CERUS CORP
Form 10-Q
November 08, 2012
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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 September 30, 2012

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 000-21937

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 Dr.	
Concord, California	**94520**
(Address of principal executive offices)	**(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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x 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.

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 October 30, 2012, there were 55,477,000 shares of the registrant s common stock outstanding.

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CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2012

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2012 (Unaudited)	December 31, 2011 (see Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,661	$ 25,497
Short-term investments	0	287
Accounts receivable, net of allowance of $0 and $5 at September 30, 2012 and December 31, 2011, respectively	3,950	6,096
Inventories	9,682	6,444
Prepaid expenses and other current assets	3,243	1,415
Total current assets	43,536	39,739
Non-current assets:		
Property and equipment, net	1,801	2,032
Goodwill	1,316	1,316
Intangible assets, net	1,597	1,748
Restricted cash	302	303
Other assets	101	229
Total assets	$ 48,653	$ 45,367
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,700	$ 4,680
Accrued liabilities	8,087	5,825
Deferred revenue	716	111
Debt - current	4,919	2,519
Warrant liability	7,876	7,979
Total current liabilities	27,298	21,114
Non-current liabilities:		
Debt - non-current	3,307	4,697
Other non-current liabilities	1,132	1,243
Total liabilities	31,737	27,054
Commitments and contingencies		
Stockholders equity:		
Preferred stock	0	9,496
Common stock	55	51
Additional paid-in capital	474,997	452,701
Accumulated deficit	(458,136)	(443,935)

Total stockholders equity	16,916	18,313
Total liabilities and stockholders equity	$ 48,653	$ 45,367

See accompanying 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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue:				
Product revenue	$ 8,252	$ 7,770	$ 26,167	$ 20,706
Government grants and cooperative agreements	0	1,479	91	1,915
Total revenue	8,252	9,249	26,258	22,621
Cost of product revenue	4,411	4,726	15,499	12,329
Gross profit	3,841	4,523	10,759	10,292
Operating expenses:				
Research and development	1,903	1,814	5,439	5,616
Selling, general and administrative	6,219	5,380	18,871	17,115
Amortization of intangible assets	50	51	151	152
Total operating expenses	8,172	7,245	24,461	22,883
Loss from operations	(4,331)	(2,722)	(13,702)	(12,591)
Non-operating income (expense), net:				
Revaluation of warrant liability	873	5,439	86	3,822
Foreign exchange gain (loss)	206	(41)	(212)	394
Interest expense	(136)	(394)	(410)	(847)
Other income (expense), net	(72)	(22)	37	(25)
Total non-operating income (expense), net	871	4,982	(499)	3,344
Net income (loss)	$ (3,460)	$ 2,260	$ (14,201)	$ (9,247)
Net income (loss) per common share:				
Basic	$ (0.06)	$ 0.05	$ (0.26)	$ (0.19)
Diluted	$ (0.08)	$ 0.05	$ (0.26)	$ (0.19)
Weighted average common shares outstanding used for calculating net income (loss) per common share:				
Basic	54,875	47,710	54,130	47,600
Diluted	55,377	48,820	54,130	47,600

See accompanying Notes to Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

UNAUDITED

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss)	$ (3,460)	$ 2,260	$ (14,201)	$ (9,247)
Other comprehensive loss:				
Net unrealized losses on available-for-sale securities, net of taxes	0	0	0	(107)
Comprehensive income (loss)	$ (3,460)	$ 2,260	$ (14,201)	$ (9,354)

See accompanying Notes to Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Nine Months Ended September 30,	
	2012	**2011**
Operating activities		
Net loss	$ (14,201)	$ (9,247)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	582	697
Stock-based compensation	1,911	1,386
Changes in revaluation of warrant liability	(86)	(3,822)
Gain on sale of fixed assets	(9)	(20)
Non-cash interest expense	15	0
Changes in operating assets and liabilities:		
Accounts receivable	2,146	9
Inventories	(3,238)	(3,372)
Other assets	(2,006)	(85)
Accounts payable	1,020	550
Accrued liabilities	2,219	(472)
Deferred revenue	605	(174)
Net cash used in operating activities	(11,042)	(14,550)
Investing activities		
Purchases of furniture, equipment and leasehold improvements	(97)	(117)
Purchases (sales) of certain other assets	1	(90)
Maturities of investments	287	497
Net cash provided by investing activities	191	290
Financing activities		
Net proceeds from equity incentives and the exercise of warrants	298	142
Net proceeds from public offering	10,823	0
Proceeds from revolving line of credit	1,219	0
Proceeds from debt, net of discount	0	4,910
Payments on revolving line of credit	(236)	0
Payments on debt and landlord provided leasehold incentives	(89)	(4,979)
Net cash provided by financing activities	12,015	73
Net increase (decrease) in cash and cash equivalents	1,164	(14,187)
Cash and cash equivalents, beginning of period	25,497	28,948
Cash and cash equivalents, end of period	$ 26,661	$ 14,761
Supplemental disclosures:		
Cash paid for interest	$ 330	$ 955
Non-cash conversion of preferred stock to common stock	$ 9,496	$ 0

See accompanying 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 and Basis of Presentation

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. Operating results for the three and nine months ended September 30, 2012, are not necessarily indicative of the results that may be expected for the year ending December 31, 2012, or for any future periods.

As previously reported in Note 20, Quarterly Financial Information, in the Notes to Consolidated Financial Statements included in the Company s 2011 Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 5, 2012, the Company restated previously reported financial statements for the three and nine months ended September 30, 2011. The adjustments related to previously capitalized inventory costs, which should have been charged to cost of product revenue as products were sold. Although the correction was immaterial to the three and nine months ended September 30, 2011, the Company decided to restate the amounts previously reported to better reflect the actual operating trends of the Company s business for 2011. The adjustments primarily increased cost of product revenue by $0.1 million and $0.3 million for the three and nine months ended September 30, 2011, respectively. The offsetting adjustment entry was a reduction to the carrying value of inventory.

These condensed consolidated financial statements and notes thereto should be read in conjunction with the Company s audited financial statements and notes thereto for the year ended December 31, 2011, which were included in the Company s 2011 Annual Report on Form 10-K, filed with the SEC on March 5, 2012. The accompanying balance sheet as of December 31, 2011, 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

The Company recognizes revenue in accordance with 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 reasonably assured. The Company s main sources of revenues for the three and nine months ended September 30, 2012, and 2011, were product revenue from sales of the INTERCEPT Blood System for platelets and plasma (platelet and plasma systems) 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 sales of the Company s INTERCEPT Blood System products, the Company uses a binding purchase order and signed sales contract as evidence of a written agreement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company s contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is

considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting based on the best

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estimated selling price. The Company has determined that vendor specific objective evidence is not discernible due to the Company s limited history of selling its products and variability in its pricing across the regions into which it sells its products. Since the Company s products are novel and unique and are not sold by others, third-party evidence of selling price is unavailable.

At September 30, 2012, and December 31, 2011, the Company had $0.7 million and $0.1 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.

Revenue related to the cost reimbursement provisions under development contracts or United States government grants is recognized as the costs on the projects are incurred. The Company has received certain United States government grants and contracts that support research in defined research projects. These grants generally have provided for reimbursement of approved costs incurred as defined in the various grants.

Research and Development Expenses

In accordance with ASC Topic 730, *Accounting for Research and Development Expenses,* research and development expenses are charged to expense when incurred, including cost incurred under each grant that has been awarded to the Company by the United States government or development contracts. 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 (see Use of Estimates above) 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 Equivalents

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. These investments primarily consist of money market instruments, and are classified as available-for-sale.

Short-Term Investments

Investments with original maturities of greater than three months but less than one year from the date of purchase as well as available-for-sale investments with original maturities of greater than one year from the date of purchase, which included United States government agency securities, are classified as short-term investments. 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. 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 and/or in Net unrealized losses on available-for-sale securities, net of taxes on the Company s condensed consolidated statements of comprehensive income (loss). 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 income (expense), net on the Company s condensed consolidated statements of operations.

Restricted Cash

The Company holds a certificate of deposit with a domestic bank 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 in Restricted cash on the Company s condensed consolidated balance sheets.

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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.

Pursuant to the Company s investment policy, substantially all of the Company s cash, cash equivalents and short-term investments are maintained 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 types of investments that exist within its investment portfolio. Generally, all of the Company s investments carry high credit quality ratings, which is in accordance with its investment policy. At September 30, 2012, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company s cash equivalents.

Concentrations of credit risk with respect to trade receivables exist. However, in connection with the Company s revolving line of credit, as discussed in Note 8 in the Notes to Condensed Consolidated Financial Statements, the Company purchased a credit insurance policy that mitigates some of its credit risk, as the policy will pay either the Company or its lender on eligible claims filed on its outstanding receivables. 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 condensed consolidated balance sheets and records a charge on its condensed consolidated statements of operations.

The Company had three customers and two customers that accounted for more than 10% of the Company s outstanding trade receivables at September 30, 2012, and December 31, 2011, respectively. These customers cumulatively represented approximately 69% and 58% of the Company s outstanding trade receivables at September 30, 2012, and December 31, 2011, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At September 30, 2012, and December 31, 2011, 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 systems disposable kits generally have a 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. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be consumed for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for the Company s production cycle for inventory to exceed twelve months. Instead, the Company uses its best judgment to factor in lead times for the production of its finished units to meet the Company s current demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At September 30, 2012, and December 31, 2011, the Company classified its work-in-process inventory as a current asset on its condensed consolidated balance sheets based on its evaluation that the work-in-process inventory would be consumed for production and subsequently sold within each respective subsequent twelve-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or market value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company s limited history selling the INTERCEPT Blood System limits the amount of historical data the Company has to perform this analysis. Generally, the Company writes-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use 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. Any 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 September 30, 2012, and December 31, 2011, the Company had $0.3 million and $0.6 million, respectively, reserved for potential obsolete, expiring or unsalable product. At September 30, 2012, the Company also wrote-down the value of certain unsaleable inventory of $1.1 million for which the Company has an offsetting warranty claim against Fenwal. See below in Note 1 in the Notes to Condensed Consolidated Financial Statements under Guarantee and Indemnification Arrangements and Note 12 in the Notes to Condensed Consolidated Financial Statements for further information regarding the Company s warranty claim with Fenwal.

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.

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Goodwill and Intangible Assets, net

Additions to goodwill and intangible assets, net are 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 a license for the right to commercialize the INTERCEPT Blood System in Asia, are subject to ratable 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 goodwill may be impaired. Such impairment analysis is performed on August 31 of each fiscal year, or more frequently if indicators of impairment exist. Effective January 1, 2012, the test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative two-step process to test goodwill for impairment; otherwise, goodwill is not considered impaired and no further testing is warranted. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative two-step process; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The first step of the two-step process compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates in one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. 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 of the two-step process, 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.

The Company performs an impairment test on its intangible assets, in accordance ASC Topic 360-10, *Property, Plant and Equipment,* if certain events or changes in circumstances occur which indicate that the carrying amounts of its intangible assets may not be recoverable. If the intangible assets are not recoverable, an impairment loss would be recognized by the Company based on the excess amount of the carrying value of the intangible assets over its fair value. For further details regarding the impairment analysis, reference is made to the section below under Long-lived Assets. Also, see Note 5 in the Notes to Condensed Consolidated Financial Statements for further information regarding the Company s impairment analysis and 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 nine months ended September 30, 2012, and 2011.

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 gains (losses) of $0.2 million and less than $(0.1) million during the three months ended September 30, 2012, and 2011, respectively, and $(0.2) million and $0.4 million during the nine months ended September 30, 2012, and 2011, respectively.

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 (i) the

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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. 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 11 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 Company classifies the warrants as a liability on its condensed consolidated balance sheets as the warrants contain certain material terms which require the Company (or its successor) to purchase the warrants for cash in an amount equal to the value of the unexercised portion of the warrants (as determined in accordance with the Black-Scholes option pricing model) in connection with certain change of control transactions. In addition, the Company may also be required to pay cash to a warrant holder under certain circumstances if the Company is unable to timely deliver the shares acquired upon warrant exercise to such holder.

The fair value of these outstanding warrants is calculated using the binomial-lattice option-pricing model and is adjusted accordingly at each reporting period. The binomial-lattice option-pricing model requires that the Company uses significant assumptions and judgment to determine appropriate inputs to the model. Some of the assumptions that the Company relies on include the probability of a change of control occurring, the volatility of the Company s 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.

Changes resulting from the revaluation of warrants to fair value are recorded in Revaluation of warrant liability on the condensed consolidated statements of operations. 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 a liability to stockholders equity on the Company s condensed consolidated balance sheets and no further adjustment to the fair value would be made in subsequent periods.

See Note 10 in the Notes to Condensed Consolidated Financial Statements for further information regarding the Company s valuation of warrant liability.

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 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 2007 through 2011 remain subject to examination by the taxing jurisdictions.

Net Income (Loss) Per Common Share

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per common share gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options, employee stock purchase plan rights, warrants and restricted stock units, which are calculated using the treasury stock method, and convertible preferred stock, which is calculated using the if-converted method. Diluted net income (loss) per common share also gives effect to potential adjustments to the numerator for changes resulting from the revaluation of warrants to fair value for the period, even if the Company is in a net loss position if the effect would result in more dilution.

Diluted net loss per common share used the same weighted average number of common shares outstanding for the nine months ended September 30, 2012, and 2011, as calculated for the basic net loss per common share as the inclusion of any potential dilutive securities would

be anti-dilutive. In addition, certain potential dilutive securities were excluded from the dilution calculation for the three months ended September 30, 2012, and 2011, as their inclusion would have been anti-dilutive.

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The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income (loss) per common share for the three and nine months ended September 30, 2012, and 2011 (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Numerator:				
Net income (loss) used for basic calculation	$ (3,460)	$ 2,260	$ (14,201)	$ (9,247)
Effect of revaluation of warrant liability	(873)	0	0	0
Adjusted net income (loss) used for diluted calculation	$ (4,333)	$ 2,260	$ (14,201)	$ (9,247)
Denominator:				
Basic weighted average number of common shares outstanding	54,875	47,710	54,130	47,600
Effect of dilutive potential common shares resulting from warrants	502	1,110	0	0
Diluted weighted average number of common shares outstanding	55,377	48,820	54,130	47,600
Net income (loss) per common share:				
Basic	$ (0.06)	$ 0.05	$ (0.26)	$ (0.19)
Diluted	$ (0.08)	$ 0.05	$ (0.26)	$ (0.19)

The table below presents common shares underlying stock options, convertible preferred stock, employee stock purchase plan rights, warrants and restricted stock units that are excluded from the calculation of the weighted average number of common shares outstanding used for the calculation of diluted net income (loss) per common share. These are excluded from the calculation due to their anti-dilutive effect for the three and nine months ended September 30, 2012, and 2011 (shares in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Weighted average anti-dilutive common shares	8,704	11,259	14,813	13,543

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. During the three months ended September 30, 2012, the Company provided for warranty obligations related to replacement costs for certain of its products that the Company identified were defective or had the potential of being defective. Prior to this incident, there have been very few warranty costs incurred. As a result, the Company had not accrued for any potential future warranty costs at December 31, 2011. In addition, the Company believes that the defective products and those that had the potential of being defective identified during the three months ended September 30, 2012 are isolated. Accordingly, the Company has not accrued for any other incremental potential future warranty costs for its products at September 30, 2012. The product warrant liability is recorded in Accrued liabilities on the Company s condensed consolidated balance sheets. A reconciliation of changes to the beginning and ending balances of the Company s product warranty liability, from December 31, 2011, to September 30, 2012, was as follows (in thousands):

Balance at December 31, 2011	$ 0
Warranties provided	857
Claims settled	(787)
Balance at September 30, 2012	$ 70

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In connection with the warranty obligations provided for in relation to certain of its products during the three months ended September 30, 2012, the Company filed a warranty claim against Fenwal, which Fenwal accepted. As a result, the Company recorded a current asset of $1.7 million on its condensed consolidated balance sheets as of September 30, 2012 representing the full amount of the warranty claim against Fenwal as Fenwal will supply the Company with replacement products or credit notes for those products. The Company also wrote-down the value of certain unsalable inventory of $1.1 million related to these products as an offsetting warranty claim against Fenwal.

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 its 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. 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. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

See Note 2 and 10 in the Notes to Condensed Consolidated Financial Statements for further information regarding the Company s valuation on financial instruments.

New Accounting Pronouncements

There have been no new accounting pronouncements issued during the three and nine months ended September 30, 2012, that are of significance, or potential significance, to the Company. Any recent accounting pronouncement that are of significance, or potential significance, to the Company are set forth in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 5, 2012, under Note 2 in the Notes to Consolidated Financial Statements.

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 September 30, 2012 (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]	$ 10,263	$ 10,263	$ 0	$ 0
Total financial assets	$ 10,263	$ 10,263	$ 0	$ 0
Warrant liability [2]	$ 7,876	$ 0	$ 0	$ 7,876
Total financial liabilities	$ 7,876	$ 0	$ 0	$ 7,876

(1) Included in cash and cash equivalents on the Company s condensed consolidated balance sheets.
(2) Included in current liabilities on the Company s condensed consolidated balance sheets.

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The fair values of certain of the Company s financial assets and liabilities were determined using the following inputs at December 31, 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]	$ 8,683	$ 8,683	$ 0	$ 0
United States government agency securities [2]	287	0	287	0
Total financial assets	$ 8,970	$ 8,683	$ 287	$ 0
Warrant liability [3]	$ 7,979	$ 0	$ 0	$ 7,979
Total financial liabilities	$ 7,979	$ 0	$ 0	$ 7,979

(1) Included in cash and cash equivalents on the Company s condensed consolidated balance sheets.
(2) Included in short-term investments on the Company s condensed consolidated balance sheets.
(3) Included in current liabilities on the Company s condensed consolidated balance sheets.

A reconciliation of the beginning and ending balances for warrant liability using significant unobservable inputs (Level 3) from December 31, 2011, to September 30, 2012, was as follows (in thousands):

Balance at December 31, 2011	$ 7,979
Decrease in fair value of warrants	(86)
Settlement of warrants exercised	(17)
Balance at September 30, 2012	$ 7,876

See Notes 1 and 10 in the Notes to Condensed Consolidated Financial Statements for further information regarding the Company s valuation techniques and unobservable inputs for warrant liability using significant unobservable inputs (Level 3).

The Company did not have any transfers among fair value measurement levels during the nine months ended September 30, 2012.

Note 3. Available-for-sale Securities

The following is a summary of available-for-sale securities at September 30, 2012 (in thousands):

	September 30, 2012		
	Carrying Value	Gross Unrealized Gain	Fair Value
Money market funds	$ 10,263	$ 0	$ 10,263

Total available-for-sale securities	$ 10,263	$ 0	$ 10,263

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The following is a summary of available-for-sale securities at December 31, 2011 (in thousands):

	December 31, 2011		
	Carrying Value	Gross Unrealized Gain	Fair Value
Money market funds	$ 8,683	$ 0	$ 8,683
United States government agency securities	287	0	287
Total available-for-sale securities	$ 8,970	$ 0	$ 8,970

Available-for-sale securities at September 30, 2012, and December 31, 2011, consisted of the following by original contractual maturity (in thousands):

	September 30, 2012		December 31, 2011	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Due in one year or less	$ 10,263	$ 10,263	$ 8,683	$ 8,683
Due greater than three years and less than five years	0	0	287	287
Total available-for-sale securities	$ 10,263	$ 10,263	$ 8,970	$ 8,970

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

The Company did not record any gross realized gains from the sale or maturity of available-for-sale investments during the three and nine months ended September 30, 2012 and three months ended September 30, 2011. Gross realized gains from the sale or maturity of available-for-sale investments were minimal during the nine months ended September 30, 2011. The Company did not record losses on investments experiencing an other-than-temporary decline in fair value nor did it record any gross realized losses from the sale or maturity of available-for-sale investments during the three and nine months ended September 30, 2012, and 2011.

Note 4. Inventories

Inventories at September 30, 2012, and December 31, 2011, consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
Work-in-process	$ 4,602	$ 2,742
Finished goods	5,080	3,702
Total inventories	$ 9,682	$ 6,444

Note 5. Goodwill and Intangible Assets, net

Goodwill

During the nine months ended September 30, 2012, the Company did not dispose of or recognize additional goodwill. On August 31, 2012, the Company performed its annual review of goodwill. As described in Note 1 above, the Company applied the enterprise approach by reviewing the quoted market capitalization of the Company as reported on the Nasdaq Global Market to calculate the fair value. In addition, the Company considered its future forecasted results, the economic environment and overall market conditions. As a result of the Company s assessment that

its fair value of the reporting unit exceeded its carrying amount, the Company determined that goodwill was not impaired during the nine months ended September 30, 2012. Accordingly, at both September 30, 2012, and December 31, 2011, the carrying amount of goodwill was $1.3 million.

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Intangible Assets, net

The following is a summary of intangible assets, net at September 30, 2012 (in thousands):

	September 30, 2012		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$ 2,017	$ (420)	$ 1,597
Total intangible assets	$ 2,017	$ (420)	$ 1,597

The following is a summary of intangible assets, net at December 31, 2011 (in thousands):

	December 31, 2011		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$ 2,017	$ (269)	$ 1,748
Total intangible assets	$ 2,017	$ (269)	$ 1,748

The Company recognized $0.05 million in amortization expense related to intangible assets for each of the three months ended September 30, 2012, and 2011, respectively, and approximately $0.2 million for each of the nine months ended September 30, 2012, and 2011, respectively. During the three and nine months ended September 30, 2012, and 2011, there were no impairment charges recognized related to the Company s intangible assets.

At September 30, 2012, the expected amortization expense of the intangible assets, net is $0.05 million for the remaining three months of 2012, $0.2 million annually each subsequent year thereafter beginning with the year ending December 31, 2013, through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Note 6. Long-Term Investments

In connection with the agreements to license the immunotherapy technologies to Aduro BioTech (Aduro) in 2009, the Company received preferred shares of Aduro. Pursuant to these license agreements, the Company is eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. As of September 2012, the Company s ownership in Aduro was less than 3% on a fully diluted basis. Since receiving preferred stock in Aduro, the Company has carried its investment in Aduro at zero in its condensed consolidated balance sheet.

Note 7. Accrued Liabilities

Accrued liabilities at September 30, 2012, and December 31, 2011, consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
Accrued compensation and related costs	$ 2,017	$ 2,027
Accrued inventory costs	3,087	1,417
Accrued contract and other accrued expenses	2,983	2,381

Total accrued liabilities	$ 8,087	$ 5,825

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Note 8. Debt

Debt at September 30, 2012, consisted of the following (in thousands):

	September 30, 2012		
	Principal	Unamortized Discount	Total
Comerica - Growth Capital Loan A, due 2015	$ 5,000	$ (57)	$ 4,943
Comerica - Revolving Line of Credit, due 2014	3,283	0	3,283
Total debt	8,283	(57)	8,226
Less: debt - current	(4,950)	31	(4,919)
Debt - non-current	$ 3,333	$ (26)	$ 3,307

Debt at December 31, 2011, consisted of the following (in thousands):

	December 31, 2011		
	Principal	Unamortized Discount	Total
Comerica - Growth Capital Loan A, due 2015	$ 5,000	$ (84)	$ 4,916
Comerica - Revolving Line of Credit, due 2014	2,300	0	2,300
Total debt	7,300	(84)	7,216
Less: debt - current	(2,554)	35	(2,519)
Debt - non-current	$ 4,746	$ (49)	$ 4,697

Principal and interest payments on debt at September 30, 2012, are expected to be as follows for each of the following five years (in thousands):

Year ended December 31,	
2012 (remaining three months)	$ 527
2013	2,072
2014 [(1)]	5,181
2015	1,334
2016	0

(1) Included outstanding revolving line of credit balance based on the Company s obligation to repay the outstanding revolving line of credit balance at the end of the revolving line of credit term.

2011 Growth Capital Facility

The Company entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, with Comerica Bank (Comerica) (collectively, the Amended Credit Agreement). The Amended Credit Agreement provides for an aggregate borrowing of up to $12.0 million, comprised of a growth capital loan of $5.0 million (Growth Capital Loan) and a formula based revolving line of credit (RLOC) of up to $7.0 million. The Company pledged all current and future assets, excluding its intellectual property and 35% of the Company s investment in its subsidiary, Cerus Europe B.V., as security for borrowings under the Amended Credit Agreement.

Growth Capital Loan

Concurrent with the execution of the original loan and security agreement in September 2011, the Company borrowed $5.0 million under the Growth Capital Loan, substantially all of which was used to repay the Company s prior debt with Oxford Finance Corporation (Oxford), with the remainder used for general corporate purposes. The Growth Capital Loan, which matures on September 30, 2015, bears a fixed interest rate of 6.37%, with interest only payments due for the first twelve months, followed by equal principal and interest payments for the remaining 36 months.

In September 2011, the Company incurred a commitment fee of $40,000 and loan fees of $50,000, which were recorded as a discount to its Growth Capital Loan and are being amortized as a component of interest expense using the effective interest method over the term of the Growth Capital Loan (discount was based on an implied interest rate of 7.07%). The Company will also be required to make a final payment fee of 1% of the amounts drawn under Growth Capital Loan due on the earlier of (i) prepayment of the Growth Capital Loan or (ii) the maturity of the Growth Capital Loan. The final payment fee will be accreted to interest expense using the effective interest method over the life of the Growth Capital Loan upon draw.

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Revolving Line of Credit

The Amended Credit Agreement also provides for a RLOC of up to $7.0 million (the RLOC Loan Amount). The amount available under the RLOC is limited to the lesser of (i) 80% of eligible trade receivables or (ii) the RLOC Loan Amount. At September 30, 2012, and December 31, 2011, the Company had $3.3 million and $2.3 million, respectively, outstanding under the RLOC. The Company is required to repay the principal drawn from the RLOC at the end of the RLOC term on June 30, 2014, or earlier if a portion or all of the outstanding RLOC exceeds the amount available under the RLOC. The RLOC bears a floating rate based on the lender s prime rate plus 1.50%, with interest only payments due each month. At both September 30, 2012, and December 31, 2011, the floating rate of the RLOC was at 4.75%. In September 2011, the Company incurred a commitment fee of $20,000. Upon amendment of the loan and security agreement in June 2012, the Company incurred another annual commitment fee of $20,000 and received a credit for the unused portion of the initial fee. The Company will incur a $20,000 commitment fee at each annual anniversary beginning June 30, 2013.

Compliance with Covenants

The Company is required to maintain compliance with certain customary and routine financial covenants under the Amended Credit Agreement, including maintaining a minimum cash balance of $2.5 million at Comerica and achieving minimum revenue levels, which are measured monthly based on a six-month trailing basis and must be at least 75% of the pre-established future projected revenues for the trailing six-month period. Non-compliance with the covenants could result in the principal of the note becoming due and payable. As of September 30, 2012, the Company was in compliance with the financial covenants as set forth in the Amended Credit Agreement.

2010 Growth Capital Facility

In March 2010, the Company entered into a growth capital facility agreement with Oxford and immediately borrowed and issued a senior secured note for $5.0 million. The note carried a fixed interest rate of 12.04%, with interest only payments due for the first nine months and then equal principal and interest payments for an additional 30 months. In September 2011, the Company repaid the outstanding balance of the debt owed to Oxford using the proceeds received from the Growth Capital Loan as discussed in further detail above. The Company also accelerated and expensed the remaining closing cost and fees of $0.2 million to interest expense during the three and nine months ended September 30, 2011.

Note 9. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, The Netherlands, 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. The operating leases expire at various dates through 2019, with certain of the leases providing for renewal options, provisions for adjusting future lease payments, which is based on the consumer price index and the right to terminate the lease early, which may occur as early as January 2015. The Company s leased facilities qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on its condensed consolidated balance sheets.

Financed Leasehold Improvements

In December 2010, the Company financed $1.1 million of leasehold improvements. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the respective leases. If the Company exercises its right to early terminate the Concord California lease, which may occur as early as January 2015, the Company would be required to repay for any remaining portion of the landlord financed leasehold improvements at such time. At September 30, 2012, the Company had an outstanding liability of $0.9 million related to these leasehold improvements, of which $0.1 million was reflected in Accrued liabilities and $0.8 million was reflected in Other non-current liabilities on the Company s condensed consolidated balance sheets.

Purchase Commitments

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

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Note 10. Stockholders Equity

Series B Preferred Stock

In March 1999, the Company issued 3,327 shares of the Company s Series B preferred stock to Fenwal, Inc. (Fenwal) (formerly, Baxter International Inc.). The Series B preferred stock had 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 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 had the ability to convert each share of Series B preferred stock into 100 shares of the Company s common stock. The Company had the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million. In June 2012, Fenwal exercised its right to convert all 3,327 shares of the Company s Series B preferred stock. As a result, the Company issued 332,700 shares of its common stock to Fenwal and retired the outstanding Series B preferred stock.

Common Stock and Associated Warrant Liability

In August 2009, the Company issued warrants to purchase 2.4 million shares of common stock, exercisable at an exercise price of $2.90 per share (2009 Warrants). The 2009 Warrants are exercisable for a period of five years from the issue date. The fair value on the date of issuance of the 2009 Warrants was determined to be $2.8 million using the binomial-lattice option valuation model and 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%.

In November 2010, the Company issued warrants to purchase 3.7 million shares of common stock, exercisable at an exercise price of $3.20 per share (2010 Warrants). The 2010 Warrants became exercisable on May 15, 2011 and are exercisable for a period of five years from the issue date. The fair value on the date of issuance of the 2010 Warrants was determined to be $5.8 million using the binomial-lattice option valuation model and 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%.

The fair value of the 2009 Warrants and 2010 Warrants was recorded on the condensed consolidated 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 modification to remove the provisions which require the warrants to be treated as a liability, at which time, these warrants would be reclassified into stockholders equity. The Company classified the 2009 Warrants and 2010 Warrants as a liability as these warrants contain certain provisions that, under certain circumstances, which may be out of the Company s control, could require the Company to pay cash to settle the exercise of the warrants or may require the Company to redeem the warrants.

The fair value of the warrants at September 30, 2012, and December 31, 2011, consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
2009 Warrants	$ 2,712	$ 3,010
2010 Warrants	5,164	4,969
Total warrant liability	$ 7,876	$ 7,979

The fair value of the Company s warrants was based on using the binomial-lattice option valuation model and using the following assumptions at September 30, 2012, and December 31, 2011:

	September 30, 2012	December 31, 2011
2009 Warrants:		
Expected term (in years)	1.90	2.65
Estimated volatility	50%	74%

Risk-free interest rate	0.23%	0.36%
Expected dividend yield	0%	0%
2010 Warrants:		
Expected term (in years)	3.11	3.86
Estimated volatility	58%	70%
Risk-free interest rate	0.31%	0.60%
Expected dividend yield	0%	0%

The Company recorded non-cash gains of $0.9 million and $5.4 million during the three months ended September 30, 2012, and 2011, respectively, and minimal amounts and $3.8 million during the nine months ended September 30, 2012, and 2011, respectively, in Revaluation of warrant liability on the condensed consolidated statements of operations due to the changes in fair value of the warrants. Significant changes to the Company s market price for its common stock will impact the implied and/or historical volatility used to fair

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value the warrants. As a result, any significant increases in the Company s stock price will likely create an increase to the fair value of warrant liability. Similarly, any significant decreases in the Company s stock price will likely create a decrease to the fair value of warrant liability. In June 2012, the 2010 Warrants to purchase 5,084 shares of common stock were exercised. At December 31, 2011, no warrants had been exercised.

Sales Agreements

The Company entered into an At-The-Market Issuance Sales Agreement in June 2011, as amended in January 2012 and August 2012 (collectively, the MLV Agreement), with MLV & Co. LLC, formerly McNicoll, Lewis & Vlak LLC (MLV) that provides for the issuance and sale of shares of the Company s common stock over the term of the MLV Agreement having an aggregate offering price of up to $20.0 million through MLV. Under the MLV Agreement, MLV acts as the Company s sales agent and receives compensation based on an aggregate of 3% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by the Company pursuant to the MLV Agreement are deemed an at-the-market offering and are registered under the Securities Act. During the year ended December 31, 2011, approximately 3.5 million shares of the Company s common stock were sold under the MLV Agreement for aggregate net proceeds of $9.7 million. During the nine months ended September 30, 2012, the Company sold approximately 3.1 million additional shares of its common stock under the MLV Agreement for aggregate net proceeds of $9.5 million. The Company did not sell any shares of its common stock under the MLV Agreement during the three months ended September 30, 2012.

The Company also entered into a Controlled Equity Offering℠ Sales Agreement (the Cantor Agreement) in August 2012, with Cantor Fitzgerald & Co. (Cantor) that provides for the issuance and sale of shares of its common stock over the term of the Cantor Agreement having an aggregate offering price of up to $30.0 million through Cantor. Under the Cantor Agreement, Cantor also acts as the Company s sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by the Company pursuant to the Cantor Agreement are deemed an at-the-market offering and are registered under the Securities Act. During the three and nine months ended September 30, 2012, approximately 0.4 million shares of the Company s common stock were sold under the Cantor Agreement for aggregate net proceeds of $1.1 million.

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 11. Stock-Based Compensation

The Company maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan (the 2008 Plan). The 2008 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 continues to have equity awards outstanding under its previous stock plans: 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan (collectively, the Prior Plans) and 1996 Equity Incentive Plan (the 1996 Plan). Equity awards issued under the Prior Plans and the 1996 Plan continue to adhere to the terms of those respective stock plans and no further options may be granted under those previous plans. However, at June 2, 2008, any shares that remained available for future grants under the Prior Plans became available for issuance under the 2008 Plan. On June 6, 2012, the stockholders approved an amendment to the 2008 Plan (Amended 2008 Plan) which increased the aggregate number of shares of common stock authorized for issuance by 3,000,000 shares, such that the Amended 2008 Plan has reserved for issuance an amount not to exceed 13,540,940 shares. At September 30, 2012, the Company had an aggregate of approximately 13.0 million shares of its common stock reserved for issuance under the Amended 2008 Plan, the Prior Plans and the 1996 Plan, of which approximately 8.8 million shares were subject to outstanding options and other stock-based awards, and approximately 4.2 million shares were available for future issuance under the Amended 2008 Plan.

The Company also maintains an Employee Stock Purchase Plan (the Purchase Plan) which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company s Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. On June 6, 2012, the stockholders approved an amendment to the Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance by 500,000 shares, such that the Purchase Plan has reserved for issuance an amount not to exceed 1,320,500 shares. At September 30, 2012, the Company had

approximately 0.6 million shares available for future issuance under the Purchase Plan.

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The Company has granted restricted stock units primarily to its senior management in accordance with the Amended 2008 Plan. Subject to each grantee s continued employment, the restricted stock units generally vest in three annual installments from the date of grant and are generally issuable at the end of the three-year vesting term.

Activity under the Company s equity incentive plans related to stock options is set forth below (in thousands except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balance at December 31, 2011	7,362	$ 4.70
Granted	1,775	3.68
Forfeited	(42)	2.52
Expired	(291)	36.35
Exercised	(113)	1.49
Balance at September 30, 2012	8,691	$ 3.49

The Company currently uses the Black-Scholes option pricing model to determine the grant-date 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, actual and projected employee stock option exercise behaviors, including forfeitures, the Company s expected stock price volatility, the risk-free interest rate and expected dividends. The Company recognizes the grant-date fair value of the stock award 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.

Stock-based compensation recognized on the Company s condensed consolidated statements of operations for the three and nine months ended September 30, 2012, and 2011, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Stock-based compensation expense by caption:				
Research and development	$ 146	$ 112	$ 423	$ 332
Selling, general and administrative	549	351	1,488	1,054
Total stock-based compensation expense	$ 695	$ 463	$ 1,911	$ 1,386

The Company did not record any stock-based compensation associated with performance-based stock options during the three and nine months ended September 30, 2012, and 2011, as the performance criteria was not probable of being achieved during these periods. Performance-based stock options of 100,000 remained outstanding at September 30, 2012.

Note 12. License Agreements

As a result of Baxter International Inc. 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% of product sales for the plasma system, 5% of product sales for the red blood cell system, and 6.5% on sales of illuminators. During the three months ended September 30, 2012, and 2011, the Company made royalty payments to Fenwal of $0.7 million and $0.6 million, respectively, and $2.1 million and $1.6 million, during the nine months ended September 30, 2012, and 2011, respectively. At both September 30, 2012, and December 31, 2011, the Company owed Fenwal $0.7 million for royalties.

In December 2008, the Company extended its agreement with Fenwal to manufacture finished INTERCEPT disposable kits for the platelet and plasma systems through December 31, 2013. Under the amended manufacturing and supply 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 $1.4 million and $2.1 million relating to the manufacturing of the Company products during the three months ended

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September 30, 2012, and 2011, respectively, and $8.9 million and $8.5 million, during the nine months ended September 30, 2012, and 2011, respectively. At September 30, 2012, and December 31, 2011, the Company owed Fenwal $5.1 million and $3.4 million, respectively, for INTERCEPT disposable kits manufactured. In connection with the warranty claims incurred by the Company and remediation of those claims during the three months ended September 30, 2012 (see Note 1 in the Notes to Condensed Consolidated Financial Statements under Guarantee and Indemnification Arrangements for more detail), the Company filed a warranty claim against Fenwal. Fenwal has accepted the warranty claim and will supply the Company with replacement product or credit notes. As a result, the Company recorded a current asset of $1.7 million on its condensed consolidated balance sheets as of September 30, 2012 representing the full amount of the warranty claim against Fenwal.

Note 13. Segment, Customer and Geographic Information

The Company continues to operate in 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. The Company considers the sale of all of its INTERCEPT Blood System products to be similar in nature and function, and any revenue earned from services is minimal.

The Company s operations outside of the United States include a wholly-owned subsidiary headquartered in Europe. The Company s operations in the United States are responsible for the research and development and global commercialization of the INTERCEPT Blood System, while operations in Europe are responsible for the commercialization efforts of the platelet and plasma systems in Europe, The Commonwealth of Independent States and the Middle East. Product revenues are attributed to each region based on the location of the customer, and in the case of non-product revenues, on the location of the collaboration partner.

The Company had the following significant customers that accounted for more than 10% of the Company s total product revenue, all of which operate in a country outside of the United States, during the three and nine months ended September 30, 2012, and 2011 (in percentages):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Etablissement Francais du Sang	22%	20%	23%	20%
Movaco, S.A.	19%	24%	19%	26%
AUM+ LTD	13%	*	*	*
Delrus Inc.	*	12%	*	*

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

The Company also recognized government grants and cooperative agreements revenue of $0.1 million, which represented less than 1% of total revenue, during the nine months ended September 30, 2012, $1.9 million, which represented 8% of total revenue, during the nine months ended September 30, 2011, and $1.5 million, which represented 16% of total revenue, during the three months ended September 30, 2011. The Company did not recognize any revenue from government grants and cooperative agreements during the three months ended September 30, 2012. The Company has historically received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense since February 2001. 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 terms of the cooperative agreements, the Company conducted research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that were of concern to the United States Armed Forces. This funding supported the development of the Company s red blood cell system.

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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 Quarterly Report on Form 10-Q and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2011. Operating results for the three and nine months ended September 30, 2012 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 preclinical and clinical development for the INTERCEPT Blood System, our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System and the timing of anticipated regulatory submissions, 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, and on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002. 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 and in our other documents filed with the Securities and Exchange Commission. 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 been focused on the research, development, clinical testing and commercialization of the INTERCEPT Blood System. The INTERCEPT Blood System is designed for three blood components. The INTERCEPT Blood System for platelets, or platelet system, and our INTERCEPT Blood System for plasma, or plasma system, have received CE marks and are being marketed and sold in a number of countries in Europe, The Commonwealth of Independent States, or CIS, the Middle East and selected countries in other regions around the world.

We are developing and plan to perform *in vitro* studies and clinical trials for our INTERCEPT Blood System for red blood cells, or the red blood cell system, in Europe and the United States. Subject to the availability of adequate funding from partners and/or the capital markets, we intend to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. In addition, in March 2012, we submitted a proposed clinical trial protocol to the United States Food and Drug Administration, or FDA, for a Phase III clinical trial evaluating the red blood cell system in patients receiving chronic red cell transfusion support for sickle cell disease or thalassemia. We understand that at least an additional Phase II clinical trial and certain other prerequisites will need to be completed satisfactorily by us and reported to the FDA before the FDA will complete its review of our proposed Phase III clinical trial protocol for the red blood cell system. These development activities will result in increased research and development expenses in future periods, and our ability to conduct and complete any clinical trials of the red blood cell system to support approval in the United States is subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources. In any event, we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system.

Based on recent discussions with the United States Food and Drug Administration, or FDA, we intend to submit a Premarket Approval Application, or PMA, shell for our plasma system. Pending FDA approval of the application shell, we intend to proceed with a

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modular PMA approach, whereby we would submit sections, or modules, of the PMA at different times and the compilation of these sections or modules become a complete PMA. We believe that the modular approach increases the likelihood that we will be able to resolve any deficiencies identified by FDA earlier in the review process. Based on our recent discussions with the FDA, we believe that our existing clinical data is sufficient to begin the PMA submission process regarding the clinical requirements for such submission. The submission of the PMA for our plasma system will result in increased research and development expenses in future periods. Should the FDA require us to complete any additional clinical trials, our ability to conduct and complete any additional clinical trials of the plasma system to support approval in the United States would be subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources before we initiate any additional trials. In any event, we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the plasma system.

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 our planned modular PMA application submission to the FDA for the plasma system and pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trial and other development activities related to our platelet, plasma and red blood cell systems, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, 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, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that cash received from product sales, our available cash balances and access to debt 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 additional capital from institutional and commercial banking sources to fund future growth outside of our amended credit agreement with Comerica Bank, as described below, on terms that may include restrictive covenants, which may comprise of 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 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 as well as general economic uncertainty, including the continued instability of the Eurozone, 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 economic conditions, general global economic uncertainty 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, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities.

We recognize product revenues from the sale of our platelet and plasma systems in Europe, the CIS, the Middle East and certain other countries around the world. Although our product revenues have grown over time and increased in the three and nine months ended September 30, 2012 compared to the comparable periods in 2011, if we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, we will have difficulties achieving profitability. In order to commercialize all of our products and product candidates, we will be required to 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. Accordingly, we may never achieve a profitable level of operations in the future.

In addition to the product revenues from sales of our platelet and plasma systems, we have recognized revenue from government grants and cooperative agreements. 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. In August 2011, we were awarded a $2.1 million grant from the DoD to support the development of our red blood cell system. We have recognized revenue associated with this award as qualified costs were incurred for reimbursement over the performance period of one year from the date of issuance. We have exhausted the remaining availability under the grant and recognized $0.1 million during the nine months ended September 30, 2012. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding and we do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

In 2009, we entered into agreements to out-license certain immunotherapy technologies to Aduro BioTech, or Aduro. In connection with those agreements, we received preferred shares of Aduro. Pursuant to these license agreements, we are eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. As of September 2012, our ownership in Aduro was reduced to less than 3% on a fully diluted basis. Since receiving preferred stock in Aduro, we have carried our investment in Aduro at zero in our condensed consolidated balance sheet.

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We pay royalties to Fenwal Inc., or Fenwal, on future INTERCEPT Blood System product sales under certain agreements which arose from the sale of the transfusion therapies division of Baxter International Inc., or Baxter, in 2007, to Fenwal, at rates of 10% of net sales for our platelet system, 3% of net sales for our plasma system, 5% of net sales for our red blood cell system, and 6.5% on net sales of illumination devices, or illuminators. We also pay Fenwal certain costs associated with the amended manufacturing and supply agreement we executed with Fenwal in December 2008, for the manufacture of finished INTERCEPT disposable kits for our platelet and plasma systems through December 31, 2013. Under the amended manufacturing and supply agreement, we pay Fenwal a set price per disposable kit, which is established annually, plus a fixed surcharge per disposable kit. In addition, volume driven manufacturing overhead is to be paid or refunded if actual manufacturing volumes are higher or lower than the annually estimated production volumes. We are also obligated to provide certain disposable kit components at no cost to Fenwal under the amended manufacturing and supply agreement. This required us to enter into manufacturing and 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 sheets, may potentially take over one year to complete production before being utilized in finished INTERCEPT disposable kits. During the three months ended September 30, 2012, we provided for warranty obligations of $0.9 million related to replacement costs for certain of our products that we identified were defective or had the potential of being defective. In connection with the warranty claims incurred by us and remediation of those claims during the three months ended September 30, 2012, we filed a warranty claim against Fenwal. Fenwal has accepted the warranty claim and will supply us with replacement product or credit notes. As a result, we have recorded a current asset of $1.7 million on our condensed consolidated balance sheets as of September 30, 2012 representing the full amount of the warranty claim against Fenwal. We also wrote-down the value of certain unsalable inventory of $1.1 million related to these products as an offsetting warranty claim against Fenwal.

In August 2010, we completed a business acquisition of certain assets of BioOne Corporation, or BioOne, including the commercialization rights that both Baxter (later Fenwal) and we granted to BioOne for both the platelet and plasma systems. Concurrent with the acquisition, Fenwal and we terminated the commercialization rights we and Fenwal granted to BioOne. 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 became worldwide. As consideration for the acquired BioOne assets, we relinquished all shares we held in BioOne valued at approximately $0.3 million and issued approximately 1.2 million shares of our common stock to BioOne valued at approximately $3.4 million, of which approximately 1.0 million shares were issued at the close of the acquisition on August 24, 2010 and the remaining 0.2 million shares were issued on February 25, 2011. Accordingly, at the acquisition date, we recorded the fair value of the assets acquired, consisting of commercialization rights in Asia 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 was recorded as goodwill of $1.3 million. The recognition of goodwill was attributable to the buyer-specific value derived by us as a result of acquiring the commercialization rights in certain Asian countries in order to complete the global commercialization rights for our platelet and plasma systems.

We entered into an At-The-Market Issuance Sales Agreement in June 2011, as amended in January 2012 and August 2012, or collectively the MLV Agreement, with MLV & Co. LLC, formerly McNicoll, Lewis & Vlak LLC, or MLV, that provides for the issuance and sale of shares of our common stock over the term of the MLV Agreement having an aggregate offering price of up to $20.0 million from time to time through MLV as our sales agent. We also entered into a Controlled Equity Offering^{SM} Sales Agreement, or the Cantor Agreement, in August 2012, with Cantor Fitzgerald & Co., or Cantor. that provides for the issuance and sale of shares of our common stock over the term of the Cantor Agreement having an aggregate offering price of up to $30.0 million through Cantor. During the year ended December 31, 2011, approximately 3.5 million shares of our common stock were sold under the MLV Agreement for aggregate net proceeds of $9.7 million. During the nine months ended September 30, 2012, we sold an aggregate of approximately 3.5 million additional shares of our common stock under the MLV Agreement and the Cantor Agreement for aggregate net proceeds of $10.6 million. At September 30, 2012, we had less than $0.1 million and approximately $28.8 million of common stock available to be sold under the MLV Agreement and Cantor Agreement, respectively.

We entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, or collectively, the Amended Credit Agreement, with Comerica Bank, or Comerica. The Amended Credit Agreement provides for an aggregate borrowing of up to $12.0 million, comprised of a growth capital loan of up to $5.0 million, or Growth Capital Loan, and a formula based revolving line of credit of up to $7.0 million. We pledged all current and future assets, excluding our intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., as security for borrowings under the Amended Credit Agreement. We are required to maintain compliance with certain customary and routine financial covenants, including maintaining a minimum cash balance of $2.5 million with Comerica and achieving certain minimum revenue levels. On September 30, 2011, we borrowed $5.0 million under the Growth Capital Loan, substantially all of which was used to repay our prior debt with Oxford Finance Corporation, or Oxford, with the remainder used for general corporate purposes. In addition, we have drawn an aggregate of $3.3 million from the revolving line of credit through September 30, 2012.

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, valuation of warrants, 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.

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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 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 reasonably assured.

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 determine whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. Once we determine if the deliverable meets the criteria for a separate unit of accounting, we must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting based on the best estimated selling price. We have determined that vendor specific objective evidence is not discernible due to our limited history of selling our products and variability in our pricing across the regions into which we sell our products. 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.

Inventory We own certain components of INTERCEPT disposable kits in the form of work-in-process inventory and finished goods, 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 potentially take over one year to complete production before being utilized in finished INTERCEPT disposable kits. We maintain an inventory balance based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory would be consumed for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for our production cycle for inventory to exceed twelve months. Instead, we use our best judgment to factor in lead times for the production of our finished units to meet our current demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year.

Under our manufacturing and supply 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, which affects the per unit carrying cost of our finished goods. 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 on our condensed consolidated statements of operations.

Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Our platelet and plasma systems disposable kits generally have a two-year shelf life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. Our limited history selling the INTERCEPT Blood System limits the amount of historical data we have to perform this analysis. Generally, we write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use 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. Any 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. We also wrote-down the value of certain unsalable inventory related to the products covered under the warranty claims against Fenwal.

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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 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.

Goodwill and intangible assets 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 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 us 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 perform an impairment test on our goodwill annually on August 31 of each fiscal year or more frequently if indicators of impairment exist. Effective January 1, 2012, the test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If we determine that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, we must then proceed with performing the quantitative two-step process to test goodwill for impairment; otherwise, goodwill is not considered impaired and no further testing is warranted. We may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative two-step process; however, we may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The first step of the two-step process compares the fair value of each reporting unit with the respective carrying amount, including goodwill. We have determined that we operate in one reporting unit and estimate the fair value of our one reporting unit using the enterprise approach under which we consider our quoted market capitalization as reported on the Nasdaq Global Market. We consider quoted market prices that are available in active markets to be the best evidence of fair value. We also consider other factors, which include future forecasted results, the economic environment and overall market conditions. 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 of the two-step process, 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. On August 31, 2012, we performed our annual review of goodwill as described above and determined that goodwill was not impaired during the nine months ended September 30, 2012. 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. No events or changes in circumstances arose during the three and nine months ended September 30, 2012 which would require us to test the recoverability of our intangible 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. We classified the warrants as a liability on our condensed consolidated balance sheets as the warrants contain certain material terms which require us (or our successor) to purchase the warrants for cash in an amount equal to the value of the unexercised portion of the warrants (as determined in accordance with the Black-Scholes option pricing model) in connection with certain change of control transactions. In addition, we may also be required to pay cash to a warrant holder under certain circumstances if we are unable to timely deliver the shares acquired upon warrant exercise to such holder.

The fair value of these outstanding warrants is calculated using the binomial-lattice option-pricing model and is adjusted accordingly at each reporting period. 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 the 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.

Changes resulting from the revaluation of warrants to fair value are recorded in Revaluation of warrant liability on the condensed consolidated statements of operations 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 a liability to stockholders equity on our condensed consolidated balance sheets and no further adjustment to the fair value would be made in subsequent periods.

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Stock-based compensation We issue stock-based awards to our employees, contractors and members of our Board of Directors, 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 record 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 stock-based awards. 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, actual and projected employee stock option exercise behaviors, including forfeitures, our expected stock price volatility, the risk-free interest rate and expected dividends. The grant-date fair value of stock-based awards 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 to be 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 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 is not an appropriate substitute for the derecognition of a tax position. 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 2007 through 2011 remain subject to examination by the taxing jurisdictions.

Results of Operations

Three and Nine Months Ended September 30, 2012 and 2011

Revenue

(in thousands, except percentages)	Three Months Ended September 30, 2012	2011	Change		Nine Months Ended September 30, 2012	2011	Change	
Product revenue	$ 8,252	$ 7,770	$ 482	6%	$ 26,167	$ 20,706	$ 5,461	26%
Government grants and cooperative agreements	0	1,479	(1,479)	(100)%	91	1,915	(1,824)	(95)%
Total revenue	$ 8,252	$ 9,249	$ (997)	(11)%	$ 26,258	$ 22,621	$ 3,637	16%

Product revenue increased by $0.5 million and $5.5 million during the three and nine months ended September 30, 2012, respectively, compared to the three and nine months ended September 30, 2011, respectively, primarily as a result of higher volumes of our platelet and plasma systems disposable kits sold to existing customers, which included higher volume purchases of disposable kits for our plasma system by the Etablissement Francais du Sang, and, to a lesser extent, new customer adoption of the INTERCEPT Blood System in countries where we sell our products.

We anticipate product revenue for both our platelet and plasma systems will continue to increase in future periods as the INTERCEPT Blood System continues to gain market acceptance in geographies where commercialization efforts are underway. The historical results may not be indicative of INTERCEPT Blood System revenue in the future.

There was no revenue derived from government grants and cooperative agreements during the three months ended September 30, 2012. Revenue from government grants and cooperative agreements decreased by $1.5 million and $1.8 million during the three and nine months ended September 30, 2012 compared to the three and nine months ended September 30, 2011, respectively. This decrease was attributable to the relatively low remaining award balance available under our DoD grant at the beginning of 2012, compared to the availability at the beginning of 2011, and the level of revenue generating activities under the award during the nine months ended September 30, 2012. During the nine months ended September 30, 2012, we recognized the final $0.1 million available under the last remaining grant available to us. We do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

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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 unsalable 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.

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands, except percentages)	**2012**	**2011**	**Change**		**2012**	**2011**	**Change**	
Cost of product revenue	$ 4,411	$ 4,726	$ (315)	(7)%	$ 15,499	$ 12,329	$ 3,170	26%

Cost of product revenue decreased by $0.3 million during three months ended September 30, 2012 compared to the three months ended September 30, 2011 as we did not incur any fees associated with contractual minimum purchase requirements with certain of our suppliers during the three months ended September 30, 2012 as compared to period costs incurred of $0.5 million during the comparable period in 2011.

Cost of product revenue increased by $3.2 million during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 primarily due to the higher volume of INTERCEPT disposable kits sold during the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011. In addition, we incurred higher manufacturing overhead absorption and experienced higher scrap charges for certain components, which were determined to be unusable, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. This was offset by fees associated with contractual minimum purchase requirements of $0.5 million that was incurred during the nine months ended September 30, 2011. We anticipate our cost of product revenue will increase in the future as a result of anticipated increased product sales.

Our gross margins on product sales were 47% during the three months ended September 30, 2012, up from 39% during the three months ended September 30, 2011. Gross margins during the three months ended September 30, 2012, were positively impacted compared to the corresponding period in 2011 primarily due to certain supplier costs incurred associated with our inventory manufacturer during the three months ended September 30, 2011, which impacted gross margins on product sales by 7%, with no comparable costs incurred during the three months ended September 30, 2012. Our gross margins on product sales were 41% during the nine months ended September 30, 2012, up slightly from 40% during the nine months ended September 30, 2011. Gross margins during the nine months ended September 30, 2012 slightly improved compared to the corresponding period in 2011, as we incurred certain supplier costs related to our inventory manufacturer during the nine months ended September 30, 2011, offset by a higher proportion of plasma kits sold to customers during the nine months ended September 30, 2012, which plasma kits have a higher production cost relative to our platelet kits.

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. We have a limited history of overseeing the manufacture of components and finished goods and as such, have limited means to predict the frequency and magnitude of events leading to higher than expected manufacturing overhead variances. Our gross margins may be impacted in the future based on all of these criteria.

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 studies 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 September 30,				Nine Months Ended September 30,			
(in thousands, except percentages)	**2012**	**2011**	**Change**		**2012**	**2011**	**Change**	
Research and development	$ 1,903	$ 1,814	$ 89	5%	$ 5,439	$ 5,616	$ (177)	(3)%

Research and development expenses increased by $0.1 million during the three months ended September 30, 2012, compared to the three months ended September 30, 2011, primarily as a result of increased research costs for our red blood cell system. During 2012, we have been conducting and are preparing to conduct *in vitro* studies, and have been preparing to conduct clinical trials in Europe that we plan to initiate towards the end of 2012 or early 2013, subject to regulatory approvals. Research and development expenses decreased by $0.2 million during

the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011, primarily due to higher costs incurred in 2011 associated with producing and qualifying the chemicals to be used in preclinical and potential clinical trials for our red blood cell system. We anticipate our research and development spending will increase over the near term as we expect to initiate planned Phase III clinical trials for our red blood cell system in Europe. In addition, we plan to perform certain additional *in vitro*

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studies and clinical development in the United States for our red blood cell system which would result in increased research and development spending. Subject to our ability to fund further development, clinical and regulatory efforts, we may also perform additional research and development activities in order to pursue regulatory approval for our products in the United States, including our planned modular PMA submission for our plasma system. In addition, we may choose to invest in ongoing research and development efforts for our existing INTERCEPT products, including a full or partial redesign of the INTERCEPT illuminator. 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 preclinical studies 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, which risks and uncertainties are discussed in further detail under Item 1A *Risk Factors* in Part II of this Quarterly Report on Form 10-Q.

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, the CIS and the Middle East, expenses for accounting, tax, and internal control, legal and facility related expenses, and insurance premiums.

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands, except percentages)	**2012**	**2011**	**Change**		**2012**	**2011**	**Change**	
Selling, general and administrative	$ 6,219	$ 5,380	$ 839	16%	$ 18,871	$ 17,115	$ 1,756	10%

Selling, general and administrative expenses increased by $0.8 million and $1.8 million during the three and nine months ended September 30, 2012, respectively, compared to the three and nine months ended September 30, 2011, respectively. The increase was primarily due to increased spending related to general corporate services, including legal fees, and higher stock-based compensation charges, and to a lesser extent, higher workforce costs.

We anticipate that selling, general and administrative expenses may increase modestly over time, as we expand our commercialization efforts in the markets where we currently sell our products and as we potentially expand commercialization efforts into new geographies.

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 determined a fair value of $2.0 million for 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 September 30,				Nine Months Ended September 30,			
(in thousands, except percentages)	**2012**	**2011**	**Change**		**2012**	**2011**	**Change**	
Amortization of intangible assets	$ 50	$ 51	($ 1)	(2)%	$ 151	$ 152	($ 1)	(1)%

Amortization of intangible assets remained relatively flat during the three and nine months ended September 30, 2012, compared to the three and nine months ended September 30, 2011 as there were no changes to the composition of our intangible assets or the assumptions used to determine the useful lives for all periods presented. In addition, no impairment charges were recognized related to our intangible assets during the three and nine months ended September 30, 2012, and 2011 as no events or changes in circumstances arose which would require us to test the recoverability of our intangible assets.

Non-Operating Income (Expense), net

Non-operating income (expense), net 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 debt, interest earned from our short-term investment portfolio, and other non-operating gains and losses.

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(in thousands, except percentages)	Three Months Ended September 30, 2012	2011	Change		Nine Months Ended September 30, 2012	2011	Change	
Revaluation of warrant liability	$ 873	$ 5,439	$ (4,566)	(84)%	$ 86	$ 3,822	$ (3,736)	(98)%
Foreign exchange gain (loss)	206	(41)	247	602%	(212)	394	(606)	(154)%
Interest expense	(136)	(394)	258	65%	(410)	(847)	437	52%
Other income (expense), net	(72)	(22)	(50)	(227)%	37	(25)	62	248%
Total non-operating income (expense), net	$ 871	$ 4,982	$ (4,111)	(83)%	$ (499)	$ 3,344	$ (3,843)	(115)%

Warrant liability

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, expire 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.

During the three months ended September 30, 2012, we recorded non-cash gains related to the change in the fair value of our warrants of $0.9 million primarily associated with a decline in our volatility, which was derived by the movement of our underlying stock price, as compared to non-cash gains related to the change in the fair value of our warrants of $5.4 million during the three months ended September 30, 2011, which was primarily due to changes in our underlying stock price, as compared to the strike price of our warrants. During the nine months ended September 30, 2012, we recorded a non-cash gain of $0.1 million associated with changes in the fair value of the warrants, as compared to non-cash gains related to the fair value of our warrants of $3.8 million during the nine months ended September 30, 2011, primarily due to changes in our underlying stock price specifically during the three months ended September 30, 2011, as compared to the strike price of the warrants.

Foreign exchange gain (loss)

Foreign exchange increased by $0.2 million during the three months ended September 30, 2012 compared to the three months ended September 30, 2011, which was primarily attributable to favorable foreign currency variations over that time period between the Euro and U.S. dollar, our functional currency. Foreign exchange declined by $0.6 million during the nine months ended September 30, 2012 compared to the nine ended September 30, 2011, which was primarily attributable to unfavorable foreign currency variations over that time period between the Euro and U.S. dollar.

Interest expense

Interest expense decreased by $0.3 million and $0.4 million during the three and nine months ended September 30, 2012, respectively, compared to the three and nine months ended September 30, 2011, respectively, due to lower interest rates from borrowings on our current credit facility with Comerica compared to our prior credit facility with Oxford, offset by interest paid for draws against our revolving credit facility with Comerica during the nine months ended September 30, 2012.

Other income (expense), net

Other income (expense), net was relatively consistent during both the three and nine months ended September 30, 2012, and 2011. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions.

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 to a lesser extent, contribution from product sales, net of expenses, and interest income.

At September 30, 2012, we had cash, cash equivalents and short-term investments of $26.7 million. Our cash equivalents and short-term investments primarily consist of money market instruments, which are classified for accounting purposes as available-for-sale.

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Operating Activities

Net cash used in operating activities was $11.0 million for the nine months ended September 30, 2012, compared to $14.6 million during the nine months ended September 30, 2011. The decrease in net cash used in operating activities was primarily related to changes in working capital with a decrease in accounts receivable during the nine months ended September 30, 2012, relative to the corresponding period in 2011 due to increased efforts in cash collections, a net increase in the combined total for our accounts payable and accrued liabilities as a result on the timing of payments, and to a lesser extent, the lower rate of inventory build during the nine months ended September 30, 2012 compared to the corresponding period in 2011. In addition, we recorded a current asset at September 30, 2012, representing the accepted warranty claim we filed against Fenwal during the three months ended September 30, 2012 relating to product warranty claims incurred and remediated by us during the quarter.

Investing Activities

Net cash provided by investing activities was $0.2 million for the nine months ended September 30, 2012, compared to $0.3 million during the nine months ended September 30, 2011. The decrease in investing activities is primarily due to the reinvestment of the proceeds received from the maturities of our then-existing investments into money market funds with original maturities of less than 90 days.

Financing Activities

Net cash provided by financing activities was $12.0 million during the nine months ended September 30, 2012, compared to $0.1 million during the nine months ended September 30, 2011. The increase in financing activities was primarily due to cash proceeds received from sales of our common stock pursuant to the MLV Agreement and the Cantor Agreement totaling $10.8 million. We also received the benefit of making interest-only payments on our growth capital facility with Comerica during the nine months ended September 30, 2012, compared to payments of both principal and interest on our prior debt during the corresponding period in 2011. In addition, we continue to utilize our revolving line of credit resulting in net cash received of $1.0 million during the nine months ended September 30, 2012, and experienced a higher volume of option exercises and employee stock purchase rights under our equity compensation plans during the nine months ended September 30, 2012, compared to the corresponding period in 2011.

Working Capital

Working capital decreased to $16.2 million at September 30, 2012, from $18.6 million at December 31, 2011, primarily due to increases in inventory levels in order to be able to fulfill anticipated future customer demand for our products coupled with the management of our supply chain, higher balances in cash and cash equivalents, which were substantially derived from cash proceeds received from the sale of our common stock pursuant to the MLV Agreement and Cantor Agreement and offset by cash used for our operations. This was also partially offset by decreases in accounts receivable due to our increased efforts to collect cash from our customers, a net increase in the combined total for our accounts payable and accrued liabilities due to our vendors, and increases on the current portion of our debt as our obligation to begin paying principal payments will occur in October 2012.

Capital Requirements

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 our planned modular PMA application submission to the FDA for the plasma system and pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trial and other development activities related to our platelet, plasma and red blood cell systems, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, 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, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that cash received from product sales, our available cash balances and access to debt 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 additional capital from institutional and commercial banking sources to fund future growth outside of our Amended Credit Agreement with Comerica on terms that may include restrictive covenants, which may comprise of covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us. The disruptions to the global credit and financial markets as well as general economic uncertainty, including the continued instability of the Eurozone, has generally made equity and debt financing more

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difficult to obtain and the terms less favorable to the companies seeking to raise financing. As a result of economic conditions, general global economic uncertainty 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, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we will need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. We do not plan on conducting any additional clinical trials of the red blood cell, platelet or plasma systems in the United States unless and until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Other Information

Historically, we have received significant awards in 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. As of March 31, 2012, we had exhausted the remaining availability under the August 2011 DoD grant. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding and we do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

We entered into the MLV Agreement in June 2011, as amended in January 2012 and August 2012, which provides for the issuance and sale of shares of our common stock over the term of the MLV Agreement having an aggregate offering price of up to $20.0 million from time to time through MLV as our sales agent. During the year ended December 31, 2011, approximately 3.5 million shares of our common stock were sold under the MLV Agreement for aggregate net proceeds of $9.7 million. During the nine months ended September 30, 2012, we sold approximately 3.1 million additional shares of our common stock for aggregate net proceeds of $9.5 million. We did not sell any shares of our common stock under the MLV Agreement during the three months ended September 30, 2012. At September 30, 2012, we have less than $0.1 million of common stock available to be sold under the MLV Agreement.

We also entered into the Cantor Agreement in August 2012 with Cantor that provides for the issuance and sale of shares of our common stock over the term of the Cantor Agreement having an aggregate offering price of up to $30.0 million through Cantor. During the three and nine months ended September 30, 2012, approximately 0.4 million shares of our common stock were sold under the Cantor Agreement for aggregate net proceeds of $1.1 million. At September 30, 2012, we have approximately $28.8 million of common stock available to be sold under the Cantor Agreement. The issuance and sale of these shares by us under the Cantor Agreement is subject to the continued effectiveness of our shelf registration statement referred to below. The offering of shares of our common stock pursuant to the Cantor Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the Cantor Agreement and (2) termination of the Cantor Agreement. The Cantor Agreement may be terminated by Cantor or us at any time upon 10 days notice to the other party, or by Cantor at any time in certain circumstances, including our undergoing a material adverse change.

In December 2011, we filed a shelf registration statement on Form S-3 to offer and sell up to $150.0 million of common stock, preferred stock, warrants, and/or debt securities, less amounts sold under the MLV Agreement following the effectiveness of the shelf registration statement. The registration statement was declared effective in January 2012 and expires in January 2015.

Commitments and Off-Balance Sheet Arrangements

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements as of September 30, 2012.

Commitments

The following summarizes our commitments at September 30, 2012 (in thousands):

	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Minimum purchase requirements	$ 2,856	$ 2,009	$ 797	$ 50	$ 0
Operating leases	2,223	845	1,282	96	0
Other commitments	1,370	485	287	287	311

Debt	9,114	2,092	7,022	0	0
Total contractual obligations	$ 15,563	$ 5,431	$ 9,388	$ 433	$ 311

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Minimum purchase requirements

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

Operating leases

We generally lease our office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. Our lease payments have increased as we exercised a ten year extension option on December 10, 2009, to extend the term of our Concord California lease and exercised a five year extension option in January 2012, to extend the term of our Amersfoort, The Netherlands lease for an additional five years following the original lease expiration of January 2013. However, we have the right to early terminate both our Concord California lease and our Amersfoort, The Netherlands lease, which may occur as early as January 2015, and February 2016, respectively. Our facility leases qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on our condensed consolidated balance sheets.

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. If we exercise our right to early terminate the Concord California lease, which may occur as early as January 2015, we would be required to pay for any remaining portion of the landlord financed leasehold improvements at such time. At September 30, 2012, we had an outstanding liability of $0.9 million related to these leasehold improvements.

Debt

The Amended Credit Agreement with Comerica provides for an aggregate borrowing of up to $12.0 million, comprised of a growth capital loan of $5.0 million, or Growth Capital Loan, and a formula based revolving line of credit, or RLOC, of up to $7.0 million. We pledged all current and future assets, excluding our intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., as security for borrowings under the Amended Credit Agreement.

Concurrent with the execution of the original loan and security agreement in September 2011, we borrowed $5.0 million under the Growth Capital Loan, substantially all of which was used to repay our prior debt with Oxford, with the remainder used for general corporate purposes. The Growth Capital Loan, which matures on September 30, 2015, bears a fixed interest rate of 6.37%, with interest only payments due for the first twelve months, followed by equal principal and interest payments for the remaining 36 months.

In September 2011, we incurred a commitment fee of $40,000 and loan fees of $50,000, which were recorded as a discount to our Growth Capital Loan and are being amortized as a component of interest expense using the effective interest method over the term of the Growth Capital Loan (discount was based on an implied interest rate of 7.07%). We will also be required to make a final payment fee of 1% of the amounts drawn under Growth Capital Loan due on the earlier of (i) prepayment of the Growth Capital Loan or (ii) the maturity of the Growth Capital Loan. The final payment fee will be accreted to interest expense using the effective interest method over the life of the Growth Capital Loan upon draw.

The Amended Credit Agreement also provides for a RLOC of up to $7.0 million, or the RLOC Loan Amount. The amount available under the RLOC is limited to the lesser of (i) 80% of eligible trade receivables or (ii) the RLOC Loan Amount. At September 30, 2012, and December 31, 2011, we had $3.3 million and $2.3 million, respectively, outstanding under the RLOC. We are required to repay the principal drawn from the RLOC at the end of the RLOC term on June 30, 2014, or earlier if a portion or all of the outstanding RLOC exceeds the amount available under the RLOC. The RLOC bears a floating rate based on the lender s prime rate plus 1.50%, with interest only payments due each month. At both September 30, 2012, and December 31, 2011, the floating rate of the RLOC was at 4.75%. In September 2011, we incurred a commitment fee of $20,000. Upon amendment of the loan and security agreement in June 2012, we incurred another annual commitment fee of $20,000 and received a credit for the unused portion of the initial fee. We will incur a $20,000 commitment fee at each annual anniversary beginning June 30, 2013.

We are required to maintain compliance with certain customary and routine financial covenants under the Amended Credit Agreement, including maintaining a minimum cash balance of $2.5 million at Comerica and achieving minimum revenue levels, which are measured monthly based on a six-month trailing basis and must be at least 75% of the pre-established future projected revenues for the trailing six-month

period. Non-compliance with the covenants could result in the principal of the note becoming due and payable. As of September 30, 2012, we were in compliance with the financial covenants as set forth in the Amended Credit Agreement.

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Financial Instruments

We maintain an investment portfolio of various securities, which are classified as available-for-sale and, consequently, are recorded on the 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. We did not have any unrealized gains or losses at both September 30, 2012, and December 31, 2011.

We invest our cash and cash equivalents in 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. Historically, our available-for-sale securities related to United States government agencies were 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. We did not record any other-than-temporary impairment losses during the three and nine months ended September 30, 2012, and 2011. Adverse global economic conditions, including the sovereign debt crisis in Europe, have had, and may continue to have, a negative impact on the market values of potential investments.

New Accounting Pronouncements

There have been no new accounting pronouncements issued during the three and nine months ended September 30, 2012, that are of significance, or potential significance, to us. Any recent accounting pronouncement that are of significance, or potential significance, to us are set forth in our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 5, 2012, under Note 2 in the Notes to Consolidated Financial Statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2012, there were no material changes to our market risk disclosures as set forth under, Item 7A *Quantitative and Qualitative Disclosures About Market Risk*, in Part II of our Annual Report on Form 10-K for the year ended December 31, 2011.

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), promulgated under 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 Quarterly Report on Form 10-Q, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of September 30, 2012.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable assurance, not absolute assurance, that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief accounting officer have concluded, that based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, 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.

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The INTERCEPT Blood System may not achieve broad market acceptance.

In order to increase market acceptance of the INTERCEPT Blood System, we must address issues and concerns from broad constituencies involved in the healthcare system, from blood centers to patients, 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 and outweigh their risks.

The 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 platelets 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 certain 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.

The INTERCEPT Blood System does not inactivate all known pathogens, and the inability of the INTERCEPT Blood System to inactivate certain pathogens may limit its market acceptance. For example, our products have not been demonstrated to be effective in the inactivation of certain non-lipid-enveloped viruses, including hepatitis A virus, due to these viruses biology. In addition, our products have not demonstrated a high level of inactivation for human parvovirus B-19, which is also a non-lipid-enveloped virus. 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 products have been demonstrated to effectively inactivate spore-forming bacteria, our products have not shown to be effective in inactivating bacterial spores, once formed. In addition, our products do not inactivate prions since prions do not contain nucleic acid. 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 studies of our products in both *in vitro* and *in vivo* 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.

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 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, their 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.

Product adoption may be negatively affected because we do not have FDA approval for any of our products. In addition, because we have not achieved widespread product adoption in key European countries, adoption in other countries has been and may in the future be adversely affected.

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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 pathogen inactivation systems in the United States is highly concentrated and 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 made 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, and may conduct and complete their own clinical trials before adopting our products. 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 implemented bacterial detection testing for platelets 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. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. 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, which may be technologically or economically infeasible for us to do.

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 since our inception. The platelet and plasma systems are not approved in the United States or in many other countries around the world. The red blood cell system is in the clinical development stage 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 in the near-term. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur. We expect to incur additional research development costs associated with our planned modular PMA application submission to the FDA for the plasma system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, and with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, which costs could be substantial and could extend the period during which we expect to operate at a loss.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Health care reform in the United States has also placed downward pressure on the pricing of medical products and has introduced new taxation on medical devices which could further impact our profit margins if we were to gain FDA approval to begin selling our products in the United States. Should we receive FDA approval to begin selling our products in the United States, recently passed legislation surrounding health care reform may impose a 2.3% excise tax on the sale of our products, regardless of our profitability. This excise tax would reduce our potential operating profits.

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

Sales of our products are dependent on purchasing decisions and/or 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 defer purchases, may be unable to satisfy their reimbursement obligations, or may delay payment for the INTERCEPT Blood System. In addition, there are concerns for the overall stability and suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European Union, or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect 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 investigational 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 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, 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 studies 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.

In 2007, we obtained a CE mark approval (extended in 2012) 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 modular pre-market approval application, or PMA, to the FDA. The modular PMA application process is a compilation of sections or modules submitted at different times that together become a complete PMA application. The content, order and submission timing of the modules must be approved by the FDA, and a modular PMA application cannot be approved until all modules have been submitted to, reviewed by and accepted by the FDA. Based on discussions with the FDA, we

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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 for platelets 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 will still 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 clinical trial. The dimensions of such a Phase III clinical 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 modular PMA for the platelet system, which we may be unable to do.

In 2006, we obtained a CE mark approval (extended in 2011) from European Union regulators for our plasma system and final French approval of INTERCEPT-treated plasma in May 2007. SwissMedic approved INTERCEPT-treated plasma in September 2010. 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. INTERCEPT-treated plasma was granted orphan drug status in February 2011 by the FDA Office of Orphan Products Development for the treatment of thrombotic thrombocytopenic purpura. Pursuant to our recent discussions with the FDA, we plan to submit a modular PMA upon FDA approval of a PMA shell for the use of our plasma system for a broad variety of indications. However, the FDA may require us to compile supplemental data or to complete additional clinical trials before any approval of our planned PMA would be granted, or for plasma derived from whole-blood collections. Our clinical trials of our plasma system were conducted solely on plasma collected by apheresis. Should the FDA require us to complete any additional clinical trials, our ability to conduct and complete any additional clinical trials of the plasma system to support approval in the United States would be subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources before we would initiate any such trials. Moreover, we must reach agreement on the content, order and submission timing of the modules for our planned plasma PMA. Should we reach agreement on the PMA shell with the FDA, the modular PMA cannot be approved until all modules have been submitted to, reviewed by, and accepted by the FDA. Should significant questions arise during the submission process or if we are required to conduct additional clinical trials to support our planned PMA submission, approval may take a significant period of time to obtain`, if ever, and we would be subject to our ability to generate sufficient cash flows from our operations or obtain adequate funding from external sources before we could undertake any additional clinical trials.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect the FDA to seek the advice of the BPAC. 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 would 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 would require both time and expense to obtain such qualification.

If one of our product candidates receives approval for commercial sale in the United States, the FDA may require a post-marketing clinical study, which can involve significant expense. Other regulatory authorities outside of the United States may also require such post-marketing studies. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

We have conducted many toxicology studies to demonstrate the platelet and plasma systems safety, and we have conducted and plan to conduct toxicology studies for the 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

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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. For example, if we determine that it is feasible for us to conduct the proposed second Phase III trial of the platelet system and adequate funding is available to us to conduct this trial, we expect that the FDA would require us to demonstrate a very low level of potential side effects in that trial.

In 2003, we terminated Phase III clinical trials evaluating a prior generation of the red blood cell system in acute and chronic anemia patients. The trials were terminated due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients in the Phase III clinical trial for chronic anemia. Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. In a subsequent Phase I clinical trial to evaluate recovery and survival of treated red blood cells with the modified process that we initiated in the fourth quarter of 2008, there were no adverse events reported. Based on the results from that trial, we plan to conduct Phase III clinical trials in Europe using the modified process in patients with acute and chronic anemia, if our clinical trial applications are approved by European regulators. However, we cannot assure you that the adverse events observed in the terminated Phase III clinical trials of our red blood cell system will not be observed in any future Phase III clinical trials of our red blood cell system. In addition, although the unblinded data from our 2003 Phase III clinical trial of the red blood cell system for acute anemia patients indicated that the primary endpoint had been met, we cannot assure you that the same result will be observed in any potential future Phase III clinical trials using our modified process.

In March 2012, we submitted a proposed clinical trial protocol to the FDA for a proposed Phase III clinical trial evaluating the red blood cell system in patients receiving chronic red cell transfusion support for sickle cell disease or thalassemia. The FDA advised us that at least an additional Phase II recovery and survival study will need to be successfully completed and reported to the FDA prior to any initiation of the proposed Phase III clinical trial. We also understand that one or more additional *in vitro* studies will be required to be successfully completed and submitted to the FDA prior to any initiation of the proposed Phase III clinical trial.

We plan to initiate Phase III clinical trials of our red blood cell system for acute anemia patients and separately, chronic anemia patients, in Europe if the proposed clinical trials are accepted by European regulators, which we cannot assure you will occur. We expect to conduct a further process validation study in Europe prior to commencement of such trial for chronic anemia patients. Such studies, including the studies required by the FDA prior to its review of the proposed United States Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a number of years, if ever. 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. We understand that while the planned acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe if the results are positive, a successful outcome in the planned Phase III chronic anemia clinical trial in Europe would also be required for our red blood cell system to achieve market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries in Europe, including France and Germany. These additional Phase III clinical trials would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells. 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. We will also need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe or the United States. Many of these activities will require capital beyond that which we currently have, and we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. 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 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.

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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, among other requirements, that 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 ability to commercialize the INTERCEPT Blood System may be irreparably harmed.

We have a wholly-owned subsidiary, headquartered in The Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in geographies where the 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 distribution agreements, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our products directly. 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. Our distributors may fail to sell product inventory they have purchased from us to end customers. Initial purchases of illuminators or INTERCEPT disposable kits by these third parties may not lead to follow-on purchases of platelet and plasma systems disposable 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. A concentrated number of distributors collectively comprise a significant portion of our overall product revenues. Accordingly, our product revenues may be adversely impacted with the loss of one or more of these distributors. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. The loss of these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us which may be difficult to do in a timely manner, or at all, which may adversely affect our product revenues. 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. Agreements with our distributors generally require compliance with local anti-corruption laws and the U.S. Foreign Corrupt Practices Act. We have limited ability to control the actions of our distributors to ensure they are compliant with both local anti-corruption laws and the U.S. Foreign Corrupt Practices Act. Noncompliance by a distributor could expose us to civil or criminal liability, and/or prohibitions on selling our products in certain countries. 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 disposable kits for platelet and plasma are manufactured and assembled by Fenwal. Fenwal has agreed, through a manufacturing and supply agreement signed with us in December 2008, to manufacture our INTERCEPT disposable kits for the platelet and plasma systems. Our manufacturing and supply agreement with Fenwal extends through December 31, 2013, and is automatically renewed for one year terms. Fenwal may terminate the manufacturing and supply agreement, provided that Fenwal notifies us with at least thirty months written notice prior to termination. Fenwal is our sole supplier for the manufacture of these products. Fenwal may fail to manufacture an adequate supply of INTERCEPT 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 Ash Stevens Inc., or Ash Stevens, for the manufacture of amotosalen, our proprietary compound for inactivating pathogens, Porex Corporation, or Porex, for the manufacture of components of the compound adsorption devices, and NOVA Biomedical Corporation, or NOVA, for the manufacture of illuminators and certain components of the INTERCEPT Blood System. These independent suppliers are our sole suppliers for such components.

Our manufacturing and supply agreement with Ash Stevens extends through December 31, 2015, and is automatically renewable thereafter for periods of two years each, but may be terminated by Ash Stevens provided that Ash Stevens notifies us in writing at least two years in advance.

Although we are not subject to minimum annual purchase requirements under the manufacturing and supply agreement with Ash Stevens, we may be required to pay a maintenance fee of up to $50,000 a year if specified quantities of amotosalen are not purchased in any year. We have incurred these penalties in the past and may incur these penalties in future periods.

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Our agreement with Porex expires on December 31, 2012. Prior to the expiration of that contract, we will need to negotiate an amendment or enter into a new contract with Porex, or identify, validate and contract with an alternate supplier for such components of the compound adsorption devices. Failure to reach agreement with Porex or an alternate supplier would impede the manufacture and supply INTERCEPT disposable kits to existing and prospective customers. We are subject to certain minimum annual purchase requirements under our agreement with Porex and are required to compensate Porex if we do not meet such minimum annual purchase requirements. We also have contracts with other companies who are our sole suppliers of raw materials used to make compound adsorption devices, which includes such companies as Brotech Corporation d/b/a Purolite Company, or Purolite. Our supplier agreement with Purolite extends through December 2013, and will automatically renew each year. Purolite may terminate the supplier agreement provided that Purolite notifies us in writing at least two years in advance. Our agreement with NOVA, which manufacturers our illuminators, extends through September 2013 and is automatically renewable for one year terms, but may be terminated by NOVA on at least twelve months prior written notice.

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 which 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.

We have a limited supply of saleable illuminators. Currently NOVA is manufacturing new illuminators to supply customer demand. Should NOVA have difficulties manufacturing sufficient quantities of illuminators in a timely manner, we may not be able to supply customer demand or provide replacement illuminators to existing customers. 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 have a limited supply of spare parts for the maintenance of illuminators used by our customers. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. We will likely need to redesign the illuminators used in the platelet and plasma systems. Such redesign may be expensive and could 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 and approvals. Fenwal is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. 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.

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In several instances over the past two years, nonconformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. During the three months ended September 30, 2012, we issued a field corrective action notice to our customers whereby we replaced certain disposable kits related to our plasma system due to non-conformities as well as for the potential of non-conformities for certain component within specific lots. Non-conformities can increase our expenses and reduce gross margins. Should similar or other non-conformities occur in the future, we may be unable to manufacture products to meet customer demand, which would result in lost sales and could cause irreparable damage to our customer relationships.

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. Many of our supply agreements 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.

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We are in the early stages of commercializing the INTERCEPT Blood System. As such, we have limited experience overseeing the manufacture of INTERCEPT disposable kits and illuminators and may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or may not accurately forecast demand ourselves 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 our suppliers fail to produce components or our finished products satisfactorily, timely, 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 systems disposable kits have a two-year shelf life from the date of manufacture. We and our distributors may be unable to ship product to customers prior to the expiration of the 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 platelet system is designed to work with platelets collected and stored in storage solutions, called Intersol and SSP+, and for platelets suspended in plasma. In addition, Fenwal is the exclusive manufacturer of Intersol and MacoPharma of SSP+, both widely-used platelet additive solutions. Many of our customers and prospective customers use Intersol or SSP+ in connection with INTERCEPT treatment. Should Fenwal or MacoPharma fail to obtain or maintain regulatory approval for Intersol or SSP+, respectively, or if either should decide to cease distribution of their respective additive solutions to customers and prospective customers, our ability to sell the INTERCEPT Blood System may be impaired.

In order to address the entire market in the United States and Japan, 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 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.

Our red blood cell system that was used in our preclinical studies and the Phase I red blood cell trial initiated in the fourth quarter of 2008 was a prototype of the system expected to be used in the final product. As a result, we plan to perform additional preclinical studies and clinical trials using the commercial version of the system to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial product, which would increase our expenses and delay the potential commercialization of our red blood cell system. 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 red blood cell system in a timely manner, 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 red blood cell system.

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We will need to identify and contract with manufacturers who can develop processes to manufacture components and 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, market their products more effectively than we market our products, or receive regulatory approval before our products, our commercial opportunities could be reduced or eliminated.

We expect our products will continue 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. If competitors products experience significant problems, customers and potential customers may question the safety and efficacy of all pathogen inactivation technologies, including the INTERCEPT Blood System. Such questions and concerns may impair our ability to market and sell the INTERCEPT Blood System.

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 certain non-lipid-enveloped viruses, such as hepatitis A virus, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, which is also a non-lipid-enveloped virus, for which our products have not demonstrated a high level of inactivation. While studies have demonstrated that our products can effectively inactivate a broad spectrum of pathogens in blood components, market acceptance of our products may be reduced if customers determine that competitors 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 competitors 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. TerumoBCT , a subsidiary of Terumo Corporation, has developed 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 TerumoBCT is also developing a pathogen inactivation system for whole blood. TerumoBCT s product candidate, if successful, may offer competitive advantages over our INTERCEPT Blood System. Terumo Corporation is 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 in Japan, may be negatively affected by Terumo s resources and their pre-existing relationships with regulators and customers.

Octapharma AG recently received a recommendation from the FDA s BPAC for its plasma product for the treatment of certain indications. Octapharma AG s product may receive FDA approval and may be commercialized ahead of our own plasma product candidate. Should Octapharma enter into exclusive agreements with key customers, our plasma product candidate, should it receive approval in the United States, may encounter market resistance and have a more limited market into which we can sell.

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. Regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets.

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.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices. 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 preclinical and clinical 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.

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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 our planned modular PMA application submission to the FDA for the plasma system and pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trial and other development activities related to our platelet, plasma and red blood cell systems, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, 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, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that cash received from product sales, our available cash balances and access to debt 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 additional capital from institutional and commercial banking sources to fund future growth outside of our Amended Credit Agreement with Comerica Bank on terms that may include restrictive covenants, which may comprise of covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us.

The disruptions to the global credit and financial markets as well as general economic uncertainty, including the continued instability of the Eurozone, 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 economic conditions, general global economic uncertainty 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, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we will need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe. We do not plan on conducting any additional clinical trials of the red blood cell, platelet or plasma systems in the United States unless and until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Historically, we have received significant awards in funding under cooperative agreements with the DoD for the INTERCEPT Blood System. By March 31, 2012, we had exhausted the remaining availability under the August 2011 DoD grant. 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 available for government funding and we do not expect any revenue from government grants and cooperative agreements for the foreseeable future, if at all.

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We have issued debt 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.

We currently maintain a credit agreement with Comerica that provides for an aggregate borrowing of up to $12.0 million, comprised of a growth capital loan of $5.0 million and a formula based revolving line of credit of up to $7.0 million. In September 2011, we borrowed $5.0 million and subsequently drew an aggregate of $3.3 million from the revolving line of credit under the credit agreement. The credit agreement is secured by all our current and future assets, except for intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V. The credit agreement requires that we comply with certain customary and routine covenants, including the requirement to maintain a minimum cash balance of $2.5 million and achieve minimum revenue levels, which are measured monthly based on a six-month trailing basis and must be at least 75% of the pre-established future projected revenues for the trailing six-month period. If we are unable to comply with the covenants in the credit agreement, the lender may call the note, which would require us to repay the principal of the note sooner than we have anticipated, and if we are unable to pay back the principal at such time, the lender would be allowed to liquidate collateralized assets. This in turn, would significantly 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 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. As a result, in order to commercialize our platelet or plasma systems in the United States, we may be required to obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all. Our patents expire at various dates between 2013 and 2027. Recent patent applications will, if

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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 at various dates from 2017 to 2024. 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, consultants and 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.

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

Product sales of the INTERCEPT blood system are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT 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 cash payments for expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of other income, net on our condensed consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. In addition, in a period where the U.S. dollar is strengthening/weakening as compared to Euros, our revenues and expenses denominated in Euros are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have 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 October 1, 2010 to September 30, 2012, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of $1.92 to a high of $4.53. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

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

biological or medical discoveries;

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

developments concerning proprietary rights, including patents and litigation matters;

regulatory developments;

status of development partnerships;

dilution from future issuances of common stock, including through the exercise of 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.

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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 accounting firm 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 accounting firm 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, our compensatory arrangements and Delaware law could make it more difficult for a third party to acquire us, even if the offer may be considered beneficial by our stockholders.

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4(1)	Certificate of Elimination of Series B Preferred Stock of Cerus Corporation.
3.5(2)	Amended and Restated Bylaws of Cerus Corporation.
4.1(3)	Specimen Stock Certificate.
4.2(4)	Rights Agreement, 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.).
4.3(5)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
4.4(6)	Form of 2009 Warrant to Purchase Common Stock.
4.5(7)	Form of 2010 Warrant to Purchase Common Stock.
10.1(8)	Controlled Equity Offering[SM] Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.2(8)	Amendment No. 2 to At-The-Market Issuance Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and MLV & Co. LLC.
10.3(9)	Second Amendment to Loan and Security Agreement, effective as of June 30, 2012, by and between Cerus Corporation and Comerica Bank.
31.1	Certification of the Principal Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(10)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS(11)	XBRL Instance Document.
101.SCH(11)	XBRL Taxonomy Extension Schema Document.
101.CAL(11)	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF(11)	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB(11)	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE(11)	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K (File No. 000-21937), filed with the SEC on August 24, 2012.
(2) Incorporated by reference to the like-described exhibit to the Registrant s Current Report on Form 8-K (File No. 000-21937), filed with the SEC on June 19, 2008.
(3) Incorporated by reference to the like-described exhibit to the Registrant s Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(4) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q (File No. 000-21937), for the quarter ended June 30, 2009.

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(9) Incorporated by reference to the like-described exhibit to the Registrant s Quarterly Report on Form 10-Q (File No. 000-21937), for the quarter ended June 30, 2012.

(10) 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 the Registrant 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.

(11) Furnished herewith. Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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SIGNATURE

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

CERUS CORPORATION

Date: November 8, 2012

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

(on behalf of registrant and as Principal Financial Officer)

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