CERUS CORP
Form 10-Q
May 12, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

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 April 24, 2014, there were 72,513,000 shares of the registrant s common stock outstanding.

Table of Contents

CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE MONTHS ENDED MARCH 31, 2014

TABLE OF CONTENTS

Table of Contents

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2014 (Unaudited)	December 31, 2013 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,992	$ 29,485
Short-term investments	24,263	28,191
Accounts receivable	4,943	6,125
Inventories	11,307	13,063
Prepaid expenses	1,661	848
Other current assets	913	442
Total current assets	67,079	78,154
Non-current assets:		
Property and equipment, net	3,166	2,189
Goodwill	1,316	1,316
Intangible assets, net	1,294	1,344
Restricted cash	308	308
Other assets	64	70
Total assets	$ 73,227	$ 83,381
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,493	$ 5,674
Accrued liabilities	8,838	9,813
Deferred revenue	279	181
Debt - current	3,268	3,366
Warrant liability	11,356	20,390
Total current liabilities	27,234	39,424
Non-current liabilities:		
Deferred income taxes	95	89
Other non-current liabilities	1,031	1,073

Total liabilities	28,360	40,586
Commitments and contingencies		
Stockholders equity:		
Common stock	72	72
Additional paid-in capital	548,202	545,905
Accumulated other comprehensive income	7	7
Accumulated deficit	(503,414)	(503,189)
Total stockholders equity	44,867	42,795
Total liabilities and stockholders equity	$ 73,227	$ 83,381

(1) The financial information in this column was derived from audited financial statements included in the Company s 2013 Annual Report on Form 10-K.

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

Table of Contents

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended March 31,	
	2014	**2013**
Revenue:		
Product revenue	$ 7,866	$ 9,733
Cost of product revenue	4,157	5,090
Gross profit on product revenue	3,709	4,643
Operating expenses:		
Research and development	4,642	2,700
Selling, general and administrative	8,236	6,853
Amortization of intangible assets	50	50
Total operating expenses	12,928	9,603
Loss from operations	(9,219)	(4,960)
Non-operating gain (expense), net:		
Gain (loss) from revaluation of warrant liability	9,034	(5,073)
Foreign exchange gain (loss)	21	(54)
Interest expense	(193)	(131)
Other income, net	170	17
Total non-operating gain (expense), net	9,032	(5,241)
Loss before income taxes	(187)	(10,201)
Provision for income taxes	38	51
Net loss	$ (225)	$ (10,252)
Net loss per share:		
Basic	$ (0.00)	$ (0.17)
Diluted	$ (0.12)	$ (0.17)
Weighted average shares outstanding used for calculating net loss per share:		
Basic	72,088	59,730
Diluted	75,158	59,730

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

4

Table of Contents

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

UNAUDITED

(in thousands)

	Three Months Ended March 31,	
	2014	**2013**
Net loss	$ (225)	$ (10,252)
Other comprehensive loss	0	0
Comprehensive loss	$ (225)	$ (10,252)

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

Table of Contents

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Three Months Ended March 31,	
	2014	**2013**
Operating activities		
Net loss	$ (225)	$ (10,252)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	325	167
Stock-based compensation	946	713
Changes in revaluation of warrant liability	(9,034)	5,073
Non-cash interest expense	0	4
Deferred income taxes	6	7
Loss on disposal of fixed assets	0	56
Changes in operating assets and liabilities, net of effects of acquired business:		
Accounts receivable	1,182	(289)
Inventories	1,117	(1,624)
Other assets	(764)	910
Accounts payable	(2,181)	(3,299)
Accrued liabilities	(1,295)	85
Deferred revenue	98	97
Net cash used in operating activities	(9,825)	(8,352)
Investing activities		
Capital expenditures	(839)	(26)
Purchases of investments and certain other assets	(460)	0
Maturities of investments	4,300	0
Net cash provided by (used in) investing activities	3,001	(26)
Financing activities		
Net proceeds from equity incentive plans	1,425	152
Net proceeds from public offering	31	51,502
Proceeds from revolving line of credit	0	526
Payments on debt, revolving line of credit and landlord provided leasehold incentives	(125)	(1,335)
Net cash provided by financing activities	1,331	50,845
Net increase in cash and cash equivalents	(5,493)	42,467

Cash and cash equivalents, beginning of period	29,485	26,696
Cash and cash equivalents, end of period	$ 23,992	$ 69,163

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

Table of Contents

CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

UNAUDITED

Note 1. Summary of Significant Accounting Policies

Principles of Consolidation 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 months ended March 31, 2014, are not necessarily indicative of the results that may be expected for the year ending December 31, 2014, or for any future periods.

These condensed consolidated financial statements and notes thereto should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2013, which were included in the Company s 2013 Annual Report on Form 10-K, filed with the SEC on March 7, 2014. The accompanying consolidated balance sheet as of December 31, 2013 has been derived from the Company s audited consolidated 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 source of revenues for the three months ended March 31, 2014 and 2013 was product revenue from sales of the INTERCEPT Blood System for platelets and plasma (platelet and plasma systems).

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 estimated selling price. The Company has determined that vendor specific objective evidence is not discernible due to the Company s 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 March 31, 2014 and December 31, 2013, the Company had $0.3 million and $0.2 million, respectively, of short-term deferred revenue on its condensed consolidated balance sheets related to future performance obligations. Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs.* Value-added-taxes (VAT) that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such VAT from product revenue.

Table of Contents

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. 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 which included corporate debt and United States government agency securities are designated as available-for-sale and classified as short-term investments. In accordance with ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities*, the Company 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 were recorded in Net unrealized gains (losses) on available-for-sale securities, net of taxes on the Company s condensed consolidated statements of comprehensive loss. Realized gains and losses from the sale of available-for-sale investments were recorded in Other income, net on the Company s condensed consolidated statements of operations. The cost of securities sold was based on the specific identification method. The Company reported the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews 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. The Company also has certain non-US dollar denominated deposits recorded as Restricted cash in compliance with certain foreign contractual requirements.

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 major financial institutions 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 March 31, 2014, 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. At March 31, 2014 and December 31, 2013, the Company had not recorded any reserves for potentially uncollectible accounts.

Table of Contents

The Company had three customers and two customers that accounted for more than 10% of the Company s outstanding trade receivables at March 31, 2014, and December 31, 2013, respectively. These customers cumulatively represented approximately 65% and 55% of the Company s outstanding trade receivables at March 31, 2014, and December 31, 2013, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At March 31, 2014, and December 31, 2013, 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 before being sold to and ultimately incorporated and assembled by Fresenius, Inc. (Fresenius) 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 sold to Fresenius 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 work-in-process and finished units to meet the Company s forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At March 31, 2014 and December 31, 2013, 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 sold to Fresenius for finished disposable kit production 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 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 March 31, 2014, and December 31, 2013, the Company had $0.3 million and $0.4 million, respectively, recorded for potential obsolete, expiring or unsalable product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, leasehold improvements, 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.

Capitalization of Software Costs

The Company capitalizes certain significant costs incurred in the acquisition and development of software for internal use, including the costs of the software, materials, consultants, and payroll and payroll-related costs for employees during the application development stage. Costs incurred prior to the application development stage, costs incurred

once the application is substantially complete and ready for its intended use, and other costs not qualifying for capitalization, including training and maintenance costs, are charged to expense.

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. 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

Table of Contents

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 segment and has 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 Unaudited 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 months ended March 31, 2014, and 2013.

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 less than $0.1 million and $(0.1) million during the three months ended March 31, 2014, and 2013, 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 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 Unaudited 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

Table of Contents

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 Unaudited 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 1998 through 2013 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

Net Income (Loss) Per Share

Basic net income (loss) per 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 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. Diluted net income (loss) per 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.

Certain potential dilutive securities were excluded from the dilution calculation for the three months ended March 31, 2014, and 2013, as their inclusion would have been anti-dilutive.

Table of Contents

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income (loss) per share for the three months ended March 31, 2014, and 2013 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2014	2013
Numerator for Basic and Diluted:		
Net loss used for basic calculation	$ (225)	$ (10,252)
Effect of revaluation of warrant liability	(9,034)	0
Adjusted net loss used for diluted calculation	$ (9,259)	$ (10,252)
Denominator:		
Basic weighted average number of shares outstanding	72,088	59,730
Effect of dilutive potential shares	3,070	0
Diluted weighted average number of shares outstanding	75,158	59,730
Net loss per share:		
Basic	$ (0.00)	$ (0.17)
Diluted	$ (0.12)	$ (0.17)

The table below presents shares underlying stock options, employee stock purchase plan rights, warrants and restricted stock units that are excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the three months ended March 31, 2014 and 2013 (shares in thousands):

	Three Months Ended March 31,	
	2014	2013
Weighted average number of anti-dilutive potential shares	16,901	15,531

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.

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 its 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 quoted prices are available in active markets for identical assets, which include the Company s cash accounts and money market funds. 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 corporate debt and United States government agency securities. The available-for-sale securities are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs (observable in the market) 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.

Table of Contents

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

New Accounting Pronouncements

There have been no new accounting pronouncements issued during the three months ending March 31, 2014 that are of significance, or potential significance, to the Company.

Note 2. Fair Value on Financial Instruments

The Company determines the fair value of an asset or liability based on the assumptions that market participants would use in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritized the inputs into three broad levels as follows:

Level 1: Quoted prices in active markets for identical instruments

Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)

Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

To estimate the fair value of Level 2 debt securities as of March 31, 2014 the Company s primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and United States government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset, a secondary pricing service is utilized.

Table of Contents

The fair values of the Company s financial assets and liabilities were determined using the following inputs at March 31, 2014 (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]	$ 9,648	$ 9,648	$ 0	$ 0
Corporate debt securities [2]	20,251	0	20,251	0
United States government agency securities [2]	4,012	0	4,012	0
Total financial assets	$ 33,911	$ 9,648	$ 24,263	$ 0
Warrant liability [3]	$ 11,356	$ 0	$ 0	$ 11,356
Total financial liabilities	$ 11,356	$ 0	$ 0	$ 11,356

(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.

The fair values of the Company s financial assets and liabilities were determined using the following inputs at December 31, 2013 (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]	$ 8,650	$ 8,650	$ 0	$ 0
Corporate debt securities [2]	23,173	0	23,173	0
United States government agency securities [2]	5,018	0	5,018	0
Total financial assets	$ 36,841	$ 8,650	$ 28,191	$ 0

Warrant liability [3]	$ 20,390	$ 0	$ 0	$ 20,390
Total financial liabilities	$ 20,390	$ 0	$ 0	$ 20,390

(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.

Table of Contents

A reconciliation of the beginning and ending balances for warrant liability using significant unobservable inputs (Level 3) from December 31, 2013 to March 31, 2014 was as follows (in thousands):

Balance at December 31, 2013	$ 20,390
Decrease in fair value of warrants	(9,034)
Balance at March 31, 2014	$ 11,356

See Note 1 and 10 in the Notes to Unaudited 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 three months ended March 31, 2014 or the year ended December 31, 2013.

Note 3. Available-for-sale Securities

The following is a summary of available-for-sale securities at March 31, 2014 (in thousands):

	March 31, 2014		
	Carrying Value	Gross Unrealized Gain	Fair Value
Money market funds	$ 9,648	$ 0	$ 9,648
Corporate debt securities	20,243	8	20,251
United States government agency securities	4,012	0	4,012
Total available-for-sale securities	$ 33,903	$ 8	$ 33,911

The following is a summary of available-for-sale securities at December 31, 2013 (in thousands):

	December 31, 2013		
	Carrying Value	Gross Unrealized Gain	Fair Value
Money market funds	$ 8,650	$ 0	$ 8,650
Corporate debt securities	23,165	8	23,173
United States government agency securities	5,019	(1)	5,018
Total available-for-sale securities	$ 36,834	$ 7	$ 36,841

Available-for-sale securities at March 31, 2014 and December 31, 2013 consisted of the following by original contractual maturity (in thousands):

	March 31, 2014		December 31, 2013	
	Carrying Value	Fair Value	Carrying Value	Fair Value
Due in one year or less	$ 33,903	$ 33,911	$ 30,700	$ 30,701
Due greater than one year and less than three years	0	0	6,134	6,140
Total cash equivalents and short-term investments	$ 33,903	$ 33,911	$ 36,834	$ 36,841

The Company did not record any gross realized gains from the sale or maturity of available-for-sale investments during the three months ended March 31, 2014 and 2013. 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 months ended March 31, 2014 and 2013, respectively.

Table of Contents

Note 4. Inventories

Inventories at March 31, 2014 and December 31, 2013 consisted of the following (in thousands):

	March 31, 2014	December 31, 2013
Work-in-process	$ 2,142	$ 4,863
Finished goods	9,165	8,200
Total inventories	$ 11,307	$ 13,063

Note 5. Goodwill and Intangible Assets, net

Goodwill

During the three months ended March 31, 2014, the Company did not dispose of or recognize additional goodwill. The Company expects to perform its annual review of goodwill on August 31, 2014, unless indicators of impairment are identified prior to that date. As of March 31, 2014, the Company has not identified any indicators of goodwill impairment.

Intangible Assets, net

The following is a summary of intangible assets, net at March 31, 2014 (in thousands):

	March 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$ 2,017	$ (723)	$ 1,294
Total intangible assets	$ 2,017	$ (723)	$ 1,294

The following is a summary of intangible assets, net at December 31, 2013 (in thousands):

	December 31, 2013		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$ 2,017	$ (673)	$ 1,344

Total intangible assets	$ 2,017	$ (673)	$ 1,344

The Company recognized $0.05 million in amortization expense related to intangible assets for each of the three months ended March 31, 2014 and 2013. During the three months ended March 31, 2014 and 2013, there were no impairment charges recognized related to the acquired intangible assets.

At March 31, 2014, the expected annual amortization expense of the intangible assets, net is $0.15 million for the remaining nine months of 2014, $0.2 million annually beginning with the year ending December 31, 2015 through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Table of Contents

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 March 2014, 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. As of March 31, 2014, the Company has not received any royalties under this agreement.

Note 7. Accrued Liabilities

Accrued liabilities at March 31, 2014 and December 31, 2013 consisted of the following (in thousands):

	March 31, 2014	December 31, 2013
Accrued compensation and related costs	$ 1,899	$ 2,527
Accrued inventory costs	2,534	3,553
Accrued professional services	2,995	2,722
Other accrued expenses	1,410	1,011
Total accrued liabilities	$ 8,838	$ 9,813

Note 8. Debt

Debt at March 31, 2014 consisted of the following (in thousands):

	March 31, 2014		
	Principal	Unamortized Discount	Total
Comerica - Revolving Line of Credit, due 2014	$ 3,268	$ 0	$ 3,268
Less: debt - current	(3,268)	0	(3,268)
Debt - non-current	$ 0	$ 0	$ 0

Debt at December 31, 2013 consisted of the following (in thousands):

	December 31, 2013		
	Principal	Unamortized Discount	Total
Comerica - Revolving Line of Credit, due 2014	$ 3,366	$ 0	$ 3,366
Less: debt - current	(3,366)	0	(3,366)

Debt - non-current	$ 0	$ 0	$ 0

Principal and interest payments on debt at March 31, 2014 are expected to be $3.3 million through June 2014 when the Revolving Line of Credit becomes due.

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.

Table of Contents

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 was scheduled to mature on September 30, 2015 and bore 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 April 2013, the Company repaid in full the Growth Capital Loan balance and all accrued interest as well as a scheduled final payment fee of $0.05 million, in an aggregate amount of $4.2 million. The Company has no further obligations under the Growth Capital Loan.

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 March 31, 2014, and December 31, 2013, the Company had $3.3 million and $3.4 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 March 31, 2014, and December 31, 2013, the floating rate of the RLOC was 4.75%.

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 March 31, 2014, the Company was in compliance with the financial covenants as set forth in the Amended Credit Agreement.

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. In June 2013, the Company entered into a new lease for additional space in Concord. The lease has a two year initial term with four (4) two year options for the Company to renew. The lease commenced on August 1, 2013 and obligates the Company to make rent payments for the remaining nine months of $115,776 and $90,048 in 2014 and 2015, respectively. 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 2010, the Company financed $1.1 million of leasehold improvements at one of its facilities in Concord, California. 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 under which such improvements were made, 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 March 31, 2014, the Company had an outstanding liability of $0.7 million related to these leasehold improvements, of which $0.1 million was reflected in Accrued liabilities and $0.6 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 Fresenius at no cost for use in manufacturing finished INTERCEPT disposable kits. Certain of these agreements require minimum purchase commitments from the Company.

Table of Contents

Note 10. Stockholders Equity

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 Black-Scholes model and/or 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 received net proceeds of approximately $19.7 million, after deducting underwriting discounts and commissions and stock issuance costs of approximately $1.3 million, from an underwritten public offering of 7.4 million units. Each unit sold consisted of one share of common stock and a warrant to purchase 1/2 of a share of common stock. Each unit was sold for $2.85, resulting in the issuance of 7.4 million shares of common stock and warrants to purchase 3.7 million shares of common stock, exercisable at an exercise price of $3.20 per share (2010 Warrants). The warrants issued in November 2010 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 Black-Scholes model and/or 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 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 March 31, 2014 and December 31, 2013 consisted of the following (in thousands):

	March 31, 2014	December 31, 2013
2009 Warrants	$ 4,637	$ 8,542
2010 Warrants	6,719	11,848
Total warrant liability	$ 11,356	$ 20,390

The fair value of the Company s warrants was based on using the binomial-lattice option valuation model and using the following assumptions at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013

2009 Warrants:		
Expected term (in years)	0.40	0.65
Estimated volatility	52%	45%
Risk-free interest rate	0.07%	0.10%
Expected dividend yield	0%	0%
2010 Warrants:		
Expected term (in years)	1.61	1.86
Estimated volatility	45%	41%
Risk-free interest rate	0.44%	0.38%
Expected dividend yield	0%	0%

The Company recorded a non-cash gain of $9.0 million and a non-cash loss of $5.1 million during the three months ended March 31, 2014, and 2013, respectively, in Gain (Loss) from 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 value the warrants. 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. During the three months ended March 31, 2014, there were no exercises of these warrants. In 2013, warrants to purchase 186,586 shares of common stock were exercised from the outstanding 2010 Warrants.

Table of Contents

Sales Agreements

The Company entered into an At-The-Market Issuance Sales Agreement in June 2011, as amended in January 2012 and August 2012 (as amended, 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. At March 31, 2014, the Company had less than $0.1 million of common stock available to be sold under the MLV Agreement. During the three months ended March 31, 2014, the Company had no sales of its common stock under the MLV Agreement. The MLV Agreement expires in June 2014.

On March 21, 2014, the Company entered into Amendment No. 1 to the Controlled Equity Offering℠ Sales Agreement, dated August 31, 2012 (as amended, the Amended Cantor Agreement) with Cantor Fitzgerald & Co. (Cantor) that provides for the issuance and sale of shares of its common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to an aggregate of $70.0 million through Cantor. Under the Amended 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 Amended Cantor Agreement are deemed an at-the-market offering and are registered under the Securities Act. During the year ended December 31, 2013, approximately 5.4 million shares of the Company s common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of $23.5 million. During the three months ended March 31, 2014, the Company had no sales of its common stock under the Amended Cantor Agreement. At March 31, 2014, the Company had approximately $41.5 million of common stock available to be sold under the Amended Cantor Agreement.

Public Offering of Common Stock

The Company completed a public offering of common stock on March 19, 2013. As a result of this offering, the Company issued approximately 8.3 million shares of its common stock at $4.20 per share. The Company provided the underwriters an overallotment of an additional approximately 1.3 million shares of its common stock, which was fully subscribed. Combined gross proceeds for the offering were approximately $40.3 million. Net proceeds to the Company were approximately $38.0 million after underwriters discount of approximately $1.8 million and offering costs of approximately $0.5 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 each of June 6, 2012 and June 12, 2013, 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 and 6,000,000 shares, respectively, such that the Amended 2008 Plan has reserved for issuance an amount not to exceed 19,540,940 shares effective June 12, 2013. At March 31, 2014, the Company had an aggregate of approximately 18.1 million shares of its common stock reserved for issuance under the Amended 2008 Plan, the Prior Plans and the 1996 Plan, of which approximately 12.3 million shares were subject to outstanding options and other stock-based awards, and approximately 5.8 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 March 31, 2014, the Company had approximately 0.5 million shares available for future issuance under the Purchase Plan.

Table of Contents

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. At March 31, 2014, all restricted stock units were fully vested.

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
Balances at December 31, 2013	10,405	$ 3.46
Granted	2,347	6.20
Forfeited	(36)	4.49
Expired	(30)	9.78
Exercised	(478)	2.65
Balances at March 31, 2014	12,208	$ 4.00

The Company 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 months ended March 31, 2014 and 2013, was as follows (in thousands):

	Three Months Ended March 31,	
	2014	2013
Stock-based compensation expense by caption:		
Research and development	$ 183	$ 87
Selling, general and administrative	762	626
Total stock-based compensation expense	$ 945	$ 713

The Company did not record any stock-based compensation associated with performance-based stock options during the three months ended March 31, 2014 and 2013 as the performance criteria was not probable of being achieved.

Performance-based stock options of 50,000 remained outstanding at March 31, 2014.

Table of Contents

Note 12. Development and License Agreements

Agreements with Fresenius

The Company has certain agreements with Fresenius which require the Company to pay royalties on INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. During the three months ended March 31, 2014, and 2013, the Company made royalty payments to Fresenius of $0.7 million and $0.8 million, respectively. At March 31, 2014, and December 31, 2013, accrued royalties due to Fresenius were $0.6 million and $0.7 million, respectively.

The Company also paid Fresenius certain costs associated with the amended manufacturing and supply agreement the Company executed with Fresenius in December 2008 (the Original Supply Agreement), for the manufacture of INTERCEPT finished disposable kits for the Company s platelet and plasma systems through December 31, 2013. Under the Original Supply Agreement, the Company paid Fresenius a set price per disposable kit, which was established annually, plus a fixed surcharge per disposable kit. In addition, volume driven manufacturing overhead was paid or refunded if actual manufacturing volumes were higher or lower than the annually estimated production volumes. The Company made payments to Fresenius of $4.6 million and $3.9 million relating to the manufacturing of the Company products during the three months ended March 31, 2014, and 2013, respectively. At March 31, 2014, and December 31, 2013, accrued amounts due to Fresenius were $3.4 million and $4.3 million, respectively, for INTERCEPT disposable kits manufactured.

In November 2013, the Company amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014 (the 2013 Amendment). Under the 2013 Amendment, Fresenius is obligated to sell, and the Company is obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, the Company is able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provides for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. In addition, the 2013 Amendment requires the Company to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of the Company s proprietary inactivation compounds and adsorption media from the Company at fixed prices. During the three months ended March 31, 2014, we sold $2.7 million of such components to Fresenius. We maintain the value of components sold to Fresenius as a current asset on our balance sheet until such time as we purchase finished disposable kits using those components. The term of the 2013 Amendment extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in the Company s case. The Company and Fresenius each have normal and customary termination rights, including termination for material breach.

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 are 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, as discussed in further detail below, 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.

Table of Contents

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 months ended March 31, 2014 and 2013 (in percentages):

	Three Months Ended March 31,	
	2014	2013
Etablissement Francais du Sang	23%	16%
Movaco, S.A.	19%	19%
Delrus Inc.	*	19%

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

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, 2013. Operating results for the three months ended March 31, 2014 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, 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 Fresenius 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.

Table of Contents

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of the INTERCEPT Blood System and, from 2001 until late 2007, immunotherapies for cancer and infectious disease. The INTERCEPT Blood System is designed for three blood components: platelets, plasma and red blood cells. 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 around the world including those in Europe, The Commonwealth of Independent States, or CIS, and the Middle East.

In 2012, the United States Food and Drug Administration, or FDA, accepted our proposed modular Premarket Approval Application, or PMA, shell for our plasma system. In November 2013, we submitted the fourth and final module under the PMA for plasma and have subsequently been informed that the FDA has confirmed the completeness of the filing and considers the application filed. The filed PMA for the plasma system is now in the 180 day substantive review period. During this review period, we will need to satisfactorily respond to any minor or major deficiency letter we may receive before the FDA can complete their review of the PMA.

In February 2013, we reached agreement with the FDA regarding our proposed modular PMA shell for the platelet system. We have submitted two of the three modules agreed upon as part of the PMA shell and expect to submit the third and final module later in the second quarter of 2014, pending our ability to successfully respond to questions posed by the FDA on the first two submitted modules and completing an *in vitro* study currently in process that will be submitted as part of the third and final module. The ongoing regulatory efforts for both the platelet and plasma system PMAs, as well as our development activities for the red blood cell system, will result in increased research and development expenses in future periods. Our ability to conduct and complete any additional clinical trials required by the FDA 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 before we initiate any such trials or studies.

We are developing the INTERCEPT Blood System for red blood cells, or red blood cell system, and are currently performing *in vitro* and license-enabling clinical trials for CE mark approval. 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 CE mark approval. We are currently conducting a Phase II recovery and lifespan study and plan to complete that study and certain other prerequisites before proposing a Phase III clinical trial protocol for the red blood cell system in support of a potential regulatory approval in the United States. 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 and Europe 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.

Table of Contents

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 the modular PMA submission process for both the platelet and plasma systems, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, including our two ongoing European Phase III clinical trials for the red blood cell system, 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 trials 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 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, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. 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, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

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.

We recognize product revenues from the sale of our platelet and plasma systems in a number of countries around the world including those in Europe, the CIS and the Middle East. Although our revenues have grown over time, if we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, we will have difficulty 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.

Collaborations

Aduro BioTech

In 2007, we spun-off our immunotherapy business, and 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. To date we have not received any royalty payments from Aduro pursuant to this agreement. As of March 31, 2014, our ownership in Aduro was less than 3% on a fully diluted basis. Since receiving preferred stock in Aduro, we have carried our investment in Aduro at zero on our consolidated balance sheet.

Fresenius Kabi

We pay royalties to Fresenius Kabi AG, or Fresenius, on 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 Inc., or

Table of Contents

Fenwal (Fenwal was acquired by Fresenius in 2012), at rates that vary by product: 10% of product sales for the platelet system, and 3% of product sales for the plasma system. Fresenius has assumed Fenwal s rights and obligations under these certain agreements, including our manufacturing and supply agreement. In this report, references to Fresenius include references to its predecessors-in-interest Fenwal and Baxter.

We also paid Fresenius certain costs associated with the amended manufacturing and supply agreement we executed with Fresenius in December 2008, or the Original Supply Agreement, for the manufacture of INTERCEPT finished disposable kits for our platelet and plasma systems through December 31, 2013. Under the Original Supply Agreement, we paid Fresenius a set price per disposable kit, which was established annually, plus a fixed surcharge per disposable kit. In addition, volume driven manufacturing overhead was paid or refunded if actual manufacturing volumes were higher or lower than the annually estimated production volumes. We were also obligated under the Original Supply Agreement to supply certain disposable kit components to Fresenius, at no cost, for the manufacture of our kits. This required us to enter into manufacturing and supply arrangements with certain other manufacturers for those components, some of which contain minimum purchase commitments.

In November 2013, we amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014, or the 2013 Amendment. Under the 2013 Amendment, Fresenius is obligated to sell, and we are obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provides for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. In addition, the 2013 Amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and adsorption media from us at fixed prices. The term of the 2013 Amendment extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. We do not currently have plans to terminate our agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement.

In August 2010, we completed an acquisition of certain assets of BioOne Corporation, or BioOne, including the commercialization rights that both Fresenius and we granted to BioOne for both the platelet and plasma systems. Concurrent with the acquisition, Fresenius and we terminated the commercialization rights we and Fresenius granted to BioOne. As a consequence of the termination, and pursuant to a pre-existing agreement with Fresenius, our commercialization rights to the platelet and plasma systems under our 2005 and 2006 agreements with Fresenius 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 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.

Equity and Debt Agreements

MLV and Cantor

We entered into an At-The-Market Issuance Sales Agreement in June 2011, as amended in January 2012 and August 2012, or 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, in August 2012, as amended in March 2014, (or the Cantor Agreement), 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 $70.0 million through Cantor as our sales agent. During the year ended December 31, 2013, we sold an aggregate of approximately 5.4 million shares of our common stock under the Cantor Agreement for aggregate net proceeds of $23.5 million. At March 31, 2014, we had less than $0.1 million and approximately $41.5 million of common stock available to be sold under the MLV Agreement and the Cantor Agreement, respectively. The MLV Agreement expires in June 2014.

Table of Contents

Debt Agreements

We entered into a loan and security agreement on September 30, 2011, as amended effective on December 13, 2011, and June 30, 2012, or 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 against our revolving line of credit and had an outstanding balance of $3.3 million at March 31, 2014. In April 2013, we repaid in full the Growth Capital Loan balance and all accrued interest, as well as a scheduled final payment, in an aggregate amount of $4.2 million. We have no further obligations, nor are there any further funds available under the Growth Capital Loan.

Critical Accounting Policies and Management Estimates

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, inventory, accrued expenses, goodwill and intangible assets, warrants stock-based compensation and income taxes to be critical policies. There have been no changes to our critical accounting policies since we filed our 2013 Form 10-K with the SEC on March 7, 2014. For a description of our critical accounting policies, please refer to our 2013 Annual Report on Form 10-K.

Results of Operations

Three Months Ended March 31, 2014 and 2013

Revenue

	Three Months Ended March 31,			
(in thousands, except percentages)	**2014**	**2013**	**Change**	
Product revenue	$ 7,866	$ 9,733	$ (1,867)	(19)%

Product revenue decreased by $1.9 million during the three months ended March 31, 2014 compared to the three months ended March 31, 2013, primarily as a result of lower sales volume of our illuminator devices and disposable kits sold to distributors. This was slightly offset by higher average selling prices for both platelet and plasma disposable kits.

We anticipate product revenue for both our platelet and plasma systems will increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are over the long-term underway and the transition in certain territories to new distribution partners or to a direct sales model is completed. For the near-term, we continue to expect that our product revenue will be adversely impacted as we

continue to transition one or more key distributor territories to new distributor partners or to a direct sales model and will remain relatively flat to 2013 product revenue with a disproportionate impact anticipated in the first half of 2014. However, we can provide no assurances that there will not be an adverse impact on future periods as well. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. The historical results may not be indicative of INTERCEPT Blood System revenue in the future.

Cost of Product Revenue

Our cost of product revenue consists of the cost of the INTERCEPT Blood System inventory sold, royalties payable to Fresenius for product sales, provisions for obsolete, slow-moving and unsaleable product, certain order fulfillment costs and to the extent applicable, costs for idle facilities. Inventory is accounted for on a first-in, first-out basis.

	Three Months Ended March 31,			
(in thousands, except percentages)	**2014**	**2013**	**Change**	
Cost of product revenue	$ 4,157	$ 5,090	$ (933)	(18)%

Table of Contents

Cost of product revenue decreased by $0.9 million during the three months ended March 31, 2014 compared to the three months ended March 31, 2013. This decrease was the result of lower sales volumes of our illuminator devices and disposable kits sold to distributors. Also contributing to the decrease were lower scrap charges taken for certain components during the three months ended March 31, 2014 when compared to the same period in 2013. These decreases were partially offset by higher charges taken for writing off expired product during the three months ended March 31, 2014 when compared to the same period in 2013. We anticipate our cost of product revenue will increase in the future as a result of increased product sales.

Our realized gross margins on product sales were 47% during the three months ended March 31, 2014, down from 48% during the three months ended March 31, 2013. Gross margins during the three months ended March 31, 2014 were unfavorably impacted as a result of higher charges taken for obsolescence when compared to the same period in 2013, partially offset by a decrease in costs of our disposable kits resulting from the decrease in sales volume, period over period.

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 may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates or delays in manufacturing products. Our gross margins may be impacted in the future based on all of these criteria.

We expect to maintain inventory at a level sufficient to meet forecasted demand for a relatively short time period and expect that inventory levels will remain flat as we transition certain of our distributor partnerships or begin selling direct in certain distributor territories. Our 2013 Amendment with Fresenius fixes pricing based on certain specified annual production levels. We expect the revised terms in the 2013 Amendment with Fresenius will provide for more stable and declining annual per unit cost of goods sold if we are able to increase the number of units that we procure from them and ultimately sell; however, actual manufacturing levels may differ from our assumptions and the time period during which we expect our inventory to remain flat may last longer that we currently expect.

Research and Development Expenses

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

	Three Months Ended March 31,			
(in thousands, except percentages)	**2014**	**2013**	**Change**	
Research and development	$ 4,642	$ 2,700	$ 1,942	72%

Research and development expenses increased $1.9 million during the three months ended March 31, 2014 compared to the three months ended March 31, 2013 due to an increased focus on the clinical trials for our red blood cell system and activities associated with obtaining FDA approval for the platelet and plasma systems in the U.S.

We anticipate our research and development spending will continue to increase over the near term as we continue our two Phase III clinical trials for the red blood cell system in Europe and the Phase II recovery and lifespan study for the red blood cell system in the U.S. In addition, we have undertaken and plan to perform certain additional *in vitro*

studies and clinical development in the United States, which will result in further increased research and development spending. We also expect to incur increasing costs associated with our pursuit of regulatory approval for our products in the U.S., including additional research and development that may be required in connection with our modular PMA submissions to the FDA for our platelet and plasma systems, including potential post-marketing studies if requested by the FDA. 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 I 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 a number of countries around the world including certain countries in Europe, the CIS and the Middle East, expenses for accounting, tax, and internal control, legal and facility and infrastructure related expenses, and insurance premiums.

Table of Contents

(in thousands, except percentages)	Three Months Ended March 31, 2014	2013	Change	
Selling, general and administrative	$ 8,236	$ 6,853	$ 1,383	20%

Selling, general, and administrative expenses increased by $1.4 million during the three months ended March 31, 2014 compared to the three months ended March 31, 2013 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 as we have begun to hire commercial resources for potential U.S. commercialization efforts for the platelet and plasma systems.

We anticipate our selling, general and administrative expenses will increase as we continue to on-board resources, develop marketing plans and prepare for a potential commercial launch of our plasma and platelet systems in the U.S. The anticipated increase in our selling, general, and administrative costs will not be fully realized unless we can successfully complete the PMA process and obtain approval for one or both of the plasma or platelet systems. In addition, we expect additional increases to our selling, general and administrative costs as a result of adding additional resources to assist with our commercialization efforts in those distributor territories that we determine to transition to a different distribution partner or to a direct sales model in connection with the strategic changes we are implementing in our distributor territories.

Amortization of Intangible Assets

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

(in thousands, except percentages)	Three Months Ended March 31, 2014	2013	Change	
Amortization of intangible assets	$ 50	$ 50	$ 0	0%

Amortization of intangible assets remained flat during the three months ended March 31, 2014 compared to the three months ended March 30, 2013.

Non-Operating Expense, net

Non-operating expense, net consists of mark-to-market adjustments related to the fair value of our outstanding warrants, foreign exchange gain (loss), interest charges incurred on our debt, interest earned from our short-term investment portfolio, (included in Other income, net) and other non-operating gains and losses.

(in thousands, except percentages)	Three Months Ended March 31, 2014	2013	Change	
Gain (loss) from revaluation of warrant liability	$ 9,034	$ (5,073)	$ 14,107	(278)%

Foreign exchange gain (loss)	21	(54)	75	(139)%
Interest expense	(193)	(131)	(62)	47%
Other income, net	170	17	153	900%
Total non-operating gain (expense), net	$ 9,032	$ (5,241)	$ 14,273	(272)%

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 is classified as a liability on the condensed consolidated balance sheets and is adjusted at each subsequent reporting period, until such time the instruments are exercised or otherwise modified to remove the provisions which require this treatment. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders equity and no further adjustment to the fair value would be made in subsequent periods. Further changes in stock price will result in similar adjustment as needed.

Table of Contents

We recognized a $9 million gain from the revaluation of warrant liability during the three months ended March 31, 2014 compared to a $5.1 million loss during the three months ended March 31, 2013. The $14.2 million change is primarily due to the change in our underlying stock price, as compared to the strike price of the warrants, partially offset by a reduction in the remaining term of the warrant.

Foreign exchange gain (loss)

Foreign exchange gain (loss) increased by $0.1 million during the three months ended March 31, 2014 compared to the three months ended March 31, 2013, which was primarily attributable to favorable foreign currency variations over that time period between the Euro and U.S. dollar, our functional currency.

Interest expense

Interest expense was relatively consistent during the three months ended March 31, 2014 and 2013.

Other income, net

Other income, net increased $0.2 million for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 primarily as a result of higher investment balances during 2014.

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

Provision for Income Taxes

For the three months ended March 31, 2014 and 2013, the provision for income taxes primarily consists of a provision for foreign taxes. In the three months ended March 31, 2014 and 2013, we recorded a provision for income taxes of $0.04 million and $0.05 million, respectively, representing effective tax rates of 0.5 % and 0.5%, respectively. Due to our history of cumulative operation losses, management concludes that, after considering all the available objective evidence, it is not likely that all our net deferred tax assets will be realized. Accordingly, all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of March 31, 2014.

As of March 31, 2014, there have been no material changes to our total amount of unrecognized tax benefits.

Liquidity and Capital Resources

In recent years, our sources of capital have primarily consisted of public offerings and equity securities, private issuance of debt instruments, and contributions from product sales.

At March 31, 2014, we had cash and cash equivalents of $24.0 million and had $29.5 million in cash equivalents at December 31, 2013. Our cash equivalents primarily consist of money market instruments, which are classified for accounting purposes as available-for-sale. Excess cash is typically invested in highly liquid instruments with high-quality credit rated corporate and government agency fixed-income securities in accordance with our investment policy. We had $24.3 million of short-term investments at March 31, 2014 and $28.2 million at December 31, 2013.

Operating Activities

Net cash used in operating activities was $ 9.8 million for the three months ended March 31, 2014 compared to $8.4 million during the three months ended March 31, 2013. The increase in net cash used in operating activities was primarily related to the increased level of cash spent for our operations during the three months ended March 31, 2014 relative to the corresponding period in the prior year. Offsetting this, we spent less paying down accounts payable during the three months ended March 31, 2014 relative to the same period in 2013 and to a lesser extent collected more outstanding receivables and sold more inventory than we purchased during the three months ended March 31, 2014 relative to the same period in the preceding year.

Investing Activities

Net cash provided by investing activities was $3.0 million for the three months ended March 31, 2014 compared to cash used of less than $0.03 million during the three months ended March 31, 2013. This change was primarily the result of maturities of investments during the three months ended March 31, 2014 in short-term available-for-sale corporate debt securities and United States government agency securities.

Table of Contents

Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2014 was $1.3 million compared to $50.8 during the three months ended March 31, 2013. The decrease in financing activities was primarily due to proceeds received from our underwritten common stock offering which generated $38.0 million (net of $1.8 million in underwriter s discount and $0.5 million in offering costs) and an additional $13.0 million received from sales of our common stock offerings pursuant to the Cantor Agreement during the three months ended March 31, 2013 relative to the same period in 2014. Subsequent to March 31, 2013, these cash equivalents were invested in short-term investments in accordance with our investment policy.

Working Capital

Working capital increased to $39.8 million at March 31, 2014, from $38.7 million at December 31, 2013, primarily due to decreases in the combined total for our accounts payable and accrued liabilities balances as a result of the timing of payments to our vendors and the recorded liability balance for our outstanding warrants. This was partially offset by lower balances in cash and investments, which was substantially the result of cash burn for routine operations and payment of accounts payables and accrued liabilities outstanding at year end, decreases in our accounts receivables due to decreased sales and timing of cash collection from our customers, and decreases in inventory levels due to the 2013 Amendment under which Fresenius is obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and adsorption media from us at fixed prices. We further expect that the potential transition to a Cerus direct sales model in certain distributor territories will negatively impact working capital in future periods resulting from longer periods for cash collection from direct sales customers when compared to timing of cash collection from our former distribution partners.

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 the modular PMA submission process for both the platelet and plasma systems, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, including our two ongoing European Phase III clinical trials for the red blood cell system 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 trials 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 equity and debt capital markets, as well as to 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. Our Amended Credit Agreement with Comerica Bank expires in June 2014. Should we either further amend our Amended Credit Agreement with Comerica or enter into agreements with different lenders, the agreements may contain terms that may include restrictive covenants, including covenants that restrict the operation of

our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent 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, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of 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, 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.

Table of Contents

Other Information

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. The MLV agreement expires in June 2014. We also entered into the Cantor Agreement in August 2012, as amended in March 2014. The Cantor Agreement 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 $70.0 million through Cantor as our sales agent. Future issuances and sales of shares of common stock by us under the MLV Agreement and the Cantor Agreement, or the Sales Agreements, are subject to the continued effectiveness of our shelf registration statement referred to below. Sales of our common stock through MLV and Cantor will be made on the Nasdaq Global Market by means of ordinary brokers transactions at market prices, in block transactions or as otherwise agreed by us and MLV or Cantor, as applicable. Subject to the terms and conditions of the MLV Agreement and the Cantor Agreement, MLV and Cantor will use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are not obligated to make any sales of common stock under the Sales Agreements.

The offering of common stock pursuant to each Sales Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the applicable Sales Agreement and (2) termination of that Sales Agreement. Each Sales Agreement may be terminated by MLV or Cantor, as applicable, or us at any time upon 10 days notice to the other party, or by MLV or Cantor, as applicable, at any time in certain circumstances, including our undergoing a material adverse change. We pay Cantor 2% of the gross proceeds of the sales price per share of any common stock sold through Cantor under the Amended Cantor Agreement. During the year ended December 31, 2013, we sold and aggregate of approximately 5.4 million shares of our common stock under the Cantor Agreement for aggregate net proceeds of $23.5 million. At March 31, 2014, we had less than $0.1 million and approximately $41.5 million of common stock available to be sold under the MLV Agreement and the Cantor Agreement, respectively, subject to the continued effectiveness of our shelf registration statement referred to below.

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 Sales Agreements 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 March 31, 2014.

Contractual Commitments

The following summarizes our contractual commitments at March 31, 2014 (in thousands):

	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Minimum purchase requirements	$ 5,022	$ 4,532	$ 490	$ 0	$ 0

Operating leases	1,710	1,062	587	61	0
Other commitments	1,501	820	298	287	96
Debt	3,315	3,315	0	0	0
Total contractual obligations	$ 11,548	$ 9,729	$ 1,375	$ 348	$ 96

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 Fresenius 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 lease in Concord, California for our headquarters and exercised a five year extension option in January 2012, to extend the term of our lease in Amersfoort, The

Table of Contents

Netherlands for an additional five years following the original lease expiration of January 2013. However, we have the right to early terminate both our Concord lease and our Amersfoort lease, which may occur as early as January 2015 and February 2016, respectively. In June 2013, we executed a new two year lease for additional space in Concord, California. The term of this new lease commenced on August 1, 2013 and continues for two years with four (4) two-year options for us to renew. The lease obligates the Company to make rent payments for the remaining nine months of $115,776 and $90,048 in 2014 and 2015, respectively. Our facility leases qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on our 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 lease under which such improvements were made. If we exercise our right to early terminate the lease in Concord, California for our headquarters, 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 March 31, 2014, we had an outstanding liability of $0.7 million related to these leasehold improvements. Our agreements with Fresenius require us to pay royalties on sales of the INTERCEPT Blood System at rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Such royalties are calculated based on future product sales and are not provided for in the table above as they are dependent on events that have not yet occurred.

Debt

The Amended Credit Agreement with Comerica Bank provided 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 was scheduled to mature on September 30, 2015. In April 2013, the Company repaid in full the Growth Capital Loan balance and all accrued interest as well as a scheduled final payment fee of $0.05 million, in an aggregate amount of $4.2 million. The Company has no further obligations, nor are there any further funds available under the Growth Capital Loan.

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 March 31, 2014 and December 31, 2013, we had $3.3 million and $3.4 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 March 31, 2014 and December 31, 2013, the floating rate of the RLOC was at 4.75%. 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 March 31, 2014 and as of the date of this report,

we were in compliance with the financial covenants as set forth in the Amended Credit Agreement.

Financial Instruments

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 currently 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. Our available-for-sale securities related to corporate debt and United States government agency securities 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 months ended March 31, 2014 or the year ended December 31, 2013. 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.

Table of Contents

New Accounting Pronouncements

There have been no new accounting pronouncements issued during the three months ended March 31, 2014 and the year ended December 31, 2013 that are of significance, or potential significance, to us.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three months ended March 31, 2014, 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, 2013.

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 March 31, 2014.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2014 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 principal executive officer and principal financial 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 effective to provide reasonable assurance that the objective of our disclosure control system were met.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Risk Factors

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

The INTERCEPT Blood System may not achieve broad market adoption.

In order to increase market adoption 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, key opinion leaders, 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. Although certain studies 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 adoption. 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

Table of Contents

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 adoption of our products. 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 adoption 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.

If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced or delayed. 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. In certain markets, potential customers may require us to develop, sell, and support a data management application for their operations before they would consider adopting INTERCEPT. Such development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Failure to do so may limit market adoption.

Market adoption 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.

For countries that do not recognize the CE Mark as being adequate for commercializing the INTERCEPT Blood System in those countries, product adoption may be negatively affected because we do not have FDA approval for any of our products. Even within countries that do recognize the CE Mark, the lack of widespread product adoption in key European countries has and may in the future be adversely affecting market adoption of the INTERCEPT Blood System.

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 PEI. Product specifications that receive marketing authorization from the PEI may differ from 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 without first 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

Table of Contents

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.

We expect to continue to generate losses.

We may never achieve a profitable level of operations. Our research and 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 and expected near-term sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer the systems are and are expected to continue to be in excess of our revenue. 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 and development costs associated with our pursuit of the PMA application submission processes for our platelet and plasma systems, 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 that 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, 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 could reduce any potential operating profits or require us to pass on the costs to our customers.

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 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 have recently been 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 projected product revenue.

Additionally a meaningful amount of our revenue currently comes from sales to our distributor in Russia. While our agreement call for sales, invoicing and collections to be denominated in Euros, the recent political conflict stemming from tensions in the Ukraine may have an impact on the Russian economy should significant sanctions be levied against Russia from the EU or United States. If such significant sanctions were to occur, the Russian economy may

weaken, the value of the Ruble may weaken and our business in Russia may be negatively impacted.

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.

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;

Table of Contents

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. Even if we are successful in obtaining FDA approval for our products, the FDA may limit the usage of the INTERCEPT Blood System to certain collection platforms or storage solutions or could restrict the claims that we are able to make for our products. For instance, in Europe, we are able to claim that using the INTERCEPT Blood System can replace bacterial detection, CMV testing and gamma irradiation, which are all common practices with the preparation of conventional blood components. We cannot be certain that the FDA would allow such claims initially or ever, which may result in limited market adoption in the United States and elsewhere.

Clinical and Preclinical

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 or complete clinical trials on schedule, if at all. 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, ministry of health or ethical committee approval to conduct a study at a prospective clinical

site, delays in recruiting subjects to participate in a study and delays in the conduct of the clinical trial by personnel at the clinical site. Each of these factors has adversely impacted our ongoing European Phase III trials for the red blood cell system. Significant delays in clinical testing could materially impact our clinical trials. Criteria for regulatory approval in blood safety indications are evolving, reflecting competitive advances in the standard of care against which new product candidates are judged, as well as 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. As a result, we do not know whether any clinical trial 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, further delaying the clinical trial process. 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. In addition, enrollment criteria have impacted the speed with which we have been able to enroll patients for our ongoing Phase III red blood cell system trial in chronic anemia in Europe. Consequently, we may be unable to recruit suitable patients into clinical trials on a timely basis, if at all, which may lead to higher costs to complete the clinical trials. 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.

We have conducted many toxicology studies to demonstrate the safety of the platelet and plasma systems, and we have conducted and plan to conduct toxicology studies for the red blood cell system throughout the product development process. At any

Table of Contents

time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products safety, which could delay commercialization. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate a redesign of our product or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. We believe the FDA and other regulatory authorities are likely to weigh the potential risks of using our pathogen inactivation products against the incremental benefits, which may be difficult or impossible to quantify.

If our product candidates receive approval for commercial sale in the United States, the FDA may require one or more post-marketing clinical studies, which can involve significant expense and will require us to secure adequate funding to complete. For example, although the FDA has indicated that no prospective Phase III clinical trials were required at this time in order to submit our proposals for modular PMA submissions for the platelet and plasma systems, the FDA has already indicated that we will likely need to commit to post-marketing studies. 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 adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

Outside the United States, regulations vary by country, including the requirements for regulatory and marketing approvals or clearance, 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. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore and elsewhere, may require, among other requirements, that our products be widely adopted commercially in Europe or approved by the FDA before they are considered for approval or may delay approval decisions until our products are more widely adopted commercially and approved by the FDA. 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.

Platelet System

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.

In the U.S., we will be required to successfully complete the submission to the FDA of all three modules of the PMA, including resolving any outstanding review letters received from the FDA, before the platelet system would be considered for approval. Once the PMA is considered filed, the FDA will commence its substantive review of the PMA, including potential inspection and audits of clinical sites and manufacturing facilities. In addition, after the PMA is considered filed, the substantive review is initially scheduled to last 180 days. During the substantive review, the 180-day time period can be suspended if and when major deficiencies are identified. Once the FDA receives the applicant s responses to any major deficiency letter, it has 90 days to review the responses and determine whether or not the applicant s responses address the deficiencies satisfactorily. Only then will the 180 substantive review be resumed. We will not receive an approval decision from the FDA until the substantive review is complete and we cannot predict the timing or outcome of the decision. Any responses, correspondence, rejections or approvals that we may receive in connection with the plasma PMA process would not be indicative or dispositive of the status of the approval process for the platelet PMA.

We completed a Phase III clinical trial of the platelet system in the United States in March 2001 and a supplemental analysis of data from this trial in 2005. We submitted this information along with other supportive clinical data to the FDA. Although FDA has indicated that no prospective Phase III clinical trials are required at this time, the FDA may require us to complete additional Phase III clinical trials before approval would be granted. If additional Phase III clinical trials are required for approval, we will likely only initiate such trials if adequate funding can be secured. We have limited experience with the modular PMA process and may encounter unanticipated difficulties complying with the prescribed submission timing or other modular PMA requirements. Such difficulties could affect our ability to complete the PMA submission process successfully or in the anticipated timeframes that we expect. Should significant questions arise during the submission process or if we are required to conduct additional clinical trials to support our PMA submission, approval may take a significant period of time to obtain, if ever.

Table of Contents

Plasma System

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 filed our agreed upon PMA for the plasma system with the FDA. The FDA is now substantively reviewing the submission and may audit us, clinical sites or manufacturing facilities that produce our product. The substantive review, initially planned for a 180-day time period, can be suspended if and when major deficiencies are identified, as discussed above. Should we have difficulties answering or remediating any deficiency letters 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.

Although we have completed Phase III clinical trials in various patient populations and have submitted supplemental data collected in commercial use in Europe, the FDA may require us to complete additional Phase III clinical trials, before approval would be granted. The FDA may also limit the particular indications or uses for our plasma system if they believe that our clinical data is insufficient for broader usage or if the collection and storage methods supporting our clinical data are considered to be incompatible with broad usage. Should the FDA require us to complete any additional clinical trials, our willingness and 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.

Before the FDA determines whether to approve the INTERCEPT Blood System products, they may seek the advice of the BPAC. Even if BPAC were to recommend approval of one or more of our products, the FDA is not required to adopt BPAC s recommendation. 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.

Red Blood Cell System

Our red blood cell system is currently in development and has not been commercialized anywhere in the world. Significant clinical, development and financial resources will be required to progress the red blood cell system into a commercially viable product and to obtain the necessary regulatory approvals for the product. We have not been successful in developing any product candidates that have received FDA approval in the past. Clinical testing and development of the red blood cell system will take many years to complete and failure can occur any time during the clinical trial process. Any failure or delay in completing clinical trials for the red blood cell system would prevent or delay its commercialization, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Many of the factors described above that can contribute to the failure or delay of a clinical trial could impact the trials we conduct for our red blood cell system. Even if we are successful in earlier clinical trials, the results of those early trials may not be predictive of results obtained in later and larger clinical trials of the red blood cell system. In those cases, the FDA or foreign regulatory agencies may require we engage in additional clinical trials or conduct further studies or analysis which may be costly and time-consuming. In some instances, we are relying on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials for the red blood cell system. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. Additionally, if we, our contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated

in those trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving the red blood cell system for commercialization. We cannot assure you that, upon inspection, the FDA or foreign regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA s cGMP regulations and similar regulations outside of the United States. Our failure or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

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 2003 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 that we initiated in the fourth quarter of 2008 to evaluate recovery and survival of treated red blood cells with the modified process, there were no adverse events reported. Based on the results from that trial, we have obtained approval for and recently commenced two Phase III clinical trials in Europe using the modified process in patients with acute and chronic anemia. However, we cannot assure you that the adverse events observed in the terminated Phase III clinical trials

Table of Contents

of our red blood cell system will not be observed in these current or 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.

The FDA has required that we successfully complete an additional Phase II recovery and survival study, which we are currently conducting, prior to reaching agreement on any Phase III clinical trial protocol which we would likely need to successfully conduct and complete before the FDA would consider our red blood cell product for approval. 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 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 a potential Phase III clinical trial. There can be no assurance that we will be able to successfully satisfy any such prerequisites, nor can there be any assurance that we and the FDA will agree to any trial protocol we propose or that we will otherwise obtain FDA clearance to initiate a potential Phase III clinical trial.

We are currently enrolling patients in two European Phase III clinical trials of our red blood cell system: one for acute anemia patients and separately, one for chronic anemia patients. Such studies, including the studies required by the FDA prior to its review of any proposed U.S. 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. We understand that while the 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 Phase III chronic anemia clinical trial would also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they 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 the 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 for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we continue to experience delays in testing, conducting trials or approvals, our product development costs will increase. Even if we were to successfully complete and receive approval for our red blood cell system, potential customers may object to working with a potent chemical, like S-303, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system.

We have limited experience operating a global commercial organization. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies.

We are responsible for worldwide sales, marketing, distribution, maintenance and regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties to support us in these areas 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 Europe, the CIS and the Middle East. 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 not only for these existing markets, but also if and as we expand into the Latin and South American and Asian markets. Many of these competencies require compliance with European Union, South American, Asian and local standards and practices, with which we have limited experience.

Should we be successful in commercializing our products in geographies beyond the current markets in which we sell our products, we may need to add resources and develop competencies to ensure compliance with local regulatory, legal and tax requirements. We have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all.

We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries.

Table of Contents

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain any necessary in-country regulatory approvals, as well as 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. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may impact our financial results. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, 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. 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. Further, 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. In addition, although our agreements with our distributors generally require compliance with local anti-corruption laws, the U.S. Foreign Corrupt Practices Act, and other local and international regulations, we have limited ability to control the actions of our distributors to ensure they are in compliance. Noncompliance by a distributor could expose us to civil or criminal liability, fines and/or prohibitions on selling our products in certain countries.

Currently, a fairly concentrated number of distributors make up a significant portion of our revenue and we may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations and contractual provisions. In 2013, we experienced weaker than expected growth due to declining performance by certain of our distributors. In the fourth quarter of 2013, we announced that we have and are planning to continue to pursue certain strategic changes to our distribution territories. We have commenced transitioning certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors. Because these are new distribution partners who have limited experience marketing and selling our products, we cannot be certain that these new distribution partners will perform better than their predecessors. In other territories, we are evaluating additional ways to optimize INTERCEPT penetration in key distributor territories, including potentially transitioning some of these territories to a Cerus direct sales model, which we believe will provide us with better visibility into and control of sales execution. We have notified one such distributor of our intention to terminate the existing distribution agreement. Implementing such changes may temporarily impact the volume of INTERCEPT disposable kit sales as distribution partners sell through their disposable kit inventory, as well as require additional resources within the impacted territories. 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. We expect that our product revenues will be adversely impacted with the loss or transition of one or more of these distributors. If we chose to terminate additional distributor agreements, we would either need to reach agreement with, qualify, train and supply a replacement distributor or supply and service end-user customer accounts in those territories ourselves. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us, there can be no assurance that this will happen in a timely manner or at all. Doing so may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. Further, if we were to service end-user accounts directly ourselves rather than through distributors, we will likely incur additional expense and our working capital may be

damaged. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected.

Our manufacturing supply chain exposes us to significant risks.

We do not own our own manufacturing facilities, but rather manufacture our products using a number of third party suppliers, many of whom are our sole suppliers for the particular product or component that we procure. We rely on various contracts and our relationships with these suppliers to ensure that the sourced products are manufactured in sufficient quantities, timely, to our exact specifications and at prices we agree upon with the supplier. Certain of our suppliers that we rely on for the manufacture of the platelet, plasma and red blood cell systems and components thereof, have not been FDA-approved for the manufacture of our products. 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 approval for the manufacture of INTERCEPT, whether in facilities owned by Fresenius or by other parties, may be costly and time-consuming. Before our products would be considered for marketing approval in the United States or elsewhere, our suppliers will have to pass an audit by the FDA or other regulatory agencies. We are dependent on our suppliers cooperation and ability to pass such audits. Such audits and any audit remediation may be costly. Failure to pass such audits by any of our suppliers would affect our ability to obtain licensure in the United States or elsewhere.

Table of Contents

In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufactures. The amended terms also provide for fixed pricing for finished kits with successive decreases in pricing at certain annual production volumes. In addition, the amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business.

We also have contracts with other third-party suppliers, including Ash Stevens for the manufacture of amotosalen, our proprietary compound for inactivating pathogens using our platelet and plasma systems; Purolite, and separately, Porex, for the manufacture of components of the compound adsorption devices used in our platelet and plasma systems; and NOVA for the manufacture of illuminators and certain components of the INTERCEPT Blood System. These independent suppliers are currently our sole qualified 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 maintenance fees in the past and may incur these maintenance fees in future periods.

Our supply agreement with Porex was amended in November 2012 and now expires on December 31, 2014. Porex is our sole supplier for such components of the compound adsorption devices. 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. Our supply agreement with Purolite extends through December 2014, and automatically renews each year for additional one year terms absent written notice of non-renewal delivered at least two (2) years in advance of any term expiration. Purolite may terminate the supply agreement provided that Purolite notifies us in writing at least two years in advance. We are currently in discussions with Purolite to amend our agreement. Our agreement with NOVA, which manufacturers our illuminators, extends through September 2014 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. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. Although we are actively evaluating alternate suppliers for certain of our products and components, we do not have qualified suppliers beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. Identification and qualification of alternate suppliers will be time consuming and costly. If we conclude that supply of the INTERCEPT Blood System or components from Fresenius

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.

Currently NOVA is manufacturing illuminators to meet customer demand and maintain our own inventory levels. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to 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. Certain of our components are in limited supply and are used as 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. Due to the obsolescence of certain parts, 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.

In the event that alternate manufacturers are identified and qualified, we will need to transfer know-how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers; however, certain of our supplier s materials, manufacturing processes and methods are proprietary to them, which will impair our ability to establish alternate sources of supply,

Table of Contents

even if we are required to do so as a condition of regulatory approval. We may be unable to establish alternate sources of supply to Fresenius, 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. Fresenius 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. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms favorable to those that we currently have with our manufacturers. Should we enter into agreements with any manufacturer with less favorable terms, our results of operations may be impacted, our recourse against such manufacturers may be limited, and the quality of our products may be impacted.

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. Non-conformities can increase our expenses and reduce gross margins. Should 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. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product, manufacturer or facility, 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 could be harmed and we would incur unforeseen losses.

In the event of a failure by Fresenius 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 or may impair our ability to supply customers with product.

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, manufacturing overhead variances 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.

We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties and harm our reputation and business.

We are subject to a number of laws that affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians, healthcare providers or other potential purchasers of our products. These laws are often broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. For example, within the European Union, the control of unlawful marketing activities is a matter of national law in each of the member states. The member states of the European Union closely monitor perceived unlawful marketing activity by companies. We could face civil, criminal and administrative sanctions if any member state determines that we have breached our obligations under its national laws. Industry associations also closely monitor the activities of member companies. If these organizations or authorities name us as having breached our obligations under their regulations, rules or standards, our reputation would suffer and our business and financial condition could be adversely affected.

We are also subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti-corruption intent in foreign countries. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement. Any violation of these laws by us or our agents or distributors could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. We currently operate in many countries where the

Table of Contents

public sector is perceived as being more or highly corrupt. Our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption activity, such as China, India and Russia. Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly. In addition, failure by us or our agents or distributors to comply with these laws, rules and regulations could delay our expansion into high-growth markets, could damage market perception of our business and could adversely affect our existing business operations. Increased business in higher risk countries could also subject us and our officers and directors to increased scrutiny and increased liability.

Our platelet products and product candidates are not compatible with some collection and storage methods or combinations thereof.

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 100% plasma. Fresenius 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 Fresenius 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 addition, we may be required to produce and demonstrate additional acceptable data for usage of the INTERCEPT Blood System with various combinations of collection platforms and storage solutions before we could receive regulatory approval from the FDA and elsewhere.

In order to address the entire market in the United States, Japan, and potentially elsewhere, we would need to develop and test additional configurations of the platelet system. For example, in the United States, we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority are 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. We may need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System for platelets compatible with their platforms and may have competing pathogen inactivation technologies. In addition, regulatory agencies such as the FDA may limit usage of the INTERCEPT Blood System to certain collection platforms, platelet additive solutions and plasma. Attaining compatibility or receiving regulatory approval with collection platforms manufactured by others in combination with additive solutions or 100% plasma may require additional clinical testing, 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 may 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.

The red blood cell systems that have been used and are currently being used in our clinical trials have been and are prototypes 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 will 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.

The design and engineering effort required to complete the final commercial version of our red blood cell system will likely be substantial and time-consuming. As with any complex development effort, we expect to encounter design, engineering and

Table of Contents

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. 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 products superior 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, successfully receive and maintain regulatory approvals, and adapt to 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 adoption 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, MacoPharma International and Kedrion Biopharma, 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. Should TerumoBCT s product be approved for use and commercialized in Japan, we would likely directly compete with them and we believe we would likely either need to establish operations in Japan or partner with a local Japanese company.

Octapharma AG received FDA approval in January 2013 to sell treated fresh frozen plasma for certain indications and will likely 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 as would a mandate of any competing technology other than INTERCEPT.

Table of Contents

We may be liable and we may need to withdraw our products from the market if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials. Our insurance coverage may be inadequate to offset losses we may incur.

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

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 the modular PMA submission process for both the platelet and plasma systems, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, including our two ongoing European Phase III clinical trials for the red blood cell system, 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 trials 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 equity and debt capital markets, as well as to 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, which could adversely affect the commercialization and clinical development activities.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth outside of our credit agreement with Comerica Bank, as described below, on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. 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, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

Table of Contents

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.

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 our debt.

We currently maintain a credit agreement with Comerica Bank that provides a formula based revolving line of credit of up to $7.0 million. 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 outstanding advances, which would require us to repay the advances sooner than we have anticipated. Our current credit agreement expires in June 2014. If we are unable to extend or amend the agreement, we will be required to pay-down the outstanding balance at that time. At March 31, 2014, the amount borrowed under the credit agreement with Comerica was $3.3 million.

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 portion 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 ability to conduct business.

If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected.

We are highly dependent upon our executive management team and other critical personnel, including our specialized research and development, regulatory and operations personnel, many of whom have been employed with us for many years and have a significant amount of institutional knowledge about us and our products. We do not carry key person insurance. If one or more members of our executive management team or other key personnel were to retire or resign, our ability to achieve development, regulatory or operational milestones for commercialization of our products could be adversely affected if we are unable to replace them with employees of comparable knowledge and experience. In addition, we may not be able to retain or recruit other qualified individuals, and our efforts at knowledge transfer could be inadequate. If knowledge transfer, recruiting and retention efforts are inadequate, significant amounts of internal historical knowledge and expertise could become unavailable to us.

We also rely on our ability to attract, retain and motivate skilled and highly qualified personnel in order to grow our company. Competition for qualified personnel in the medical device and pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, results of operations and growth prospects could be adversely affected.

All of the employees of our subsidiary, Cerus Europe B.V., are employed outside the United States, including in France where labor and employment laws are relatively stringent and, in many cases, grant significant job protection to certain employees, including rights on termination of employment. In addition, one of our manufacturing partners is located in France and may have employees that are members of unions or represented by a works council as required by law. These more stringent labor and employment laws to the

Table of Contents

extent that they are applicable, coupled with the requirement to consult with the relevant unions or works councils, could increase our operational costs with respect to our own employees and could result in passed through operational costs by our manufacturing partner. If the increased operational costs become significant, our business, financial condition and results of operations could be adversely impacted.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on complex and interdependent information technology systems, including internet-based systems, databases and programs, to support our business processes as well as internal and external communications. These computer systems are potentially vulnerable to breakdown, malicious intrusion and computer viruses which may result in the impairment of production and key business processes or loss of data or information. Additionally, our systems are potentially vulnerable to data security breaches whether by employees or others which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

In addition, our existing enterprise resource planning system, a critical system used to run our business, will no longer be supported by the developer. Accordingly, we are endeavoring to implement a new enterprise resource planning system which is complex, time consuming and expensive, and we may be unable to implement such a new system in a timely manner, at a reasonable cost or at all. Our inability to implement such a new system in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Our prior and potential future equity offerings and other changes in our stock ownership, some of which are outside of our control could in the future result in an ownership change. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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 2014 and 2027. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates from 2015 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.

Table of Contents

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 requiring us 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 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.

We currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.

Our shares of common stock are currently quoted on the Nasdaq Global Market under the symbol CERS . The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market increases price volatility and reduces the liquidity of our

common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered, which may limit our ability to effectively raise money. In addition, due to the limitations of our market and the volatility in the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to sell. As a result of this lack of trading activity, the quoted price for our common stock is not necessarily a reliable indicator of its fair market value.

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

Table of Contents

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.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation of Cerus Corporation
3.2 (1)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3 (1)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4 (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)	Amendment No 1. to Controlled Equity Offering[SM] Sales Agreement, dated March 21, 2014, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.2	Cerus Corporation Amended and Restated Non-Employee Director Compensation Policy.
10.3	Equity Change in Control Agreement with Caspar Högeboom, dated March 7, 2014.
10.4	2013 and 2014 Executive Officer Compensation Arrangements.
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 (9)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) 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 September 30, 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.

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Table of Contents

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(8) 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 March 21, 2014.
(9) 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.

Table of Contents

SIGNATURES

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

CERUS CORPORATION

Date: May 9, 2014

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

(on behalf of registrant and as Principal Financial Officer)

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