock. The holder of 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 preferred stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder may convert each share of Series B preferred stock into 100 shares of the Company s common stock. If all shares of Series B preferred stock were converted to common stock, 332,700 shares of common stock would be issued, which represents approximately 1% of the outstanding common stock of the Company at June 30, 2011. 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 Associated 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.

In November 2010, the Company received net proceeds of approximately $19.7 million, after deducting underwriting discounts and commissions and stock issuance costs of approximately $1.3 million, from an underwritten public offering of 7.4 million units. Each unit sold consisted of one share of common stock and a warrant to purchase 1/2 of a share of common stock. Each unit was sold for $2.85, resulting in the issuance of 7.4 million shares of common stock and warrants to purchase 3.7 million shares of common stock, exercisable at an exercise price of $3.20 per share. The warrants contain certain provisions that, under certain circumstances that 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 fair value of the August 2009 and November 2010 warrants is recorded on the consolidated condensed balance sheets 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 and will be adjusted to fair value at each financial reporting date thereafter until the earlier of exercise or expiration, at which time, these warrants would be reclassified into stockholders equity.

These offerings were made pursuant to the Company s shelf registration statement on Form S-3.

2009 Warrants

The warrants issued in August 2009 are exercisable for a period of five years from the issue date. The fair value on the date of issuance of the warrants was determined to be $2.8 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 2.48%, (ii) an expected term of 5.0 years, (iii) no dividend yield and (iv) a volatility of 77%.

At June 30, 2011, the fair value of the warrants issued in August 2009 was determined to be approximately $3.9 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 0.81%, (ii) an expected term of 3.15 years, (iii) no dividend yield and (iv) a volatility of 81%.

2010 Warrants

The warrants issued in November 2010 are exercisable beginning on May 10, 2011 and are exercisable for a period of five years from the issue date. The fair value on the date of issuance of the warrants was determined to be $5.8 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 1.23%, (ii) an expected term of 5.0 years, (iii) no dividend yield and (iv) a volatility of 85%.

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At June 30, 2011 the fair value of the warrants issued in November 2010 was determined to be approximately $6.2 million using the binomial-lattice option valuation model applying the following assumptions: (i) a risk-free rate of 1.29%, (ii) an expected term of 4.37 years, (iii) no dividend yield and (iv) a volatility of 74%.

For the three months ended June 30, 2011 and 2010, due to the increase in fair value of the warrants, the Company recorded losses of $0.3 million and $0.6 million, respectively, on its condensed consolidated statement of operations within non-operating income (expense), net. For the six months ended June 30, 2011 and 2010, due to the increase in fair value of the warrants, the Company recorded losses of $1.6 million for each period on its condensed consolidated statement of operations within non-operating income (expense), net. At June 30, 2011, no warrants had been exercised.

At-the-Market Agreement

In June 2011, the Company entered into an agreement (the Sales Agreement) with McNicoll, Lewis & Vlak LLC (MLV), which allows the Company to offer and sell shares of its common stock up to an aggregate price of $20.0 million through MLV. In conjunction with the sales agreement, MLV will act as the Company s sales agent and will receive compensation based on an aggregate of 3% of the gross proceeds on the sale price per share of its common stock. Any sales made pursuant to the sale agreement are deemed an at-the-market offering and would be made pursuant to the Company s shelf registration statement on Form S-3. The Company did not place common stock under the Sales Agreement during the three months ended June 30, 2011.

Stockholder Rights Plan

In October 2009, the Company s Board of Directors adopted an amendment to its 1999 stockholder rights plan, commonly referred to as a poison pill, to reduce the exercise price, extend the expiration date and revise certain definitions under the plan. The stockholder rights plan is intended to deter hostile or coercive attempts to acquire the Company. The stockholder rights plan enables stockholders to acquire shares of the Company s common stock, or the common stock of an acquirer, at a substantial discount to the public market price should any person or group acquire more than 15% of the Company s common stock without the approval of the Board of Directors under certain circumstances. The Company has designated 250,000 shares of Series C Junior Participating preferred stock for issuance in connection with the stockholder rights plan.

Note 10. Stock-Based Compensation

The Company maintains an equity incentive plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. 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. 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 its Senior Management. 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 Black-Scholes option pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and subjective variables, which 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.

Total stock-based compensation recognized on the Company s condensed consolidated statements of operations for the three and six months ended June 30, 2011 and 2010, was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Stock-based compensation expense by caption:				
Research and development	$ 111	$ 99	$ 220	$ 162

Selling, general and administrative	340	374	703	636
Total stock-based compensation expense	$ 451	$ 473	$ 923	$ 798

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The Company did not record any stock-based compensation associated with the stock options exercisable for 50,000 shares of Common Stock with performance based vesting during the three and six months ended June 30, 2011 and 2010 as the performance criteria was not probable of being achieved. These performance-based stock options remain outstanding at June 30, 2011.

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, 2010	7,007	$ 6.42
Granted	723	2.66
Cancelled	(728)	14.24
Exercised	(11)	0.94
Balances at June 30, 2011	6,991	$ 5.22

Note 11. Comprehensive Loss

Comprehensive loss and its components for the three and six months ended June 30, 2011, and 2010 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net loss	($ 6,313)	($ 5,559)	($ 11,323)	($ 10,832)
Other comprehensive loss:				
Net unrealized loss on available-for-sale securities	(22)	39	(107)	86
Comprehensive loss	($ 6,335)	($ 5,520)	($ 11,430)	($ 10,746)

Note 12. Development and License Agreements

Agreements with Fenwal, Related Party

In December 2009, the Company and Baxter International Inc. (Baxter) entered into a settlement agreement regarding disputed amounts for certain transition services provided in 2006 by Baxter in conjunction with the transfer of commercialization rights to the Company. In consideration for agreeing to the settlement, with both parties waiving all rights and obligations, the Company agreed to pay Baxter $0.5 million, which was recorded as a payable on its December 31, 2009 consolidated balance sheet, and subsequently paid by the Company in 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, and 6.5% on sales of illuminators. During the three months ended June 30, 2011 and 2010, the Company made royalty payments to Fenwal of $0.5 million and $0.4 million, respectively, and $1.0 million and $0.8 million during the six months ended June 30, 2011 and 2010, respectively. At June 30, 2011 and December 31, 2010, the Company owed royalties to Fenwal of $0.6 million and $0.5 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 to be paid or refunded if actual manufacturing volumes are lower or higher than the estimated production volumes. The Company made payments to Fenwal of $4.1 million and $1.3 million relating to the manufacturing of the Company products during the three months ended June 30, 2011, and 2010, respectively, and

$6.3 million and $4.7 million during the six months ended June 30, 2011 and 2010, respectively. At June 30, 2011 and December 31, 2010, the Company owed Fenwal $3.4 million and $2.3 million, respectively, for INTERCEPT disposable kits manufactured.

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Cooperative Agreements with the United States Armed Forces

Since February 2001, the Company has received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received these awards in order to develop its pathogen inactivation technologies for the improved safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the conditions of the agreements, the Company is conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that are of concern to the United States Armed Forces. This funding supports advanced development of the Company s red blood cell system. The Company recognized $0 and $0.2 million of revenue under these agreements during the three months ended June 30, 2011, and 2010, respectively, and $0.4 million and $0.5 million for the six months ended June 30, 2011 and 2010, respectively.

Note 13. Segment, Customer and Geographic Information

At June 30, 2011 and 2010, 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 loss of the blood safety segment.

During the three and six months ended June 30, 2011 and 2010, the Company had the following significant customers listed as a percentage of product revenue:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Movaco, S.A. (Spain and other EU countries)	27%	15%	27%	20%
Etablissement Francais du Sang (France)	15%	19%	20%	22%
Service Francophone du Sang (Belgium)	*	12%	*	13%
Delrus Inc. (CIS countries)	*	21%	*	16%

* Represents an amount less than 10% of product revenue.

Each of the above customers operates in a country outside of the United States. During both the six months ended June 30, 2011 and 2010, the Company also recognized government grants and cooperative agreement revenue which represented 4% of total revenue in each period. During the three months ended June 30, 2010, the Company recognized government grants and cooperative agreement revenue which represented 3% of total revenue. No revenue was recognized from government grants and cooperative agreement during the three months ended June 30, 2011.

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

This discussion and analysis should be read in conjunction with our 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, 2010. Operating results for the three and six months ended June 30, 2011 are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. The forward-looking statements are contained principally in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations and in Item 1A, 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 System, the anticipated progress of our research, development and clinical programs, our ability to manage cost increases associated with pre-clinical and clinical development for the INTERCEPT Blood System, our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System, the ability of our products to inactivate pathogens that may emerge in the future, 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. Certain important factors could cause actual results to differ materially from those discussed in such statements, including our need for additional financing, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products, market acceptance of our products, reimbursement, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fenwal and third parties to manufacture certain components of the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete certain of our product components commercial design, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our limited operating history and expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, legal proceedings, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002 and other factors discussed below and under the caption Risk Factors, in Item 1A of this Quarterly Report on Form 10-Q and in our other documents filed with the Securities and Exchange Commission. 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.

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, or collectively known as our INTERCEPT Blood System. Our INTERCEPT platelet system, or the platelet system, and our INTERCEPT plasma system, or the plasma system, have received CE marks and are being marketed in a number of countries in Europe, The Commonwealth of Independent States, or CIS, and the Middle East and selected countries in other regions around the world. In addition, we plan to continue development of our INTERCEPT red blood cell system, or the red blood cell system. Subject to the availability of adequate funding from partners, government grants and/or capital markets, we also plan to pursue regulatory approval of the platelet and plasma systems in the United States.

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 red blood cell system, costs associated with pursuing regulatory approval in geographies where we do not currently sell INTERCEPT, 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

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private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations. We believe that cash received from product sales and our available cash balances, net of debt owed, 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 may borrow additional capital from institutional and commercial banking sources to fund future growth on terms that 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 that we raise additional capital by issuing equity securities, including common stock issued pursuant to the Sales Agreement, as described below, 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 disruptions to the global credit and financial markets and general economic uncertainty has generally made equity and debt financing more difficult to obtain and the terms less favorable to the companies seeking to raise financing. 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 reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets and general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities.

Historically, we have received significant awards in funding under cooperative agreements with the United States Department of Defense, or DoD, for the INTERCEPT Blood System. Any such funding is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount of government funding available. Further funding awarded under federal grants and cooperative agreements for the INTERCEPT Blood System may continue to decline in the future. This risk is enhanced by the deficit reduction initiatives currently underway in the United States Congress. If we are unable to obtain federal grant and cooperative agreement funding for the continued development of the INTERCEPT Blood Systems 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. We recognize growing, but still relatively modest, product revenues from the sale of our platelet and plasma systems in Europe, the CIS countries, the Middle East, and certain other countries. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our product candidates, which, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses at least until after our platelet and plasma systems gain widespread commercial adoption in markets where our products are approved for commercialization and 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.

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

In 2007, we spun-off our immunotherapy business, and in 2009 entered into agreements to license the immunotherapy technologies to Aduro BioTech, or Aduro. In connection with those agreements, we received and currently hold preferred shares representing less than 10% of Aduro s capital. Pursuant to these license agreements, we will obtain a 1% royalty fee on any future sales resulting from certain 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 to determine that such equity will have monetary value at such time we are allowed to sell it or that we will receive any royalties from Aduro.

In August 2010, we completed an acquisition of certain assets of BioOne Corporation, or BioOne, including the commercialization rights that Baxter International Inc. (later Fenwal) and we had granted to BioOne for both the platelet and plasma systems. Concurrently with the acquisition, Fenwal and we terminated such commercialization rights. As a consequence of the termination, and pursuant to a pre-existing agreement with Fenwal, our commercialization rights to the platelet and plasma systems under our 2005 and 2006 agreements with Baxter International Inc. became worldwide. As consideration for the acquired BioOne assets, at the closing of the acquisition, we issued 937,886 shares of our common stock to BioOne and relinquished all of the shares we previously held in BioOne. In addition, six months from the closing date of the acquisition, we issued an additional 234,471 shares of our stock to BioOne. Accordingly, at December 31, 2010, we had recorded the

fair value of the assets acquired, consisting of

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commercialization rights of $2.0 million and illuminators of $0.4 million with the excess of the purchase price over the fair value of the asset acquired being recorded as goodwill. The $1.3 million in goodwill represents the buyer-specific value derived by Cerus as a result of acquiring the commercialization rights in certain Asian countries in order to complete the global commercialization rights for platelets and plasma.

In June 2011, we entered into an At-The-Market Issuance Sales Agreement, or Sales Agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we may, but are not required to, issue and sell shares of our common stock having an aggregate offering price of up to $20.0 million from time to time through MLV as our sales agent.

Through June 30, 2011, 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. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventory valuation, accrued liabilities, valuation and impairment of purchased intangibles and goodwill, non-cash stock compensation assumptions, and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

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

Revenue We recognize revenue in accordance with the 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.

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 defective or 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. Prior to adoption of ASU No. 2009-13, consideration received was allocated to elements that were identified as discrete units of accounting based on the relative fair value method. Beginning January 1, 2011, consideration received is allocated to elements that are identified as discrete units of accounting based on the best estimated selling price, or BESP. We have determined that VSOE is not discernable due to our limited history of selling our products and variability in our pricing. Since our products are novel and unique and are not sold by others, third-party evidence of selling price is unavailable. Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs* 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, UVA 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, 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 without production as a component of cost of product revenue.

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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. Illumination devices 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 to net realizable value in the period that it is first recognized, by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. The write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of product revenue on our condensed consolidated statements of operations.

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.

Intangible assets and goodwill In August 2010, we acquired certain assets from BioOne. We accounted for the acquisition as a business combination in accordance with ASC Topic 805, *Business Combinations.* In connection with the acquisition, we used significant judgment, including, but not limited to, judgments as to cash flows, discount rates, and economic lives, in identifying the assets acquired and in determining the fair values to record the purchased assets on our condensed consolidated balance sheet. In addition, under ASC Topic 805, we were required to assess the fair value of the non-controlling interest that we held in BioOne prior to the acquisition. We determined that a considerable amount of the purchase consideration was goodwill, which represents value unique to Cerus as the holder of worldwide rights to the INTERCEPT Blood System. We may be unable to realize the recorded value of the acquired assets and our assumptions may prove to be incorrect, which may require us to write-down or impair the value of the assets if and when facts and circumstances indicate a need to do so. We will perform an impairment test on our goodwill annually during the end of the third quarter of each fiscal year or more frequently if indicators of impairment exist. The test for goodwill impairment is a two-step process. The first step compares the fair value of each reporting unit with the respective carrying amount, including goodwill. If the fair value of the reporting unit exceeds the carrying amount, goodwill of the reporting unit is not considered impaired and, therefore, the second step of the impairment test is unnecessary. The second step, which is used to measure the amount of impairment loss, compares the implied fair value of each reporting unit s goodwill with the respective carrying amount of that goodwill. If the carrying amount of the reporting unit s goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. We will perform an impairment test on our intangible assets by continually monitoring events and changes in circumstances that could indicate carrying amounts of our intangible assets may not be recoverable. When such events or changes in circumstances occur, we assess recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, we then measure the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets.

Warrants In August 2009 and November 2010, we issued warrants to purchase 2.4 million and 3.7 million shares of common stock, respectively. The material terms of the warrants were identical under each issuance except for the exercise price, date issued and expiration date. The fair value of these outstanding warrants, which uses the binomial-lattice option-pricing model, is classified as a liability on the condensed consolidated balance sheet and is adjusted at each subsequent reporting period, until they are either exercised or are otherwise modified to remove the provisions which require this treatment. Gains and losses from warrant revaluation are recorded in Loss from revaluation of warrant liability on the condensed consolidated statements of operations. The binomial-lattice option-pricing model requires that we use significant assumptions and judgment to determine appropriate inputs to the model. Some of the assumptions that we rely on include probability of a change of control occurring, the volatility of our stock over the life of the warrant, and assumptions and inputs used to value the warrants under the Black-Scholes model should a change of control occur. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders equity and no further adjustment to the fair value would be made in subsequent periods.

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 also maintain an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. We recorded stock-based compensation expense for employee awards in accordance with ASC Topic 718, *Compensation Stock Compensation.* We use the Black-Scholes option pricing model to determine the grant-date fair value of a stock award. The Black-Scholes option pricing model requires that we use assumptions regarding a number of complex and subjective variables to determine appropriate inputs to the model, which include the expected term of the grants, our expected stock price volatility, actual and projected employee stock option exercise behaviors,

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including forfeitures, the risk-free interest rate and expected dividends. The grant-date fair value of a stock award is then recognized as stock-based compensation expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved. We continue to apply the provisions of ASC Topic 505-50, *Equity Based Payment to Non-Employees* for our stock-based awards issued to non-employees. 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.

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 June 30, 2011 or December 31, 2010. We recognize accrued interest and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our condensed consolidated 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. Our tax years 2006 through 2010 remain subject to examination by the taxing jurisdictions.

Results of Operations

Three and Six Months Ended June 30, 2011 and 2010

Revenue

(in thousands, except percentages)	Three Months Ended June 30, 2011	2010	Change		Six Months Ended June 30, 2011	2010	Change	
Product revenue	$ 6,753	$ 5,690	$ 1,063	19%	$ 12,936	$ 11,190	$ 1,746	16%
Government grants and cooperative agreements	0	245	(245)	(100)%	436	467	(31)	(7)%
Total revenue	$ 6,753	$ 5,935	$ 818	14%	$ 13,372	$ 11,657	$ 1,715	15%

Product revenue increased by $1.1 million and $1.7 million for the three and six months ended June 30, 2011 compared to the three and six months ended June 30, 2010, respectively, primarily as a result of an increase in sales volume of our disposable platelet and plasma system kits sold to customers, which was partially offset by a decline in the sales volume of our illuminators. Sales of disposable platelet and plasma system kits directly to existing customers continued to grow due to increased market penetration and customer adoption of the INTERCEPT Blood System in Europe, the CIS countries, and the Middle East. We expect product revenues for both the platelet and plasma systems will continue to increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway. These quarterly results may not be indicative of INTERCEPT Blood System revenue in the future.

Revenue from government grants and cooperative agreements decreased by $0.2 million for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 as we consumed the remaining available funds for reimbursement under current awards with the DoD for research activities related to our red blood cell system during the three months ended March 31, 2011. Revenue from government grants and cooperative agreements was relatively consistent during the six months ended June 30, 2011 and 2010.

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, provisions for obsolete, slow-moving and unsaleable product, certain order fulfillment costs and to the extent applicable, costs for idle facilities.

Inventory is accounted for on a first-in, first-out basis.

(in thousands, except percentages)	Three Months Ended June 30, 2011	2010	Change		Six Months Ended June 30, 2011	2010	Change	
Cost of product revenue	$ 3,978	$ 2,934	$ 1,044	36%	$ 7,423	$ 6,092	$ 1,331	22%

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Cost of product revenue increased by $1.0 million and $1.3 million for the three and six months ended June 30, 2011 compared to the three and six months ended June 30, 2010, respectively, primarily due to a higher number of disposable kits sold. We anticipate our cost of product revenue will increase in the future as a result of anticipated increases in future product sales.

Our realized gross margins on product sales were 41% during the three months ended June 30, 2011 down from 48% during the three months ended June 30, 2010. For the six months ended June 30, 2011, our realized gross margins on product sales were 43%, down from 46% for the six months ended June 30, 2010. 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, non-cash stock-based compensation, payments to consultants, costs to prepare and conduct preclinical and clinical trials, third-party costs for development activities, certain regulatory costs, costs for licensed technologies, costs associated with our infrastructure, and laboratory chemicals and supplies.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2011**	**2010**	**Change**		**2011**	**2010**	**Change**	
Research and development	$ 1,994	$ 1,244	$ 750	60%	$ 3,802	$ 2,494	$ 1,308	52%

Research and development expenses increased by $0.8 million and $1.3 million for the three and six months ended June 30, 2011 compared to the three and six months ended June 30, 2010, respectively, primarily due to increased costs related to our efforts to further advance the development of our red blood cell system program. Of the total research and development costs incurred, non-cash stock-based compensation represented $0.1 million for both of the three months ended June 30, 2011 and 2010 and $0.2 million for both of the six months ended June 30, 2011 and June 30, 2010, respectively.

We anticipate our research and development spending will continue to increase over the near term to further our red blood cell system development efforts or pursue regulatory approval for our products 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, non-cash 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.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2011**	**2010**	**Change**		**2011**	**2010**	**Change**	
Selling, general and administrative	$ 6,207	$ 5,304	$ 903	17%	$ 11,735	$ 10,574	$ 1,161	11%

Selling, general, and administrative expenses increased by $0.9 million and $1.2 million for the three and six months ended June 30, 2011 compared to the three and six months ended June 30, 2010, respectively, primarily due to increased spending related to the expansion of our marketing efforts in Europe. Of these amounts, non-cash stock-based compensation represented $0.3 million and $0.4 million for the three months ended June 30, 2011 and 2010, respectively, and $0.7 million and $0.6 million for the six months ended June 30, 2011 and June 30, 2010, respectively.

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

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Amortization of Intangible Assets

Amortization of intangible assets relates to a license to commercialize the INTERCEPT Blood System in certain Asian countries in connection with our acquisition of certain assets from BioOne. The BioOne transaction was accounted for as a business combination under ASC Topic 805, *Business Combination,* which assigned a fair value of $2.0 million to the intangible assets in August 2010. These intangible assets are being amortized over an estimated useful life of ten years and will be reviewed for impairment as facts and circumstances arise.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2011**	**2010**	**Change**		**2011**	**2010**	**Change**	
Amortization of intangible assets	$ 51	$ 0	$ 51	100%	$ 101	$ 0	$ 101	100%

Amortization of intangible assets increased by $0.05 million and $0.1 million for the three and six months ended June 30, 2011 compared to the three and six months ended June 30, 2010, respectively, as the acquisition of purchased intangible assets related to our license to commercialize the INTERCEPT Blood System in certain Asian countries occurred during the second half of 2010.

Acquisition Related Costs, net

Acquisition related costs, net represented transaction costs associated with our acquisition of certain assets of BioOne in 2010. These transaction costs included, but were not limited to, legal fees, transfer agent fees, accounting fees, and consulting fees directly attributable to the business combination.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2011**	**2010**	**Change**		**2011**	**2010**	**Change**	
Acquisition related costs, net	$ 0	$ 132	($ 132)	(100)%	$ 0	$ 383	($ 383)	(100)%

All acquisition related costs, net related to the acquisition of certain assets from BioOne were recorded in 2010, in which $0.1 million and $0.4 million were recorded during the three and six months ended June 30, 2010, respectively. There were no acquisition related costs, net recorded during the three and six months ended June 30, 2011.

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.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2011**	**2010**	**Change**		**2011**	**2010**	**Change**	
Loss from revaluation of warrant liability	($ 339)	($ 653)	$ 314	48%	($ 1,617)	($ 1,615)	($ 2)	(0)%
Foreign exchange gain (loss)	(258)	(975)	717	74%	439	(1,073)	1,512	141%
Interest expense	(220)	(227)	7	3%	(453)	(232)	(221)	(95)%
Other expense, net	(19)	(25)	6	24%	(3)	(26)	23	88%
Total non-operating expense	($ 836)	($ 1,880)	$ 1,044	56%	($ 1,634)	($ 2,946)	$ 1,312	45%

Warrant liability

Loss from revaluation of warrant liability declined by $0.3 million for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 primarily due to the change in the our underlying stock price related to the strike price of the warrants. Loss from revaluation of warrant liability was relatively consistent during the six months ended June 30, 2011 and 2010. In August 2009 and November

2010, we issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively, in connection with offerings of our common stock. The fair value of these outstanding warrants, which uses the binomial-lattice option-pricing model, is classified as a liability on the condensed consolidated balance sheets and is adjusted at each subsequent reporting period, until such time the instruments are exercised or otherwise modified to remove the provisions which require this treatment. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders equity and no further adjustment to the fair value would be made in subsequent periods. Further changes in stock price will result in similar adjustment as needed.

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Foreign exchange gain (loss)

Foreign exchange gain (loss) improved by $0.7 million and $1.5 million for the three and six months ended June 30, 2011 compared to the three and six months ended June 30, 2010, respectively, which was primarily attributable to favorable foreign currency variations between the Euro and U.S. dollar, our functional currency.

Interest expense

Interest expense was relatively consistent during the three months ended June 30, 2011 and 2010. Interest expense increased by $0.2 million for the six months ended June 30, 2011 compared to the six months ended June 30, 2010, primarily due to interest incurred from borrowings on our credit facility, which was entered into on March 31, 2010, and to a lesser extent, from the financing of leasehold improvements for our headquarters.

Other expense, net

Other expense, net was relatively consistent during the three and six months ended June 30, 2011 and June 30, 2010.

We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. We generally hold such investments until such time as we liquidate them to meet an operating cash need. Interest paid on our investment portfolio may decrease and the value of certain securities we hold may decline, which could negatively affect our financial condition, cash flow and reported earnings.

Liquidity and Capital Resources

In recent years, our sources of capital have primarily consisted of public offerings and private placements of equity securities, debt instruments, United States government grants and cooperative agreements, and contribution from product sales, net of expenses, and interest income.

At June 30, 2011, we had cash, cash equivalents and short-term investments of $17.8 million. Net cash used in operating activities was $11.0 million for the six months ended June 30, 2011, compared to $8.3 million during the six months ended June 30, 2010. The increase in net cash used in operating activities was primarily due to changes in our operating assets and liabilities, notably inventory and accounts payable. We significantly increased our inventory balances during the six months ended June 30, 2011. Offsetting this cash consumption was the effect of increases to our accounts payable balances. Net cash provided by investing activities during the six months ended June 30, 2011, was $0.2 million compared to $0.1 million during the six months ended June 30, 2010. Despite increased maturities of investments during the six months ended June 30, 2010, we made offsetting investments in leasehold improvements during that same time as a function of consolidation of our facilities. There were no such offsetting leasehold investments during the six months ended June 30, 2011. In addition, over the past year, as our investments have matured 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 used in financing activities during the six months ended June 30, 2011, was $0.9 million, compared to $5.0 million net cash provided by financing activities during the six months ended June 30, 2010. The decrease in cash provided from financing activities during the six months ended June 30, 2011 was primarily due to proceeds received from the issuance of a long-term note payable issued on March 31, 2010. Working capital decreased to $10.9 million at June 30, 2011, from $22.1 million at December 31, 2010, primarily due to lower balances in cash and investments and increased balances on accounts payable and on our warrant liability, which was only partially offset by higher inventories and increased prepaid assets.

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 red blood cell system, costs associated with pursuing regulatory approval in geographies where we do not currently sell our platelet and plasma 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 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, net of debt owed, 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.

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We may borrow additional capital from institutional and commercial banking sources to fund future growth on terms that 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, including common stock issued pursuant to the Sales Agreement, 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 disruptions to the global credit and financial markets and general economic uncertainty has generally made equity and debt financing more difficult to obtain and the terms less favorable to the companies seeking to raise financing. 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 reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets and general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities.

Historically, we have received substantial funding under cooperative agreements with the DoD for the INTERCEPT Blood System. Any such funding is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount of government funding available. Further funding awarded under federal grants and cooperative agreements for the INTERCEPT Blood systems may continue to decline in the future. This risk is enhanced by the deficit reduction initiatives currently underway in the United States Congress. 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, which registration statement expires in December 2011. We have issued approximately $34.2 million of the securities registered for issuance pursuant to the shelf registration statement.

In June 2011, we entered into the Sales Agreement with MLV, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $20.0 million from time to time through MLV as our sales agent. The issuance and sale of these shares by us under the Sales Agreement, if any, is subject to the effectiveness of our shelf registration statements on Form S-3, initially filed with the SEC in October 2008 and August 2009. Sales of our common stock through MLV, if any, will be made on The NASDAQ Global Market by means of ordinary brokers transactions at market prices, in block transactions or as otherwise agreed by us and MLV. Subject to the terms and conditions of the Sales Agreement, MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are not obligated to make any sales of common stock under the Sales Agreement. The offering of shares of our common stock pursuant to the Sales Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the Sales Agreement and (2) termination of the Sales Agreement. The Sales Agreement may be terminated by MLV or us at any time upon 10 days notice to the other party, or by MLV at any time in certain circumstances, including our undergoing a material adverse change. We will pay MLV an aggregate commission rate equal to 3.0% of the gross proceeds of the sales price per share of any common stock sold through MLV under the Sales Agreement.

Commitments and Off-Balance Sheet Arrangements

Commitments

The following summarizes our commitments at June 30, 2011 (in thousands):

	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Minimum purchase requirements	$ 3,561	$ 2,718	$ 843	$ 0	$ 0
Operating leases	1,966	732	1,043	191	0
Other commitments	1,258	179	301	287	491
Long-term note payable	5,271	2,326	2,945	0	0
Total contractual obligations	$ 12,056	$ 5,955	$ 5,132	$ 478	$ 491

Minimum purchase requirements

Our minimum purchase commitments include certain components of our INTERCEPT blood safety system which we purchase from third party manufacturers and supply to Fenwal at no cost for use in manufacturing finished disposable kits.

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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 have increased. Our facility leases qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on our condensed consolidated balance sheet.

Other commitments

Our other commitments primarily consist of obligations for landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space. 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. Our Concord California lease may be canceled no earlier than December 2014, at which time we would be required to pay for any remaining portion of the landlord financed leasehold improvements. At June 30, 2011, we had an outstanding liability of $1.0 million related to these leasehold improvements.

Long-term note payable

On March 31, 2010, we entered into a growth capital facility agreement, under which we immediately borrowed and issued a senior secured long-term note payable for $5.0 million. 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 are being 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 is being 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, an additional $5.0 million was available to be drawn between September 30, 2010 and December 31, 2010. As of December 31, 2010, we had not drawn down on the additional $5.0 million, and we incurred a non-utilization fee of $0.1 million as a result. In March 2011, we entered into an amendment with the lender. Under the terms of the amended agreement, we may borrow an additional $5.0 million through September 30, 2011. The terms of the additional $5.0 million note would be identical to the first note issued under the growth capital facility. We would not incur any additional upfront facility fees. As of June 30, 2011, we had not drawn down on the additional $5.0 million.

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. Under the amended agreement, our 2011 revenues are required to be at least 80% of our projected revenues on a trailing six-month basis. For 2012 and beyond, our revenues are required to be at least 5.7 million per quarter. As of June 30, 2011 we were in compliance with financial covenants set forth in the growth capital facility.

Financial Instruments

We maintain an investment portfolio of various securities, which are generally classified as available-for-sale and, consequently, are recorded on the condensed consolidated 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 were minimal at June 30, 2011. Unrealized gains totaled $0.1 million at December 31, 2010.

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. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our available-for-sale securities related to United States government agencies and corporate debt securities are classified as Level 2 in the fair value hierarchy, which uses observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. Certain of the investments in our portfolio are subject to general market risk and more specifically, the United States mortgage industry and

financial institutions. We did not

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record any other-than-temporary impairment losses during the three and six months ended June 30, 2011. During the three and six months ended June 30, 2010, we recorded minimal other-than-temporary impairment losses. 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 June 30, 2011, we had no contractual arrangements that create potential material risk for us and are not recognized in our condensed consolidated balance sheets.

New Accounting Pronouncements

In May 2011, the FASB issued updated fair value measurement guidance under ASU No. 2011-14 *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs,* surrounding changes in the valuation premise of highest and best use of an asset, the application of premiums and discounts, and enhanced disclosure requirements. Under ASU No. 2011-14, the measurement of fair value of financial instruments will primarily be measured at the level of the unit of account whereas it was historically able to utilize the valuation premise of highest and best use of an asset, which can be applied primarily to measuring the fair value of nonfinancial assets only going forward. In addition, the application of blockage factors and other premiums and discounts in a fair value measurement will be prohibited in the valuation of all fair value levels of the hierarchy. The new disclosure requirements include, but are not limited to, further qualitative and quantitative discussions regarding level 3 fair value measurements, specifically significant unobservable inputs used, description of the valuation processes and sensitivity analysis, the disclosure of any transfers and the reasons thereof between levels 1 and 2, and the determination of assets and liabilities that are not recorded at fair value to be categorized under the fair value hierarchy. The updated fair value measurement guidance is effective for interim and annual periods beginning after December 15, 2011, which will begin for us on January 1, 2012. We do not anticipate that the additional disclosure requirements will have a material impact on the condensed consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05 *Presentation of Comprehensive Income,* which eliminates the presentation of other comprehensive income from the consolidated statements of stockholders equity. Instead, companies would have the option to display net income and other comprehensive income in two separate, but consecutive statements or combine net income and other comprehensive income in one continuous statement, which would be referred to the consolidated statements of comprehensive income. The new presentation requirements under this guidance are effective for interim and annual periods beginning after December 15, 2011, which will begin for us on January 1, 2012, and retrospective application is required for all periods presented. We do not anticipate that the additional disclosure requirements will have a material impact on the condensed consolidated financial statements.

Additional recent accounting pronouncements that are of significance, or potential significance, to us are set forth in the our Annual report on Form 10-K for the year ended December 31, 2010, filed with the SEC on March 16, 2011 under Note 1 of the Notes to Consolidated Financial Statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three and six months ended June 30, 2011, 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, 2010.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our principal executive officer and principal financial 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 principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective as of June 30, 2011.

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 June 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 principal executive officer and principal financial officer have concluded, that based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objective of our disclosure control system were met.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS
None.

ITEM 1A. RISK FACTORS
Risk Factors

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this report. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business. Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations.

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 our 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. We may be unable to 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, our customers or prospective customers believe that the loss of platelet reduces the efficacy of the transfusion unit, 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. Similarly, although our product has been demonstrated to effectively inactivate spore-forming bacteria, our products have not been shown to be effective in inactivating bacterial spores, once formed. 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 detective 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.

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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 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 is 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, our 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 identify enough cost offsets to afford to purchase our products. Budgetary concerns may be further exacerbated by the economic austerity programs implemented in European countries, which 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. The recently enacted health care reform laws in the United States and proposed restructuring of the Medicare and Medicaid systems have also placed downward pressure on the pricing of medical products.

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 effectively market, promote, distribute, price or sell our products to any of these large customers could significantly delay or even 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 Germany, France, and England. 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. Customers or prospective customers may conduct and complete their own clinical trials before adopting 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. Decisions on product adoption in England are centralized with the National Blood Service and we understand that the National Blood Service has decided to implement bacterial detection testing before considering pathogen inactivation. 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. Before the Japanese Red Cross considers our products, we understand that we may need to commit to making certain product configuration changes in order to allow the INTERCEPT Blood System to integrate with the collection platforms of the Japanese Red Cross.

Adverse market and economic conditions may exacerbate certain risks affecting our business.

Sales of our products are dependent on reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economies and credit and financial markets, including the current sovereign debt crisis in certain countries in Europe and disruptions due to political instability or otherwise, these organizations may be unable to satisfy their reimbursement obligations, or may delay payment for the INTERCEPT Blood System. In addition, political and economic instability in Europe may in turn diminish the value of the Euro, which could reduce our reported product revenue.

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.

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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.

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. For our product candidates, 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. The process of obtaining FDA and other required regulatory approvals is expensive and uncertain, and typically takes a number of years. We may continue to encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

Clinical trials are particularly 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. 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. For instance, clinical trials previously conducted using INTERCEPT-treated plasma for patients with thrombotic thrombocytopenic purpura lasted approximately four years due in part, to the difficulties associated with enrolling qualified patients. Consequently, we may be unable to recruit suitable patients into clinical trials 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.

Outside the United States, regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation.

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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. 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 understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the FDA s questions. In November 2009, we and the FDA presented a proposed clinical trial protocol for a second Phase III clinical trial to the FDA s Blood Product Advisory Committee, or BPAC. Although the BPAC agreed with the proposed trial design, safety endpoints and efficacy endpoints, we believe we will need to reach agreement with the FDA on the means necessary to satisfy the BPAC s request for more stringent safety margins than we had proposed. 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 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 obtained a CE mark approval in Europe for our plasma system in November 2006 and final French approval of INTERCEPT-treated plasma in May 2007. In February 2011, the first approval for use of INTERCEPT-treated plasma was obtained from the Paul Ehrlich Institute by a blood center in Germany. 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.

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 have not submitted any applications for regulatory approval of the plasma system in the United States or any other regions other than in Europe. INTERCEPT-treated plasma was recently granted orphan drug status by the FDA for the treatment of thrombotic thrombocytopenic purpura. Although we have completed clinical trials in this patient population, the FDA may require us to complete additional clinical trials before approval would be granted. Should the FDA require us to complete additional clinical trials, we would need to secure adequate funding before we would initiate a trial.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by BPAC. Should the FDA ask BPAC questions, we expect BPAC to answer those questions and make recommendations to the FDA. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily have to approve those products. If BPAC were to answer FDA questions recommending 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 in the United States, 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. It will require both time and expense to obtain such qualification.

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.

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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 a redesign of 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 difficult or impossible to quantify. We expect 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.

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 and development activities on our red blood cell system 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 our 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.

We plan to initiate a Phase III clinical trial in Europe upon acceptance of a clinical trial application by European regulators. Regulators could require that an additional recovery and lifespan study would need to be completed prior to initiating our planned Phase III clinical trial, which could prolong development of the red blood cell program. Significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain regulatory approval for the product. A number of trial design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical 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 research and development expenses incurred to date in the red blood cell system program. 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.

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, Austria, 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 are 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. 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 certain assets from BioOne, we regained the rights to commercialize the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. 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 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.

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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 a number of countries. We rely on these distributors to obtain any necessary in-country regulatory approvals, market and sell the INTERCEPT Blood System, 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 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. Accordingly, we may be unable to ensure our distributors properly maintain illuminators sold or provide quality technical services to the blood banking customers to which they sell. 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 exposes us to significant risks

INTERCEPT platelet and plasma disposable kits are manufactured and assembled by Fenwal. Fenwal has agreed, through a supply agreement signed with us in December 2008, to manufacture disposable kits for the platelet and plasma systems for us. After 2013, Fenwal may terminate the supply agreement, provided that Fenwal shall have provided us thirty months prior notice of termination. Fenwal is our sole supplier for manufacture of these products. 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 if production of INTERCEPT disposable kits is produced at a facility that also produces Fenwal-branded products. Should production for Fenwal s own products decline, our products may absorb more overhead, which would negatively impact our gross margins. We also have contracts with independent suppliers, including NOVA Biomedical Corporation, or NOVA, for the manufacture of illuminators and certain components of the INTERCEPT Blood System which are manufactured or assembled at facilities not owned by Fenwal. These contractors are our sole suppliers for such components. NOVA has not manufactured illuminators for a number of years. Should NOVA have difficulties manufacturing illuminators, we may not be able to supply customer demand or provide replacement 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. 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 illuminators 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 illuminators 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 used in clinical studies or sold in the United States, our products 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 attempt to establish alternate manufacturers, we will 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

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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.

Our product supply chain requires us to purchase certain components in minimum quantities and may result in a production cycle of more than one year. Significant disruptions to any of the steps in our supply chain process may result in longer productions cycles which could lead to inefficient use of cash.

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.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System compatible with their platforms and may have competing pathogen inactivation technologies. 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.

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Our red blood cell system that was used in our preclinical studies and Phase I red blood cell trial was a prototype of the system to be used in the final products. As a result, we plan 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 the red blood cell system may not be commercially feasible from potential customers perspectives. If we fail to develop commercial versions of the INTERCEPT red blood cell system on schedule, our potential revenue would be delayed or diminished and our potential competitors may be able to bring products to market before we do.

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

We will need to identify and contract with manufacturers who can develop processes to manufacture the compounds used in the red blood cell system. For commercial manufacturing, we will need to demonstrate to regulatory authorities that the commercial scale manufacturing processes comply with government regulations and that the compounds are equivalent to originally licensed compounds. It may be difficult to economically manufacture the red blood cell system on a commercial scale.

If our competitors develop superior products to ours or market their products more effectively than we market our products, our commercial opportunities could 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 customer and prospective customer needs and medical and technological changes brought about by the development and introduction of new products. 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 addition, customers and prospective customers may believe that our competitor s products are safer or more cost effective than INTERCEPT Blood System products. 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. CaridianBCT s product candidate, if successful, may offer competitive advantages over our INTERCEPT Blood System. We understand CaridianBCT was recently acquired by Terumo Corporation, a large Japanese-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly Japan, may be negatively affected by Terumo s resources and their pre-existing relationships with regulators and customers. Other companies developing competing products may also offer and sell other blood-banking products and services. As a result, competitors may have pre-existing long-term relationships with customers and may be able to offer synergies for both pathogen inactivation and non-pathogen inactivation products that we are unable to offer.

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.

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.

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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 red blood cell system, costs associated with pursuing regulatory approval in geographies where we do not currently sell the INTERCEPT Blood System, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive 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, net of debt owed 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 that 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.

The disruptions to the global credit and financial markets and general economic uncertainty has generally made equity and debt financing more difficult to obtain and the terms less favorable to the companies seeking to raise financing. 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 reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets and general economic uncertainty or other factors, we may need to curtail planned development or commercialization

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activities. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, the CIS, the Middle East and in selected countries in other regions around the world. In addition, we are developing and plan to perform the required clinical trials for product approval and commercialization of the red blood cell system. To the extent that we are able to find funding, we will seek regulatory approval of the platelet or plasma systems in the United States.

Historically, we have received significant awards in funding under cooperative agreements with the DoD. 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. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount of government funding available. Further funding awarded under federal grants and cooperative agreements for the INTERCEPT Blood systems may continue to decline in the future. This risk is enhanced by the deficit reduction initiatives currently underway in the United States Congress. If we are unable to obtain federal grant and cooperative agreement funding for future research and development activities at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs.

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 reach agreement on a clinical pathway with the FDA for our platelet or plasma products and if we choose to pursue such opportunities, we would expect to incur substantial costs which could 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, or the Credit Agreement, for $10.0 million, of which we immediately borrowed and issued a note payable for $5.0 million. In March 2011, we entered into an amendment of the Credit Agreement. The amended Credit Agreement and loan are secured by all of our U.S. assets, except for intellectual property. The amended Credit 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 2011, our revenues, on a trailing six-month basis, are required to be at least 80% of our projected revenues. For 2012 and beyond, our revenues are required to be at least 5.7 million per quarter. If we are unable to increase our product revenues to comply with the covenants in the amended 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 us into bankruptcy.

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

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

We 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 patents generally expire at various dates between 2012 and 2027. 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 2016 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.

Our patents do not cover all of the countries in which we are selling, and planning to sell, our products. We will not be able to prevent potential competitors from using our technology in countries where we do not have patent coverage.

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.

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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 certain 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 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.

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, 2009 to June 30, 2011, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of $0.59 to a high of $4.01. 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 common stock issued pursuant to the Sales Agreement, through the exercise of warrants and 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

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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. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

Amendment to 2008 Equity Incentive Plan

On June 1, 2011, at our 2011 Annual Meeting of Stockholders (the Annual Meeting), our stockholders approved an amendment (the Amendment) to our 2008 Equity Incentive Plan (the 2008 Plan) to increase the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 2,000,000 shares. The terms of the 2008 Plan provide for the grant of stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards that may be settled in cash, stock, or other property. Our employees (including officers), consultants and directors, and employees (including officers) and consultants of our affiliates, are eligible participants in the 2008 Plan. The Amendment previously had been approved, subject to stockholder approval, by our Board of Directors. A more detailed summary of the material features of the 2008 Plan is set forth in our definitive proxy statement for the Annual Meeting filed with the Securities and Exchange Commission on April 22, 2011. That summary and the foregoing description is qualified in its entirety by reference to the text of the 2008 Plan, which is filed as Exhibit 10.42 hereto.

Annual Meeting Results

As previously disclosed on a current report on Form 8-K filed with the SEC on June 8, 2011, we held our Annual Meeting of Stockholders on June 1, 2011 (the Annual Meeting). The following is a brief description of each matter voted upon at the Annual Meeting, as well as the number of votes cast for or against each matter and the number of abstentions and broker non-votes with respect to each matter. A more complete description of each matter is set forth in our definitive proxy statement filed with the Securities and Exchange Commission on April 22, 2011.

Each of the three directors proposed by us for re-election was elected by the following votes to serve until our 2014 Annual Meeting of Stockholders or until their respective successor has been elected and qualified. The tabulation of votes on this matter was as follows:

Nominee	Shares Voted For	Shares Withheld
Timothy B. Anderson	16,282,983	460,953
Bruce C. Cozadd	16,249,222	494,714
William M. Greenman	16,372,538	371,398

There were 23,558,270 broker non-votes for this proposal.

Our stockholders also approved an amendment to our 2008 Equity Incentive Plan (the 2008 Plan) to increase the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 2,000,000 shares. The tabulation of votes on this matter was as follows:

Votes For	Votes Against	Votes Abstaining	Broker Non-Votes
14,192,149	2,447,174	104,613	23,558,270

Our stockholders approved, on a non-binding advisory basis, the compensation of our named executive officers. The tabulation of votes on this matter was as follows:

Votes For	Votes Against	Votes Abstaining	Broker Non-Votes
15,670,724	859,504	213,708	23,558,270

Our stockholders approved, on a non-binding advisory basis, a preferred frequency of stockholder advisory votes on the compensation of our named executive officers of One-Year. Based on the voting results for this proposal, we have decided to conduct a stockholder advisory vote on the compensation of our named executive officers in its proxy materials on an annual basis. The tabulation of votes on this matter was as follows:

Three Years	Two Years	One Year	Votes Abstaining	Broker Non-Votes
819,898	1,980,062	13,428,997	514,979	23,558,270

Finally, our stockholders ratified the selection of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2011. The tabulation of votes on this matter was as follows:

Votes For	Votes Against	Votes Abstaining	Broker Non-Votes
39,164,336	1,003,852	134,018	0

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ITEM 6. EXHIBITS

3.1(1)	Restated Certificate of Incorporation of Cerus Corporation.
3.2(2)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(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.
4.6(8)	Form of Warrant to Purchase Common Stock.
10.40(9)(**)	Employment Letter, by and between Cerus Corporation and William M. Greenman, dated May 12, 2011.
10.41(10)	At-The-Market Issuance Sales Agreement, dated June 3, 2011, by and between Cerus Corporation and McNicoll, Lewis & Vlak LLC.
10.42(11)(**)	2008 Equity Incentive Plan, as amended.
31.1(11)	Certification of the Principal Executive Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2(11)	Certification of the Principal Financial Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(11)(*)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS(12)	XBRL Instance Document
101.SCH(12)	XBRL Taxonomy Extension Schema Document
101.CAL(12)	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF(12)	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB(12)	XBRL Taxonomy Extension Label Linkbase Document
101.PRE(12)	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to Cerus Current Report on Form 8-K (No. 333-72185), filed with the SEC on November 12, 1999.
(2) Incorporated by reference to Cerus Quarterly Report on Form 10-Q (File No. 000-21937) for the quarter ended June 30, 2010.
(3) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 000-21937), dated June 17, 2008.
(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 (File No. 000-21937), 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 Current Report on Form 8-K (File No. 000-21937), filed with the SEC on November 12, 2010.
(9) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 000-21937), filed with the SEC on May 18, 2011.
(10) Incorporated by reference to Cerus Current Report on Form 8-K (File No. 000-21937), filed with the SEC on June 6, 2011.
(11) Filed herewith.
(12) XBRL Interactive Data File will be filed by amendment to this Form 10-Q within 30 days of the filing date of this Form 10-Q, as permitted by Rule 405(a)(2)(ii) of Regulation S-T.
(*) 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.

(**) Compensatory plan.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CERUS CORPORATION

Date: August 5, 2011

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

(on behalf of registrant and as Principal Financial Officer)

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